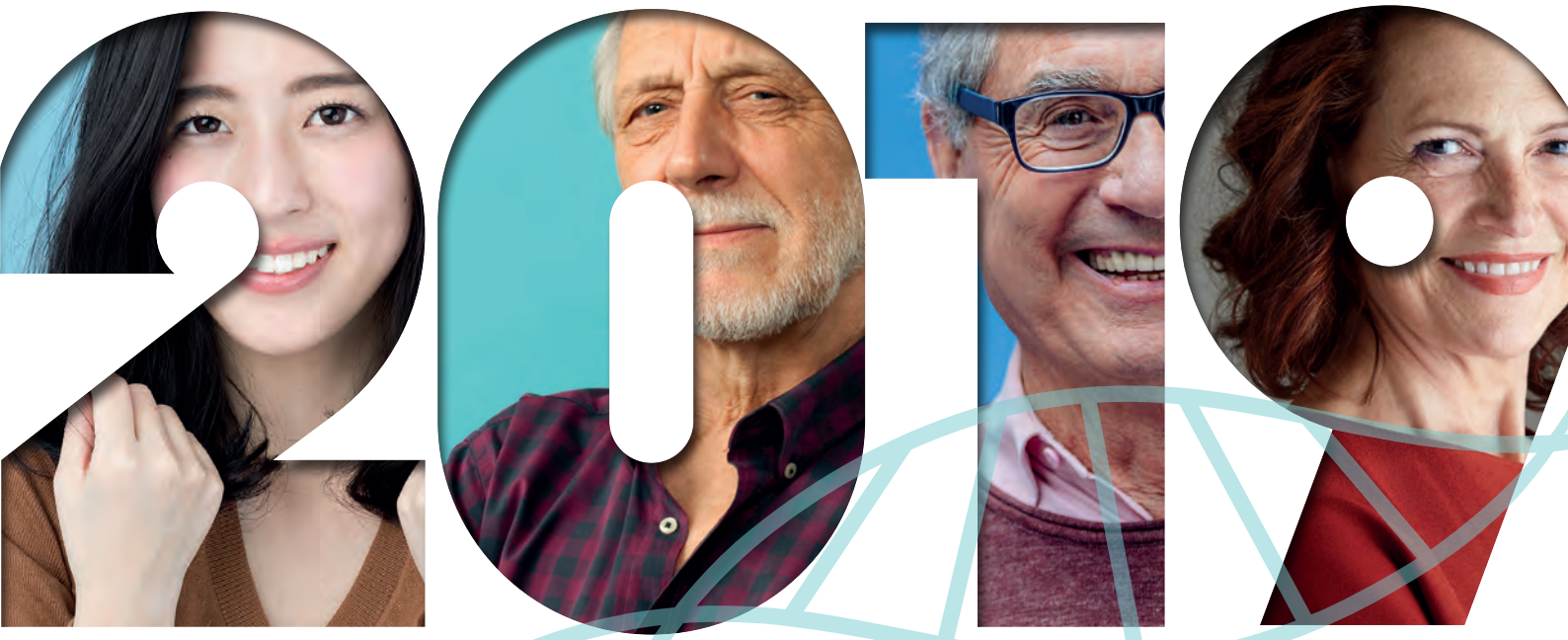

UNIVERSAL REGISTRATION DOCUMENT

GenSight BIOLOGICS

GenSight Biologics S.A.

Corporation *(société anonyme)* with a share capital of €820,684.05

Registered Office:
74, rue du Faubourg Saint-Antoine
75012 Paris, France
751 164 757 Paris Trade and Companies Register

2019
UNIVERSAL REGISTRATION DOCUMENT

AUTORITÉ DES MARCHÉS FINANCIERS
AMF

This Universal Registration Document (URD) was filed on April 8, 2020 with the AMF (the French Financial Markets Regulator), as the 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 a public offer of securities or the admission of securities to trading on a regulated market if it supplemented by a securities note and, as the case may be, by a summary and all the amendments to the Universal Registration Document. These documents are together approved by the AMF in accordance with Regulation (EU) 2017/1129.

A concordance table is provided in this Universal Registration Document in order to facilitate the retrieval of the information incorporated by reference and that which are updated or amended.

Copies of this Universal Registration Document are available free of charge from GenSight (74, rue du Faubourg Saint-Antoine 75012 Paris, France) and on its website (https://www.gensight-biologics.com).

CONCORDANCE TABLE

The concordance table below makes it possible to identify in this Universal Registration Document:

- the information which forms the annual financial report (article L.451-1-2 of the French Monetary and Financial Code and article 222-3 of the General Regulation of the AMF); and
- the information which forms the annual management report (article L.225-100 *et seq.* of the French Commercial Code).
- the information which forms the Corporate Governance report.

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• Outlook of the Company and the Group	Section 10
• Key financial and non-financial indicators of the Company and the Group	Sections 18.1, 7 and 8
• Post-closing events of the Company and the Group	Section 18.1
• Internal control and risk management procedures relating to the preparation and processing of the accounting and financial information of the Company and the Group	Section 3.7
• Information on the use of financial instruments including financial risks and exposure to price, credit, liquidity and cash flow risks of the Company and the Group	Section 3.4
• Principal risks and uncertainties incurred by the Company and the Group	Section 3
• Financial risks linked to the effects of climate change and presentation of the measures taken to reduce them (low carbon strategy) by the company and the group	Section 5.7.4
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• Subsidiaries	Section 6
4.2. Legal, financial and tax information on the Company	
• Shareholder structure and changes thereto	Section 16
• Names of company controlled participating in indirect control in the Company and the share of the capital they hold	N/A
• Material holdings in companies having their registered office in France	N/A
• Notice of holding more than 10% in the capital of other joint stock companies; transfer of cross-holdings	N/A
• Purchase and disposal by the Company of own shares (share buybacks)	Section 19.1.3
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• Summary of powers in progress granted by the General Meeting for capital increases	Section 19.1.6
• Reference to possible adjustments:	
– for securities giving access to the capital and stock options in the case of share buybacks;	Section 19.1.3
– for securities giving access to the share capital in the case of corporate actions.	N/A
• Disclosure of dividends distributed for the past three financial periods	Sections 18.5
• Amount of expenses and charges not deductible from taxable income	N/A

	Section(s) of the Document
• Aged trial balance information for trade payables and receivables by maturity date	Section 18.1 and Annex I
• Injunctions or fines for anticompetitive practices	N/A
• Agreements entered into between a director and/or officer or a shareholder holding more than 10% of the voting rights and a subsidiary of the Company (excluding ordinary agreements)	N/A
• Amount of inter-company loans	N/A
• Information on the operation of a SEVESO installation	N/A
4.3. Information concerning officers	
• Summary of dealings in own shares of the Company by executives and related parties	Section 12.1.5
4.4. CSR information of the Company	N/A
5. STATUTORY AUDITORS' REPORT ON THE COMPANY'S ANNUAL FINANCIAL STATEMENTS – FRENCH STANDARDS (FRENCH-GAAP)	Section 18.1.4
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• Results of the last five financial years	Annex I
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7. BOARD'S REPORT ON CORPORATE GOVERNANCE	
7.1. Information relating to remuneration	
• Principles and criteria for determining, distributing and allocating fixed, variable and exceptional items making up the total remuneration and benefits of any kind attributable to corporate officers as a result of the mandate	Section 13.1.1
• Compensation and benefits of any kind paid during the period to each executive officer by the Company, companies that it controls and the company controlling it	Section 13.1.2
• Undertakings linked to assuming, terminating or changing functions	N/A
• In the case of stock option grants, reference to information according to which the Board of Directors took the decision to:	
– either prohibit executive managers from exercising their options prior to ceasing to exercise their functions;	N/A
– or to impose lockout obligations to registered holders until they cease to occupy their functions on all or part of the shares resulting from options already exercised (by specifying accordingly the portion that was set)	N/A
7.2. Information concerning the composition, operation and powers of the Board	
• List of offices and responsibilities exercised in any company by each executive officer during the year	Section 12.1.1 and 12.1.2
• Agreements concluded between a corporate officer or a shareholder holding more than 10% of the voting rights and a subsidiary (excluding current agreements)	Section 17.3
• Summary of powers in progress granted by the General Meeting for capital increases	Section 19.1.6
• Choice made on one of the two methods for exercising executive management in the event of a modification	N/A
• Composition, conditions of preparation and organisation of the Board's work	Section 14
• Diversity Policy	Section 15.1.2
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• Reference to a corporate governance code or, failing this, justification and indication of the rules adopted in addition to the legal requirements	Section 14.4.1
• Specific terms and conditions of shareholder participation in the general meeting or provisions of the statutes providing for such terms and conditions	Section 19.2.5
• Procedure implemented to review the ordinary agreements with related parties	Section 14.5.5

		Section(s) of the Document
7. 3. Information related to the items having a potential impact in the event of public offerings:		
i.	Capital structure of the Company;	Section 19.1
ii.	Restrictions under the articles of association on the exercise of voting rights or the transfer of shares disclosed in accordance with article L.223-11 of the French Commercial Code;	N/A
iii.	Direct or indirect holdings in the share capital of the Company of which it is informed under articles L.233-7 and L.233-12 of the French Commercial Code;	Section 16.1.2
iv.	Holders of any securities conferring special rights of control and descriptions thereof;	Section 16.2 – 16.3
v.	Control mechanisms provided for in a potential employee stock ownership system where control rights are not exercised by the latter;	N/A
vi.	Shareholders' agreements known to the Company and which may result in share transfer and voting rights restrictions;	Section 16.2
vii.	Rules and regulations pertaining to the appointment and replacement of members of the Board of Directors and modifications to the bylaws of the Company;	Section 19.2.2
viii.	Powers of the Board of Directors for the issuance and buybacks of shares;	Section 19.1.3 and 19.1.6
ix.	Agreements concluded by the Company that may be modified or terminated in the event of a change in control of the Company, except if such disclosure, excluding the case where legally required, materially adversely affect its interest;	N/A
x.	Agreements providing for severance payments for members of the Board of Directors or employees in the event of resignation, dismissal without just and sufficient cause or termination of employment resulting from a public offering.	Section 17.2.3

The report on Corporate Governance and the information required under this report were prepared and elaborated by the board of directors pursuant to article L.225-37 of the French Commercial Code, with the involvement of the executive and management committees.

The report was adopted by the board of directors held on March 11, 2020, upon recommendation of the audit committee, which previously met the same day, and was sent to the statutory auditors.

NOTE

In this Universal Registration Document, the terms "Company," "GenSight Biologics," "we," "us" and "our" mean GenSight Biologics S.A. All references herein to "$" are to United States dollars, the currency of the United States of America.

This Universal Registration Document describes the Company as of the date hereof.

This Universal Registration Document includes our annual financial statements prepared in accordance with French accounting standards for the fiscal year ended December 31, 2019.

This Universal Registration Document also includes our consolidated financial statements prepared in accordance with International Financial Reporting Standards, or IFRS, as adopted by the European Union for the fiscal year ended December 31, 2019.

The Document may be consulted on the Company's website (www.gensight-biologics.com).

Unless otherwise indicated the selected financial information and comments on the consolidated financial statements presented in this Universal Registration Document have been prepared on the basis of the consolidated financial statements prepared in accordance with IFRS as adopted by the European Union.

A glossary defining some of the terms used herein is appended to this Universal Registration Document.

Forward-looking Statements

This Universal Registration Document contains statements regarding our prospects and growth strategies. These statements are sometimes identified by the use of the future or conditional tense, or by the use of forward-looking terms such as "considers", "envisages", "believes", "aims", "expects", "intends," "should", "anticipates", "estimates", "thinks", "wishes" and "might", or, if applicable, the negative form of such terms and similar expressions or similar terminology. Such information is not historical in nature and should not be interpreted as a guarantee of future performance. Such information is based on data, assumptions, and estimates that we consider reasonable. Such information is subject to change or modification based on uncertainties in the economic, financial, competitive or regulatory environments. This information is contained in several sections of this Universal Registration Document and includes statements relating to our intentions, estimates and targets with respect to our markets, strategies, growth, results of operations, financial situation and liquidity. Our forward-looking statements speak only as of the date of this Universal Registration Document. Absent any applicable legal or regulatory requirements, we expressly disclaim any obligation to release any updates to any forward-looking statements contained in this Universal Registration Document to reflect any change in our expectations or any change in events, conditions or circumstances, on which any forward-looking statement contained in this Universal Registration Document is based. We operate in a competitive and rapidly evolving environment; it is therefore unable to anticipate all risks, uncertainties or other factors that may affect our business, their potential impact on our business or the extent to which the occurrence of a risk or combination of risks could have significantly different results from those set out in any forward-looking statements, it being noted that such forward-looking statements do not constitute a guarantee of actual results.

Information on the Market and Competitive Environment

This Universal Registration Document contains, in particular in Section 5, "Business Overview", information relating to our markets and to our competitive position. Unless otherwise indicated, the information contained in this Universal Registration Document related to market shares and the size of relevant markets are our estimates and are provided for illustrative purposes only. We believe that the information contained herein in relation to our markets and competitive position is reliable, but the information has not been verified by an independent expert, and we cannot guarantee that a third-party using different methods to collect, analyze or compute market data would arrive at the same results.

Risk Factors

Investors should carefully consider the risk factors in Section 3, "Risk Factors". The occurrence of all or any of these risks could have an adverse effect on our business, reputation, results of operation, financial condition or prospects.

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PERSON RESPONSIBLE, THIRD PARTY INFORMATION, EXPERTS' REPORTS AND COMPETENT AUTHORITY APPROVAL

1

PERSON RESPONSIBLE, THIRD PARTY INFORMATION, EXPERTS' REPORTS AND COMPETENT AUTHORITY APPROVAL

1.1 IDENTITY OF THE PERSON RESPONSIBLE

Bernard Gilly, Chief Executive Officer of GenSight Biologics S.A. is responsible for the information contained in this Universal Registration Document.

1.2 DECLARATION OF THE PERSON RESPONSIBLE

I hereby declare that, after having taken all reasonable care to that purpose, to the best of 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 hereby declare that, to the best of my knowledge, the financial statements have been prepared in accordance with the applicable accounting standards and present a fair view of the assets, liabilities, financial position and results of the Company and all the other companies included in the scope of consolidation, and that the Annual Management Report for which a table of cross-references is presented in this Universal Registration Document, provides a fair presentation of the business developments, results and financial position of the Company and all the other companies included in the scope of consolidation, as well as a description of the main risks and contingencies to which they might be exposed.

April 8, 2020

Bernard Gilly, Chief Executive Officer of GenSight Biologics S.A.

1.3 EXPERTS' REPORTS

N/A

1.4 THIRD PARTY INFORMATION

N/A

1.5 COMPETENT AUTHORITY APPROVAL

N/A

STATUTORY AUDITORS

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STATUTORY AUDITORS

2.1 STATUTORY AUDITORS

Deloitte & Associés

Represented by Stéphane Lemanissier

Tour Majunga, 6 place de la Pyramide, 92908 Paris-La Défense Cedex

Deloitte & Associés is a member of the *Compagnie Régionale des Commissaires aux Comptes de Versailles* (the Regional Association of Auditors of Versailles).

Becouze

Represented by Fabien Brovedani

34, rue de Liège –75008 Paris, France

Becouze is a member of the *Compagnie Régionale des Commissaires aux Comptes d'Angers* (the Regional Association of Auditors of Angers).

Deloitte & Associés's initial appointment as statutory auditor has been expressed in the bylaws of April 17, 2012, for a six-year term, which has been renewed at the general shareholder's meeting of the Company on June 11, 2019 for a six-year term and Becouze's appointment as statutory auditor was approved by the general shareholders' meeting of the Company on May 19, 2016 for a six-year term, which will end at the close of the shareholders' meeting called to approve the financial statements for the fiscal year ending on December 31, 2021.

The alternate statutory auditor is:

Guillaume Saby (substitute to Becouze)

1, rue Buffon – 49100 Angers, France

Guillaume Saby is a member of the *Compagnie Régionale des Commissaires aux Comptes d'Angers* (the Regional Association of Auditors of Angers).

Guillaume Saby was appointed substitute statutory auditor by our general shareholders' meeting on May 19, 2016 for a six-year term, which will end at the close of the shareholders' meeting called to approve the financial statements for the fiscal year ending on December 31, 2021.

2.2 CHANGE IN STATUTORY AUDITORS

As of the date of this Universal Registration Document, none of the statutory auditors or substitute statutory auditors have resigned or been revoked.

RISK FACTORS

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RISK FACTORS

The Company has opted for a presentation of its risk factors by category of risk, with a hierarchization of these risks within each category from riskier to less risky.

Investors should carefully consider all of the information set forth in this Universal Registration Document before making an investment decision, including the risk factors set forth in this Section. Such risks are, as of the date of this Universal Registration Document, the risks that we believe, were they to occur, could have a material adverse effect on our business, results of operations, financial condition and prospects.

In order to identify and assess the risks likely to have an adverse impact on its business, prospects, financial position, results (or ability to achieve its objectives) and development, the Company has mapped the risks associated with its business since 2012. This enabled the Company first to identify potential risks and assess their probability of impact and, where possible, to assess their potential impact from a financial, legal and reputation point of view, as well as on the achievement of the Company's objectives. This then made it possible to identify and evaluate ways to control these risks. Risk mapping is a management tool. It is reviewed periodically by the Management Committee and the Audit Committee. At the time of the periodic risk review, all risks and mitigation measures are reviewed and reassessed. This tool is also supplemented by a detailed analysis of the causes and impacts in the event of the occurrence of any significant risk and takes into account the actions and control measures implemented by the Company. This methodology should provide an overview of the risk environment affecting the Company and should enable the Company to define, if necessary, the action plan for risk management and the areas of internal control and audit for the coming year.

The risk mapping exercise enabled the Company to summarize the main risks and group them into the categories indicated below. The Company has grouped these risks into five categories, with no hierarchy between them.

The table below summarizes the main risk factors identified by the Company and indicates, for each of them, the criticality level (combination of the probability of their occurrence and their negative impact on the Company) as at the filing date of this Universal Registration Document, taking into account the actions and control measures implemented by the Company as at the filing date of this Universal Registration Document. The probability of occurrence is assessed on three levels ("low", "moderate" and "high") and the magnitude of their negative impact is assessed on four levels ("low", "moderate", "high" and "critical"). In each of the five categories above, risks have been classified according to this classification, with risks with the highest probability of occurrence and the highest negative impact being placed first.

		Criticality level	
Ref.	Risk Factors	Probability of Occurrence	Magnitude of Negative Impact
1.	**FINANCIAL RISKS**		
1.1	Liquidity Risk	High	Critical
1.2	We have never generated revenue from product sales and have incurred significant operating losses since our inception. We expect to continue to incur significant losses for the foreseeable future and may never achieve profitability.	Moderate	Critical
1.3	We will need to raise additional capital in the future, which may not be available on acceptable terms, or at all, and failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.	Moderate	Critical
1.4	We may lose access to research tax credits in the event of regulatory or legislative changes or challenges by tax authorities.	Low	Moderate
1.5	Our current and future shareholders may experience dilution.	High	Low
2.	**RISKS RELATED TO THE DISCOVERY AND DEVELOPMENT OF AND OBTAINING REGULATORY APPROVAL FOR OUR PRODUCT CANDIDATES**		
2.1	The regulatory approval process of the FDA, the EMA and other regulatory authorities and the clinical trials that our product candidates will need to undergo, are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure.	High	Critical
2.2	Our product candidates are based on novel technologies, including gene therapy, which may implicate ethical, social and legal concerns about genetic testing and genetic research in general, and such novel technologies make it difficult to predict the timing and costs of development of new and unforeseen regulatory requirements and of subsequently obtaining regulatory approval.	Low	High
2.3	We may encounter substantial delays in our clinical trials, and we cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all.	Moderate	Moderate

Ref.	Risk Factors	Criticality level: Probability of Occurrence	Criticality level: Magnitude of Negative Impact
2.4	Our product candidates and the process for administering our product candidates using AAV vectors may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.	Moderate	Moderate
2.5	Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.	Moderate	Moderate
3.	**RISKS RELATED TO MANUFACTURING AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES**		
3.1	Gene therapies are novel, complex and difficult to manufacture. We have limited manufacturing experience and could experience production problems that result in delays in our development or commercialization programs.	High	Critical
3.2	We rely, and expect to continue to rely, on Brammer and other third parties to conduct, supervise and monitor manufacturing for our preclinical studies and clinical trials. If these third parties do not meet our deadlines, successfully carry out their contractual duties or otherwise conduct the manufacturing for these studies and trials as required, we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.	Moderate	High
3.3	We rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials. If these third parties do not meet our deadlines or otherwise conduct the studies and trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.	Moderate	High
3.4	Future insurance coverage and reimbursement status of our product candidates is uncertain.	Moderate	High
3.5	If we are unable to establish sales, marketing and distribution capabilities for our product candidates, whether it be an internal infrastructure or an arrangement with a commercial partner, we may not be successful in commercializing those product candidates if and when they are approved.	Low	Moderate
3.6	The commercial success of any of our product candidates will depend upon their degree of market acceptance by physicians, patients, third-party payors and others in the medical community.	Low	Moderate
4.	**RISKS RELATED TO OUR BUSINESS OPERATIONS**		
4.1	Risks related to the impacts of the COVID-19	High	Moderate
4.2	Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel, and members of our management team may be affected by conflicts of interest to the extent that they serve in management or directorship capacities at our competitors.	Moderate	Moderate
4.3	We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success.	Moderate	Moderate
4.4	We may be subject to product liability lawsuits.	Low	Moderate
5.	**LEGAL RISKS AND RISKS RELATED TO OUR INTELLECTUAL PROPERTY**		
5.1	We do not own any issued patents and our rights to develop and commercialize our product candidates are subject to the terms and conditions of intellectual property licenses granted to us by others.	Low	Critical
5.2	We or our licensors may be unable to obtain and maintain adequate patent protection for our product candidates and technology.	Low	Critical
5.3	We may fail to comply with our obligations under the agreements under which we in-license intellectual property and could thereby lose license rights that are important to our business.	Low	Critical
5.4	We may not be able to protect our intellectual property rights throughout the world.	Moderate	Moderate
5.5	Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.	Low	Moderate

3.1 FINANCIAL RISKS

3.1.1 LIQUIDITY RISK.

As of December 31, 2019, the Group does not have sufficient net working capital to meet its obligations during the next 12 months.

Since its incorporation, the Company has funded its activities through several equity financings, grants, conditional advances and Research Tax Credit. In 2019, the Company started to generate revenue from the sale of LUMEVOQ™ (GS010) to the *CHNO des Quinze-Vingts* in Paris, since the National Drug Safety Agency (ANSM) granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™. To date, the Company continues to actively prepare for the launch of LUMEVOQ™ in Europe in 2021 and in the United States in 2022.

Current cash and cash equivalents on hand are not projected to be sufficient to support the Company's current operating plan for a period of 12 months following the date of issuance of the 2019 annual consolidated financial statements. Considering the cash position as of December 31, 2019 (amounting to €19.2 million), the reimbursement of the 2019 Research Tax Credit contemplated in 2020 for a consideration of €4.2 million and additional expected income related to the ATU in France cautiously forecasted at €7.0 million, the Company expects to cover its cash requirements until the end of November 2020.

We believe that the €7.0 million income from the ATU in France, representing 10 patients treated, is a cautious estimate. Any additional request approved would reduce the need for financing and extend the runway accordingly.

In order to meet these obligations and subject to the realization of a Qualifying Financing[(1)] of €10 million, the Company will be able to receive a second tranche of €4.0 million from the bond issuance with Kreos Capital. The Company will also explore other financing options through debt or equity in order to complete its working capital needs and to finance its operating expenses. In this respect, a third optional tranche of €2 million could be made available to the Company by Kreos Capital at a later date.

The annual consolidated financial statements have been prepared on a going concern basis assuming that the Company will either be successful in its additional financing objections or that the Company will modify its operating plans, in particular by delaying or limiting the scope of its research and development programs. However, no assurance can be given at this time as to whether the Company will be able to achieve these financing objectives. As such, there are material uncertainties regarding the Company's ability to continue as a going concern. As such, no adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should the Company not be able to continue as a going concern.

The Company has also decided to continue the current development activities of its GS030 product but not to undertake any studies or uninitiated costs to date, focusing primarily on its GS010 product. In this context, we are actively working on the implementation of a long-term refinancing, which could take the form of a strategic partnership/or fundraising, depending on market conditions. The consolidated financial statements have been prepared on a going concern basis assuming that the Company will either be successful in its additional financing objections or that the Company will modify its operating plans, in particular by delaying or limiting the scope of its research and development programs. We will need to raise additional capital, which may not be available on acceptable terms, or at all, and failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations of this Universal Registration Document. As such, there are material uncertainties regarding the Company's ability to continue as a going concern.

3.1.2 WE HAVE NEVER GENERATED REVENUE FROM PRODUCT SALES AND HAVE INCURRED SIGNIFICANT OPERATING LOSSES SINCE OUR INCEPTION. WE EXPECT TO CONTINUE TO INCUR SIGNIFICANT LOSSES FOR THE FORESEEABLE FUTURE AND MAY NEVER ACHIEVE PROFITABILITY.

Since inception, we have devoted substantially all of our efforts to research and development, including preclinical and clinical development of our product candidates, as well as to building our team. We have never generated revenue from product sales, and we have incurred operating losses since inception. We incurred net losses of €33.5 million and €31.1 million for the fiscal years ended December 31, 2018 and 2019, respectively, and these losses have adversely impacted and will continue to adversely impact, our equity attributable to shareholders and net assets. We anticipate that our operating losses will continue for at least the coming years as we continue with our research and development activities and until we generate substantial revenues from approved product candidates. As of December 31, 2019, we had an accumulated deficit of approximately €144 million.

Our capacity to generate revenues from product sales and to achieve profitability will depend on our ability, alone or with

(1) Qualifying Financing means a financing of the Company in the form of equity (or Non-Dilutive Payment or subordinated convertible bonds, or a combination of the above) from existing shareholders and/or new top tier investors reasonably satisfactory to Kreos, with a minimal amount of gross proceeds of €10 million, being specified that such amount may be reduced, up to a maximal amount of €2 million, by the proceeds susceptible to be received by the Company under *Autorisations Temporaires d'Utilisation payantes*.

collaborative partners, to successfully complete the development of and to obtain the regulatory approvals necessary to commercialize product candidates with significant market potential. We do not currently have the required approvals to market our lead product candidate, GS010, and our second most advanced product candidate, GS030 or any other product candidates and we may never obtain such approvals or be able to commercialize any of our current or future product candidates. Our ability to generate future revenues from product sales will depend heavily mainly on our and any of our collaborators' success in:

- continuing our research and development of our two lead product candidates, including our Phase III clinical trials for GS010, and Phase I/II clinical trial for GS030;
- preparing our biologic license application, or BLA, and European Union centralized marketing authorization application, or MAA, for GS010 and GS030, and seeking marketing approvals for any of our other product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical supply and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates, if approved, as a viable treatment option and satisfying any post-marketing requirements;
- avoiding and defending against third-party interference or infringement claims; and
- attracting, hiring and retaining qualified personnel.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an annual basis and may need to obtain additional funding to continue operations. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, diversify our product pipeline or continue our operations. A decline in the value of our Company could also cause investors to lose all or part of their investment.

3.1.3 WE WILL NEED TO RAISE ADDITIONAL CAPITAL IN THE FUTURE, WHICH MAY NOT BE AVAILABLE ON ACCEPTABLE TERMS, OR AT ALL, AND FAILURE TO OBTAIN THIS NECESSARY CAPITAL WHEN NEEDED MAY FORCE US TO DELAY, LIMIT OR TERMINATE OUR PRODUCT DEVELOPMENT EFFORTS OR OTHER OPERATIONS.

Our operations have consumed significant cash since inception. To date, we have financed our activities primarily through private placements of our ordinary shares and preferred shares, funding received from Bpifrance Financement, research tax credits *(crédit d'impôt recherche)*, or CIR, and a sale of our ordinary shares in connection with our July 2016 initial public offering on the regulated market of Euronext Paris, or Euronext Paris.

We are currently advancing our product candidates through clinical development. Developing product candidates is expensive, lengthy and risky, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate further clinical trials of and seek marketing approval for, our product candidates. Our expenses could increase beyond our current expectations, mainly depending on:

- the scope, progress, results and costs of drug discovery, laboratory testing, preclinical development and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates, including, in particular, if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory agencies to perform clinical trials and other studies in addition to those that we currently anticipate;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Until such time that we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of our existing liquidity sources and the proceeds of any future financings. If we are unable to generate revenue from product sales, in particular from GS010, within our expected timeframes, or if our expenses increase to a level or at a rate beyond our expectations, we will need to raise additional capital. However, we may be unable to raise additional funds or enter into other funding arrangements when needed on favorable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

To the extent that additional capital is raised through the sale of equity or equity-linked securities, the issuance of those securities could result in substantial dilution for our current shareholders and the terms may include liquidation or other preferences that adversely affect the holdings or the rights of our current shareholders. To the extent that additional capital is raised through a debt offering, the incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct

our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

3.1.4 WE MAY LOSE ACCESS TO RESEARCH TAX CREDITS IN THE EVENT OF REGULATORY OR LEGISLATIVE CHANGES OR CHALLENGES BY TAX AUTHORITIES.

Since incorporation, we have received the CIR, which is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. For the year ended December 31, 2018, we recorded CIR in the amount of approximately €4.3 million, which was reimbursed in cash in December 2019. For the year ended December 31, 2019, we recorded CIR in the amount of approximately €4.2 million, we expect will be reimbursed before the end of the fiscal year 2020.

Companies demonstrating that they have expenditures that meet the required criteria, including research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area, or the EEA, that has concluded a tax treaty with France that contains an administrative assistance clause, receive a tax credit which can be used against the payment of the corporate tax due the fiscal year in which the expenditures were made and during the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenditures taken into account for the calculation of the CIR only involve research expenses.

Legislative or regulatory changes relating to CIR or challenges by the French tax authorities with respect to our research expenditures or our eligibility to receive CIR could have a material adverse effect on our ability to operate our business and our financial condition, results of operations and prospects.

3.1.5 OUR CURRENT AND FUTURE SHAREHOLDERS MAY EXPERIENCE DILUTION.

Since incorporation, we have issued or allotted share warrants for founders (*Bons de souscription de parts de créateur d'entreprise*, or BCE), share warrants (*Bons de souscription d'actions*, or BSA) and free shares (*Attributions gratuites d'actions*, or AGA). As of December 31, 2019, 666,302 BCE, 862,040 BSA, 1,005,000 AGA have been allotted (giving the right to subscribe for or acquire, respectively, 666,302, 862,040 and 1,005,000 new shares). See Section 19.1.5.1, "Warrants" of this Universal Registration Document.

In the context of the "Kreos Transaction" completed in December 2019, part of the bond issuance was in the form of convertible bonds (*Obligations Convertibles en Actions* or OCA) (giving the right to subscribe to 801,781 new shares) and we have also issued 534,521 share warrants (BSA) subscribed by Kreos, giving the right to subscribe to 534,521 new shares.

As of December 31, 2019, the exercise of all BCE, all BSA, all OCA and the definitive acquisition of all AGA allotted and outstanding will thus allow for a subscription or acquisition of 3,869,644 new ordinary shares, generating a dilution of 11.79% based on fully diluted capital (see Section 19.1.5.1, "Warrants" of this Universal Registration Document).

Moreover, the exercise of delegations of authority granted to the Board of Directors by the mixed general meeting of June 11, 2019 to carry out one or more capital increases could lead to additional dilution. See Section 19.1.5, "Other Securities Giving Access to Share Capital" of this Universal Registration Document.

As part of our policy to provide incentives for our executive officers and employees, and in order to attract additional expertise, we may in the future issue or allot shares or new financial instruments giving access to our share capital, which could result in additional, potentially significant, dilution for our current and future shareholders.

3.1.6 THE REALIZATION OF THE SECURITY INTERESTS ATTACHED TO OUR BOND FINANCING COULD HAVE AN ADVERSE IMPACT ON OUR CAPACITY TO OPERATE OUR BUSINESS.

The bonds and convertible bonds issued in relation to the Kreos Transaction occurred in December 2019 benefit from pledge agreements on our bank accounts, on our business assets, on the intellectual property rights owned by us (trademarks, patents, software, and domain names) and on our receivables. In the event of default by us in our obligations, including our repayment obligations under the Kreos Transaction, Kreos may be granted ownership of the pledged rights and may proceed against the collateral granted to it to secure repayment of these amounts. In such event, our ability to develop its products could be affected or delayed, which would consequently have a material adverse effect on us, our business, prospects, ability to achieve our objectives, our financial position or operating result.

3.2 RISKS RELATED TO THE DISCOVERY AND DEVELOPMENT OF AND OBTAINING REGULATORY APPROVAL FOR OUR PRODUCT CANDIDATES

3.2.1 THE REGULATORY APPROVAL PROCESS OF THE FDA, THE EMA AND OTHER REGULATORY AUTHORITIES AND THE CLINICAL TRIALS THAT OUR PRODUCT CANDIDATES WILL NEED TO UNDERGO, ARE TIME-CONSUMING AND EXPENSIVE, THE OUTCOMES OF WHICH ARE UNPREDICTABLE, AND FOR WHICH THERE IS A HIGH RISK OF FAILURE.

The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. As of the date of this Universal Registration Document, Spark

Therapeutics' Luxturna, has received marketing approval by both the FDA and the EMA, and GlaxoSmithKline plc's Strimvelis is the only other gene therapy products currently approved by the EMA, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or how long it will take to commercialize our product candidates. Approvals by the EMA may not be indicative of what the FDA may require for approval, and vice versa.

In addition, we believe that certain of our product candidates, such as GS010 and GS030, and certain of our underlying technology platforms, such as Mitochondrial Targeting Sequence and Optogenetics, may be immediately transferable to the treatment of other diseases, including dry age-related macular degeneration, or dry AMD, and geographic atrophy, or GA, as well as diseases outside of ophthalmology, including central nervous system, or CNS, disorders. These other indications, as well as additional potential product candidates, will require additional, time-consuming and costly development efforts prior to commercial sale, which may be unpredictable and may differ significantly from those of our initial product candidates.

3.2.2 OUR PRODUCT CANDIDATES ARE BASED ON NOVEL TECHNOLOGIES, INCLUDING GENE THERAPY, WHICH MAY IMPLICATE ETHICAL, SOCIAL AND LEGAL CONCERNS ABOUT GENETIC TESTING AND GENETIC RESEARCH IN GENERAL, AND SUCH NOVEL TECHNOLOGIES MAKE IT DIFFICULT TO PREDICT THE TIMING AND COSTS OF DEVELOPMENT OF NEW AND UNFORESEEN REGULATORY REQUIREMENTS AND OF SUBSEQUENTLY OBTAINING REGULATORY APPROVAL.

We have concentrated our research and development efforts on gene therapy approaches using our core platform technologies, mitochondrial targeting sequence, or MTS, and optogenetics, and our future success depends on our successful development of viable product candidates. We may experience problems or delays in developing GS010, GS030, or any other new product candidates, and such problems or delays may result in unanticipated costs, and there can be no assurance that any such development problems can be solved. We also may experience unanticipated problems or delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials, meeting the obligations of our collaborations or commercializing our products on a timely or profitable basis, if at all. For example, we, a collaborator or another group may uncover a previously unknown risk associated with the adeno-associated virus, or AAV, which is the vector currently used in our gene therapy approaches, and this may prolong the period of observation required for obtaining regulatory approval or may necessitate additional clinical testing.

Because human gene therapy is a relatively new and expanding area of novel therapeutic interventions, and because we are developing product candidates for the treatment of mitochondrial and neurodegenerative diseases of the eye and central nervous system for which there are no or limited therapies and/or treatments, and for which there is little clinical trial experience, there is an increased risk that the FDA, EMA or other regulatory authorities may not consider the endpoints of our clinical trials to be sufficient for marketing approval. In addition, ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use. The product specifications and the clinical trial requirements of the FDA, EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidate. The regulatory approval process for novel product candidates such as ours is unclear and may be lengthier and more expensive than the process for other, better-known or more extensively studied product candidates. For example, clinical trial protocols for some gene therapies are potentially subject to review by the Recombinant DNA Advisory Committee, or RAC, a committee of the U.S. National Institutes of Health, or NIH, and the RAC review process can delay the initiation of a clinical trial, even if the FDA has approved the initiation of the trial. In addition, the FDA generally requires multiple well-controlled clinical trials to provide the evidence of effectiveness necessary to support a BLA, although FDA guidance provides that reliance on a single pivotal trial may be appropriate if the trial has demonstrated a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potential serious outcome, and where confirmation of the result in a second trial would be practically or ethically impossible.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review.

CBER and its Advisory Committee, and any new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current or future product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. These additional processes may result in a review and approval

process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be harmed. Even if our product candidates are approved, we expect that the FDA will require us to submit follow-up data regarding our clinical trial subjects for a number of years after approval. If these follow-up data show negative long-term safety or efficacy outcomes for these patients, the FDA may revoke its approval or change the label of our products in a manner that could have an adverse impact on our business.

In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of our product candidates. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines.

As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for GS010, GS030, or any other new product candidates in either the United States or the European Union or how long it will take to commercialize our other product candidates. Approvals by the EMA may not be indicative of what the FDA may require for approval and vice versa.

3.2.3 WE MAY ENCOUNTER SUBSTANTIAL DELAYS IN OUR CLINICAL TRIALS, AND WE CANNOT GUARANTEE THAT ANY CLINICAL TRIALS WILL BE CONDUCTED AS PLANNED OR COMPLETED ON SCHEDULE, IF AT ALL.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and time-consuming and the results are uncertain. We cannot guarantee that any clinical trial will be conducted as planned or completed on schedule, if at all. Failure of a clinical trial can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in raising, or inability to raise, sufficient capital to fund the planned or ongoing clinical trials;
- delays in reaching a consensus with the FDA, EMA or regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening clinical trial sites or obtaining required independent IRB approval in the United States or approval by an independent ethics committee in the European Union at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities, including as a result of a serious adverse event or after a negative finding following an inspection of our clinical trial operations or clinical trial sites;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical trial sites, including delays by any third parties with whom we have contracted to perform certain of those functions;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data.

We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any inability to successfully complete preclinical and clinical development could result in additional costs or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial conditions, results of operations and prospects.

3.2.4 OUR PRODUCT CANDIDATES AND THE PROCESS FOR ADMINISTERING OUR PRODUCT CANDIDATES USING AAV VECTORS MAY CAUSE UNDESIRABLE SIDE EFFECTS OR HAVE OTHER PROPERTIES THAT COULD DELAY OR PREVENT THEIR REGULATORY APPROVAL, LIMIT THEIR COMMERCIAL POTENTIAL OR RESULT IN SIGNIFICANT NEGATIVE CONSEQUENCES FOLLOWING ANY POTENTIAL MARKETING APPROVAL.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether the product candidate being studied caused these conditions. Various illnesses, injuries and discomforts have been reported from time to time during clinical trials of our product candidates. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in

previous trials, will be reported by patients. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase III clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that our product candidates cause serious or life-threatening side effects, the development of our product candidates may fail or be delayed, or, if the product candidate has received regulatory approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition.

Our product candidates may lead to undesirable side effects or adverse reactions. In previous studies involving gene therapy treatments, some subjects experienced significant adverse side effects, including reported cases of leukemia and death seen in other clinical trials using other vectors. While new recombinant vectors have been developed to reduce these side effects, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. Insertional oncogenesis, where the vector is inserted near a cancer causing gene, or an oncogene, may cause adverse immunologic reactions and we cannot assure that such reactions will not occur in any of our planned or future studies. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.

Possible adverse side effects that could occur with treatment with gene therapy products include an immunologic reaction shortly after administration which, while not necessarily adverse to the patient's health, could substantially limit the effectiveness of the treatment. In previous clinical trials involving AAV vectors for gene therapy, some patients experienced the development of a T-cell response, whereby after the vector is within the target cell, the cellular immune response system triggers the removal of transduced cells by activated T-cells. If our products demonstrate a similar effect, we may decide or be required to halt or delay further clinical development of our product candidates. There are also risks inherent in intravitreal injections, including those used to administer GS010 and GS030, such as intraocular inflammation, cataract, sterile and culture-positive endophthalmitis, retinal detachment and retinal tear.

In addition to any potential side effects caused by our product candidates, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur, our clinical trials could be suspended or terminated.

If in the future we are unable to demonstrate that such adverse events were not caused by the product candidate, the FDA, the EMA or other regulatory authorities could deny approval or order us to cease further development of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the clinical trial. Moreover, if we elect or are required to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly.

Additionally, if any of our product candidates receives marketing approval, the FDA and the EMA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, or a Risk Management Plan, or RMP, to ensure that its benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to healthcare practitioners.

Furthermore, if we or others later identify undesirable side effects caused by any of our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could significantly harm our business, prospects, financial condition and results of operations.

3.2.5 EVEN IF WE COMPLETE THE NECESSARY CLINICAL TRIALS, WE CANNOT PREDICT WHEN, OR IF, WE WILL OBTAIN REGULATORY APPROVAL TO COMMERCIALIZE A PRODUCT CANDIDATE AND THE APPROVAL MAY BE FOR A NARROWER INDICATION THAN WE SEEK.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, regulatory authorities may not complete their review processes in a timely manner and may recommend non-approval or may place restrictions on approval. In addition, we may experience delays or rejections as a result of future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested, may require precautions or contraindications or they may grant approval subject

to the performance of costly post-marketing clinical trials or implementation of REMS. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing events could materially harm the commercial prospects for our product candidates.

3.3 RISKS RELATED TO MANUFACTURING AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

3.3.1 GENE THERAPIES ARE NOVEL, COMPLEX AND DIFFICULT TO MANUFACTURE. WE HAVE LIMITED MANUFACTURING EXPERIENCE AND COULD EXPERIENCE PRODUCTION PROBLEMS THAT RESULT IN DELAYS IN OUR DEVELOPMENT OR COMMERCIALIZATION PROGRAMS.

We have limited experience manufacturing our product candidates. We may be unable to produce commercial materials or meet demand to support a commercial launch for our product candidates. Any such failure could delay or prevent the development of our product candidates and would have a negative impact on our business, financial condition and results of operations.

As of the date of this Universal Registration Document, we have contracts with Brammer to manufacture clinical and commercial supplies of our product candidates, and we expect to continue to rely on third parties for our manufacturing needs. This is and will continue to be especially challenging as the manufacturing process to produce our product candidates is complex, novel and has not been validated for commercial use. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our current and future suppliers.

Our product candidates require processing steps that are more complex than those required for most chemical pharmaceuticals because the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control the manufacturing process to assure that the product candidate is made in strict and consistent compliance with our requirements. Problems with the manufacturing process, including even minor deviations from our requirements, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. In addition, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

The FDA, the EMA and other regulatory authorities may also require submission of samples of any lot of an approved product together with the protocols showing the results of applicable tests. Under some circumstances, the FDA, the EMA or other regulatory authorities may require that a lot not be distributed until the agency authorizes its release. Slight deviations in the manufacturing requirements, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We may also encounter problems hiring and retaining the experienced specialist scientific, quality control and manufacturing personnel needed to supervise manufacturing processes carried out by third parties, which could result in delays in our production or difficulties in complying with applicable regulatory requirements.

Any problems in the manufacturing process or facilities for our product candidates could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in our manufacturing process or facilities also could restrict our ability to meet market demand for our products.

3.3.2 WE RELY, AND EXPECT TO CONTINUE TO RELY, ON BRAMMER AND OTHER THIRD PARTIES TO CONDUCT, SUPERVISE AND MONITOR MANUFACTURING FOR OUR PRECLINICAL STUDIES AND CLINICAL TRIALS. IF THESE THIRD PARTIES DO NOT MEET OUR DEADLINES, SUCCESSFULLY CARRY OUT THEIR CONTRACTUAL DUTIES OR OTHERWISE CONDUCT THE MANUFACTURING FOR THESE STUDIES AND TRIALS AS REQUIRED, WE MAY NOT BE ABLE TO OBTAIN REGULATORY APPROVAL FOR OR COMMERCIALIZE OUR PRODUCT CANDIDATES WHEN EXPECTED OR AT ALL.

We currently rely and expect to continue to rely to a significant degree, on Brammer and other third parties to carry out the production of our preclinical study, clinical trial and commercial materials (see Section 20.3 “Manufacturing Agreement”). We can control only certain aspects of these third-party activities.

Under certain circumstances, Brammer is entitled to terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on Brammer for certain manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. If Brammer does not successfully carry out their contractual duties, meet expected deadlines or manufacture our clinical trial

materials in accordance with regulatory requirements, or if there are disagreements between us and Brammer, we will not be able to complete, or may be delayed in completing, the preclinical studies required to support future IND submissions and the clinical trials required for approval of our product candidates. In such instances, we would need to find an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, causing additional delay or increased expense prior to the approval of our product candidates.

In addition to Brammer, we rely on additional third parties to manufacture ingredients of our product candidates and to perform quality testing, and reliance on these third parties rather than manufacturing the product candidates ourselves, exposes us to additional risks, including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of such manufacturing agreements in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future product candidates. Some of these events could be the basis for FDA, EMA or other regulatory authority action, including injunction, recall, seizure or partial or total suspension of product manufacture.

3.3.3 WE RELY ON THIRD PARTIES TO CONDUCT, SUPERVISE AND MONITOR OUR PRECLINICAL STUDIES AND CLINICAL TRIALS. IF THESE THIRD PARTIES DO NOT MEET OUR DEADLINES OR OTHERWISE CONDUCT THE STUDIES AND TRIALS AS REQUIRED, OUR CLINICAL DEVELOPMENT PROGRAMS COULD BE DELAYED OR UNSUCCESSFUL AND WE MAY NOT BE ABLE TO OBTAIN REGULATORY APPROVAL FOR OR COMMERCIALIZE OUR PRODUCT CANDIDATES WHEN EXPECTED OR AT ALL.

We do not have the ability to conduct all aspects of our preclinical studies or clinical trials ourselves. We rely, and expect to continue to rely, on medical institutions, clinical investigators, CROs, contract laboratories and collaborators to carry out our preclinical studies and clinical trials and to perform data collection and analysis. Such third parties play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. While we have agreements governing their activities, we have limited influence over their actual performance and will control only certain aspects of such third parties' activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable legal, regulatory, ethical and scientific standards, and our reliance on the third party does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's, the EMA's and other regulatory authorities' GCP, cGMP, Good Laboratory Practice, or GLP, and other applicable requirements for conducting, recording and reporting the results of our preclinical studies and clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected (See Section 9 "Regulatory Environment"). Regulatory authorities around the world, including the FDA and the EMA, enforce these requirements through periodic inspections of study sponsors, CROs, principal investigators and clinical trial sites. If we, our CROs, our investigators or trial sites fail to comply with applicable GCP, GLP and cGMP requirements, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA, the EMA or other regulatory authorities around the world may require us to perform additional clinical trials before issuing any marketing authorizations for our product candidates. Upon inspection, the FDA or EMA may determine that our clinical trials did not comply with GCP and cGMP requirements, which may render the data generated in those trials unreliable or unusable for the purpose of supporting the marketing authorization applications for our products. In addition, our future clinical trials will require a sufficient number of study subjects to evaluate the safety and efficacy of our product candidates. Accordingly, if, for example, our CROs fail to comply with these regulations or if trial sites fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials or incur delays in the performance of such trials, which would delay the regulatory approval process.

Therefore, the timing of the initiation and completion of trials is largely controlled by such third parties and may occur at times substantially different from our estimates. Our development activities, including preclinical studies and clinical trials conducted in reliance on third parties, may be delayed, suspended or terminated if:

- we are unable to negotiate agreements with third parties under reasonable terms;
- termination or nonrenewal of agreements with third parties occurs in a manner or at a time that is costly or damaging to us;
- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory or ethical requirements, or for other reasons.

Third party performance failures in connection with our preclinical studies and clinical trials may increase our costs, delay our ability to obtain regulatory approval, delay or prevent starting or completion of clinical trials and delay or prevent

commercialization of our product candidates. In the event of a default, bankruptcy or shutdown of, or a dispute with, a third party, we may be unable to enter into a new agreement with another third party on commercially acceptable terms. In addition, our third-party agreements usually contain a clause limiting such third party's liability, such that we may not be able to obtain full compensation for any losses we may incur in connection with the third party's performance failures. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

3.3.4 FUTURE INSURANCE COVERAGE AND REIMBURSEMENT STATUS OF OUR PRODUCT CANDIDATES IS UNCERTAIN.

We expect the cost of a single administration of our products candidates to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our product candidates will depend substantially, in the United States and the European Union in particular, on the extent to which the costs of our product candidates will be paid or reimbursed by government authorities, private health coverage insurers and other third-party payors. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. 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 our product candidates. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In many countries outside the United States, product sales generally are subject to extensive government price controls and other market regulations (see Section 9 "Regulatory Environment").

Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations additional legislative changes and downward pressure on healthcare costs in general. As a result, increasingly high barriers are being erected to the entry of new products such as ours.

3.3.5 IF WE ARE UNABLE TO ESTABLISH SALES, MARKETING AND DISTRIBUTION CAPABILITIES FOR OUR PRODUCT CANDIDATES, WHETHER IT BE AN INTERNAL INFRASTRUCTURE OR AN ARRANGEMENT WITH A COMMERCIAL PARTNER, WE MAY NOT BE SUCCESSFUL IN COMMERCIALIZING THOSE PRODUCT CANDIDATES IF AND WHEN THEY ARE APPROVED.

Other than the appointment of our Vice President of Marketing, we currently have no sales, marketing, or distribution capabilities. To successfully commercialize any of our product candidates, we will need to develop these capabilities, either on our own or with others, which will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We intend to commercialize our products, on our own or with strategic partners, in Europe and the United States and expect to seek partnership agreements in Asia for sales, marketing and distribution. If any current or future collaborators do not commit sufficient resources to commercialize our products, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Without an internal team or the support of a third party to perform marketing, sales and distribution functions, we may be unable to compete successfully against more established companies.

3.3.6 THE COMMERCIAL SUCCESS OF ANY OF OUR PRODUCT CANDIDATES WILL DEPEND UPON THEIR DEGREE OF MARKET ACCEPTANCE BY PHYSICIANS, PATIENTS, THIRD-PARTY PAYORS AND OTHERS IN THE MEDICAL COMMUNITY.

Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential products. If any

of our product candidates is approved but fails to achieve market acceptance among physicians, patients or third- party payors, we will not be able to generate significant revenues from such product.

The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including:

- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- patient awareness of genotyping;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

3.4 RISKS RELATED TO OUR BUSINESS OPERATIONS

3.4.1 RISKS RELATED TO THE IMPACTS OF THE COVID-19

The **REVERSE and RESCUE** Phase III trials of LUMEVOQ® (GS010) for the treatment of Leber Hereditary Optic Neuropathy (LHON) are completed, and patients have been transferred to long-term follow-up for an additional 3-year period. As of today, 10 out of 61 patients are due to attend their first annual follow-up visit (at Year 3 after injection) in the coming weeks and months. Given the follow-up nature of these visits and the stability of patients with no safety concern, delaying some of these visits is an acceptable precautionary measure, which should have no impact on the conduct of the trial, and will be properly documented and reported to regulators.

The **strategic manufacturing partner (CDMO)** for LUMEVOQ® is maintaining its operations and has indicated that no delay is currently expected in the planned activities to support the filing to the European Medicines Agency (EMA) in Europe. We are actively working with our partner to complete this key part of the regulatory dossier.

We held a **pre-submission meeting with the EMA** on March 19, 2020, as planned, in the form of a teleconference. Official minutes of the meeting are expected by the end of April, and the Company remains on track for regulatory filing in Europe (MAA filing with EMA) in Q3 2020, with potential approval in H2 2021.

The **REFLECT** Phase III trial of LUMEVOQ® is fully recruited with a primary endpoint at 78 weeks. Although some on-site visits are being postponed, the Company is closely partnering with clinical sites, and investigators continue to assess the safety of all patients remotely, in accordance with regulators' guidelines. Safety monitoring is an absolute priority and will not be disrupted. Most patients are due to make their 78-week visit in the near future, and some may be delayed as a result. This will be properly documented and reported to regulators, as well as pre-specified in the Statistical Analysis Plan (SAP), in agreement with biostatisticians, before database lock. Accordingly, we foresee limited impact on the trial and no consequence on the primary endpoint other than a possible delay in data availability from Q1 to Q2 2021, which will be confirmed as soon as possible. The regulatory filing target with the FDA in the US remains H2 2021.

The **PIONEER** Phase I/II clinical trial of GS030, combining gene therapy and optogenetics for the treatment of retinitis pigmentosa (RP), has fully completed recruitment of the second cohort. The Data Safety Monitoring Board (DSMB) is expected to make a recommendation in a few days about proceeding to the third cohort with a higher dose, based on an interim look at the safety database. The use of corticosteroids pre and post gene therapy injection, performed as part of the protocol to minimize inflammatory response, was deemed by the Company and investigators to expose patients to a higher risk of COVID-19 infection. In order to protect patients, the Company and investigators have together decided to delay recruiting new patients into the third cohort until the COVID-19 situation has improved, as RP is a chronic disease, and does not require an urgent treatment. In the interim, the six patients in the first two cohorts are being remotely monitored for safety aspects by investigators. Consequently, recruitment may take longer than expected; this limited impact will be more precisely assessed as soon as possible.

A patient was treated with LUMEVOQ® under a first **Temporary Authorization for Use (ATU)** granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) in December 2019. A second patient was treated early 2020, and several additional ATUs have been requested and are being reviewed by the ANSM. Hospitals focusing their resources on the current COVID-19 situation may delay requesting additional ATUs as well as the treatment of patients

in the next few weeks. We expect any delay to be overcome as soon as patients can get normal access to treatment sites, with no material impact on the related revenues expected in 2020; this will be more precisely assessed as soon as the situation improves. In addition, the Company is currently discussing with the ANSM the possibility to broaden individual named patient ATUs to a cohort ATU as soon as feasible to further facilitate access to LUMEVOQ® for patients in Europe.

We have implemented measures to protect its staff against COVID-19 by putting in place remote working for all employees.

The Company is financed until the end of 2020 and is investigating other financing options through debt or equity, seeking in priority several non-dilutive financing initiatives promoted by the French government and Bpifrance in addition to existing commitments from Kreos Capital, in order to increase cash available for operations and ensure that the Company is able to face any evolution of the COVID-19 situation with as much flexibility and foresight as possible.

3.4.2 OUR FUTURE SUCCESS DEPENDS ON OUR ABILITY TO RETAIN KEY EMPLOYEES, CONSULTANTS AND ADVISORS AND TO ATTRACT, RETAIN AND MOTIVATE QUALIFIED PERSONNEL, AND MEMBERS OF OUR MANAGEMENT TEAM MAY BE AFFECTED BY CONFLICTS OF INTEREST TO THE EXTENT THAT THEY SERVE IN MANAGEMENT OR DIRECTORSHIP CAPACITIES AT OUR COMPETITORS.

We are highly dependent on members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current employees might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is a shortage of skilled individuals with substantial gene therapy experience, which is likely to continue. As a result, competition for skilled personnel, including the area of gene therapy research and vector manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and could have a material adverse effect on our business, financial condition, results of operations and prospects.

3.4.3 WE MAY NOT BE SUCCESSFUL IN OUR EFFORTS TO IDENTIFY OR DISCOVER ADDITIONAL PRODUCT CANDIDATES AND MAY FAIL TO CAPITALIZE ON PROGRAMS OR PRODUCT CANDIDATES THAT MAY BE A GREATER COMMERCIAL OPPORTUNITY OR FOR WHICH THERE IS A GREATER LIKELIHOOD OF SUCCESS.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources towards particular product candidates may not lead to the development of viable commercial products and may divert resources away from more promising opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties with respect to some of our product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the pharmaceutical industry, our business prospects could be harmed.

The success of our business currently depends primarily upon our ability to identify, develop and commercialize our lead product candidates, GS010 and GS030, as well as to identify other product candidates based on our MTS and optogenetics technology platforms. However, we may be unsuccessful in identifying potential product candidates for development. Alternatively, our potential product candidates may be shown to have harmful side effects or other characteristics that could make the products unmarketable or unlikely to receive marketing approval. If we are forced to abandon our development efforts for a program or programs, this would likely have a material adverse effect on our business and could potentially cause us to cease operations.

3.4.4 WE MAY BE SUBJECT TO PRODUCT LIABILITY LAWSUITS.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and may face an even greater risk if we commercialize any products that we may develop. If we cannot successfully defend ourselves against

claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

3.5 LEGAL RISKS AND RISKS RELATED TO OUR INTELLECTUAL PROPERTY

3.5.1 WE DO NOT OWN ANY ISSUED PATENTS AND OUR RIGHTS TO DEVELOP AND COMMERCIALIZE OUR PRODUCT CANDIDATES ARE SUBJECT TO THE TERMS AND CONDITIONS OF INTELLECTUAL PROPERTY LICENSES GRANTED TO US BY OTHERS.

Although since 2016 we have in-licensed at least 10 U.S. and foreign patent applications and at least 22 U.S. and foreign patents, we do not currently own any issued patents, and we are heavily reliant upon licenses to certain patent rights and other third party intellectual property rights that are important or necessary to the development and commercialization of our technology and products, including technology related to our manufacturing process and our gene therapy product candidates. Any of our patent applications may not be granted, and these intellectual property licenses and any patents that issue from these applications may not provide us with rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. In particular, there may be unforeseen areas of technology over which the licensed rights, or any patents that issue from our pending applications, may not extend and for which we may be unable to obtain rights in the future. To the extent our licenses do not cover a relevant field or territory, the third-party licensor of applicable intellectual property rights may block our ability to develop or commercialize our technology and products in such field or territory unless we are able to extend our license to cover such field or territory. Further, our licenses may not provide us with exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competing products in fields and/or territories included in our licenses.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology licensed to us by third parties. For example, pursuant to our intellectual property license agreement with Adverum Biotechnologies, Inc., or Adverum, Adverum retains control of such activities. Therefore, we cannot be certain that the Adverum patent applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensors fail to prepare, file, maintain or enforce such patents or patent applications, or lose rights to such patents or patent applications, the rights licensed to us may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition, we face similar risks and uncertainties regarding our pending patent applications and any other patent rights that we may own in the future.

In some circumstances, our license agreements provide that we must grant, on a non-exclusive royalty-free basis, a license to the licensor to exploit technological improvements we have made to the licensed technology. Such "grant-back" provisions may limit our exclusive rights in technology we develop in-house, and so may hinder the extent to which we can prevent competitors from developing and commercializing competing products relating to those technologies.

We also in-licensed certain patents owned by the Regents of the University of California as Head Licensor through our license agreement with Adverum and we in-license certain patent rights from the Massachusetts Institute of Technology, or M.I.T. Under applicable law, to the extent that the research giving rise to the patents or technology so licensed was funded by the U.S. government, the U.S. government may have certain rights, including (1) a non-exclusive, irrevocable, paid-up license to practice or have practiced such patents or technology on behalf of the United States and (2) "march-in rights" requiring the grant of licenses under such patent rights and technology to one or more third parties. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents and inventions, including a non-exclusive license to practice or have practiced on behalf of the U.S. government such patents and inventions. These rights may further permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we or our licensors fail to achieve practical application of the U.S. government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, our

rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our business, financial condition, results of operations and prospects.

In addition, licenses to additional third-party technology and materials that may be required for our development programs, including additional technology and materials owned by any of our current licensors, may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have an adverse effect on our business and financial condition.

3.5.2 WE OR OUR LICENSORS MAY BE UNABLE TO OBTAIN AND MAINTAIN ADEQUATE PATENT PROTECTION FOR OUR PRODUCT CANDIDATES AND TECHNOLOGY.

Our success depends, in large part, on our and our licensors' ability to obtain and maintain patent protection in the United States, the European Union and other countries with respect to our proprietary product candidates and manufacturing technology. We or our licensors have sought and we intend to further seek, to protect our proprietary position by filing patent applications in the United States, the European Union and other jurisdictions related to many of our novel technologies and product candidates that are important to our business. If we or our licensors fail to obtain and maintain patent or other protection for this proprietary intellectual property, we could lose our rights to such intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using such intellectual property.

The patent prosecution process is expensive, time-consuming and complex and we or our licensors may not be able to, or may choose not to, file, prosecute, maintain or enforce in a timely manner, or at all, all issued patents or patent applications that we believe are necessary or desirable for our business. In addition, patents might not be issued or granted with respect to our patent applications that are currently pending, and any issued patents may be challenged, invalidated, circumvented or rendered unenforceable. We cannot assure that either we or our licensors will be successful should such patents be challenged. If our or our licensors' patent claims are rendered invalid or unenforceable, or narrowed in scope, it could seriously impair our competitive position.

Consequently, we would not be able to assert any such patents to prevent others from using our technology for, and developing and marketing competing products to treat, our indications of interest. It is also possible that we will fail to identify patentable aspects of our research and development output in timely manner to obtain patent protection.

In some cases, the work of certain academic researchers in the gene therapy field has entered the public domain, which we believe precludes our ability to obtain patent protection for certain inventions relating to such work. Consequently, we will not be able to assert any such patents to prevent others from using our technology for, and developing and marketing competing products to treat, our indications of interest. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We may not be aware of all third-party intellectual property rights potentially relating to our current and future product candidates. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and filings of patent applications, we cannot be certain of the priority of inventions covered by any pending patent applications.

Accordingly, with respect to our current patent applications and any patent applications that we may file in the future in the European Union or the United States, we may not be the first to file patent applications covering such subject matter, meaning that we may be unable to protect or exploit the invention(s) concerned.

Furthermore, for U.S. patent applications in which all claims are entitled to a priority date before March 16, 2013, we may become subject to interference proceedings or derivation proceedings before the United States Patent and Trademark Office, or the USPTO, to determine priority of invention. For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the U.S. patent laws in view of the passage of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, which brought into effect significant changes to these laws, including new procedures for challenging pending patent applications and issued patents.

Even if the patent applications that we own or license from third parties or may own in the future do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to design around or otherwise circumvent our or our licensors' patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our licensors' patents, or any patents that we may independently seek may be challenged in the courts or patent offices in the United States, the European Union or elsewhere. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or

commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property rights may not provide us with sufficient protection to exclude others from commercializing product candidates similar or identical to ours.

3.5.3 WE MAY FAIL TO COMPLY WITH OUR OBLIGATIONS UNDER THE AGREEMENTS UNDER WHICH WE IN-LICENSE INTELLECTUAL PROPERTY AND COULD THEREBY LOSE LICENSED RIGHTS THAT ARE IMPORTANT TO OUR BUSINESS.

We are a party to a number of intellectual property license agreements, including agreements with Inserm Transfert S.A., Adverum and M.I.T. that are important to our business, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that any future license agreements will impose, various diligence, development and commercialization timelines, milestone payments, royalties and other obligations on us. See Section 5.5.5 "Intellectual Property" and Section 20.2 "In-License Agreements" of this Universal Registration Document for a description of our license agreements. If we fail to comply with our obligations under these agreements, or are subject to a bankruptcy or certain other specified events, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Further, in certain of our license agreements, we have the first right to bring actions against any third party infringers of the patents licensed to us. Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing product candidates and minimum yearly diligence obligations in developing and commercializing the product. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of intellectual property and other rights under our collaborative development, manufacturing and other third-party relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of intellectual property resulting from the joint creation or use of intellectual property by our licensors, consultants, contractors, collaborators or partners and us; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

3.5.4 WE MAY NOT BE ABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS THROUGHOUT THE WORLD.

Our patent applications and in-licensed patent rights may not have corresponding patents or patent applications in other countries. In addition, the laws of some other countries do not protect intellectual property rights to the same extent as federal and state laws in the United States or patent laws in Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States and Europe, or from selling or importing products made using our inventions in and into the United States or in Europe or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States or in Europe. These products may compete with our products, patents or other intellectual property rights that we license from third parties.

Proceedings to enforce our intellectual property rights in other jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our in-licensed patents, or patents we may own, at risk of being invalidated or interpreted narrowly and our in-licensed patent applications, or patent applications we own or may own in the future, at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

3.5.5 THIRD PARTIES MAY INITIATE LEGAL PROCEEDINGS ALLEGING THAT WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY RIGHTS, THE OUTCOME OF WHICH WOULD BE UNCERTAIN AND COULD HAVE A MATERIAL ADVERSE EFFECT ON THE SUCCESS OF OUR BUSINESS.

Our commercial success depends upon our ability and the ability of our existing or future collaborators and third-party service providers to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of

third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference proceedings, post-grant review and *inter partes* review before the USPTO, the EPO or equivalent measures outside the United States and the European Union.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. We are aware of certain third-party patents relating to gene delivery to ocular cells and certain vector manufacturing methods that may relate to, and potentially could be asserted to encompass our product candidates. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed by us, which could materially and adversely affect our ability to commercialize our GS010 or GS030 product candidates or any other of our product candidates or technologies covered by the asserted third-party patents. In several major territories, including the United States, in order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this is a high burden requiring to present clear and convincing evidence as to the invalidity of such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. In addition, even if we were to prevail in any such litigation, the cost and diversion of management and employee attention could be significant and could adversely affect our business. Where a patent issued by the EPO, otherwise known as a European Patent, is concerned, it may be necessary to do this on a country-by-country basis, leading to increased litigation costs and diversion of management and employee attention. The risks of such third-party action equally apply outside the United States or the European Union, where it may also be necessary to establish, through a court or other procedure, that a patent is invalid.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations or prospects. We may be able to avoid such an outcome by obtaining a license from such third party to continue developing, manufacturing and marketing our product candidates and technology; however, we may not be able to obtain such a license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments.

3.6 INSURANCE AND RISK MANAGEMENT

We have implemented a policy to cover the main insurable risks with coverage amounts that we deem compatible with the nature of our operations. The total amount of premiums booked for all of our insurance policies for the fiscal year ended December 31, 2019 amounted to €143K.

As a development-stage business, we are unable to quantify risk to determine a coverage amount, in particular with respect to civil liability. However, we consider that the insurance policies described below adequately cover the risks inherent to our operations and that our insurance policy is consistent with practice in our sector. We do not envisage any particular difficulty in maintaining appropriate levels of insurance in the future subject to market conditions and capacities.

Our insurance policies are summarized below:

Risks covered	Insurer	Amount	Excess per claim
Comprehensive professional insurance	**GENERALI (N°AR520316)**	Globally capped at €5,900 K (2019 amounts)	
Sub-limits for operating direct damages and additional costs combined:			
• Climate events (excluding natural disasters)		€1,000 K	
• Electrical damages		€300 K	
• Machinary breakdown		€900 K	
• Costs and losses		€1,000 K	
• Liability, including use of third parties		€4,500 K	
• Automatic guarantee		€500 K	
• Error or omissions		€500 K	
• Other damages		€2,000 K	
Sub-limits for direct damages			
• Theft		€100 K	
• Computer equipment breakdown		€700 K	
• Asset in travel status and/or transport for own account		€100 K	
• Asset in deposit with third parties, limited to fire and assimilated events		€2,000 K	
• Glass breakage		€20 K	
• Research and Development expenses		€250 K	
Directors & Officers civil liability insurance: claims made or pursued world-wide	**AIG (7.919.283) and AIG (7.919.284)**	Capped at €5,000 K except for : (per "insured year")	
Reputation damage		€100 K	
Psychological support		€50 K	
Consulting fees in case of extradition		€50 K	
Support expenses in case of property restrictive measures		€60 K per insured person with a maximum amount of €200 K per insured year	
Risk mitigation expenses		€500 K per insured year, with a maximum amount of €1,000K for all insured persons	
Consulting fees related to a judicial liquidation		€50 K	
Preliminary investigation expenses following a social action *ut singuli*		€250 K	
Non-separable fault		€5,000 K	
Fund for prevention for financial difficulties		€30 K	
Consulting fees on the WCAM regulation within the framework of a group action related to financial securities		€50 K	

Risks covered	Insurer	Amount	Excess per claim
Emergency fees		€1,000 K	
Independent director		€1,000 K	
Claim related to a pollution		€1,000 K	
Civil Liability	**CHUBB (N° RC0099500275)**		
Civil operating liability:			
All damage taken together including bodily harm:		€7,500 K per "claim"	
• Inexcusable fault		€1,000 K per victim capped at €3,000 K per "insured year"	
• All "material" and "non-material" damage including:		€1,500 K per "claim"	
– "non-consecutive non-material damage"		€200 K per "claim"	€1,500
– "property damage"		€50 K per "claim"	€1,500
– "any damage resulting from accidental pollution"		€300 K per "insured year"	€1,500
Criminal defense-Appeal		€30 K per dispute	€1,500
Civil product liability:			
All damage taken together including bodily harm:		€5,000 K	€10 K
• "Non-consecutive non-material damage"		€200 K except for professional civil liability €1,000 K	€10 K
Employee Travel Insurance	**CHUBB (N° FRBBBA22378)**		
Death or total permanent invalidity		Up to €500 K depending on the person insured	
Assistance (for individuals and legal assistance abroad, business assistance, travel incident assistance)		Travel incidents: up to €15 K, Legal assistance: up to €20 K	
Medical insurance and luggage and professional equipment insurance		No limitation for medical insurance out of the country of residence and €5 K for luggage and professional equipment	
Civil responsibility		Up to €7,500 K	
Research sponsor's civil liability insurance			
Study GS-LHON-CLIN-03A in mainland France and its overseas departments and territories:	HDI Gerling		
• Victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
• Research protocol		€6,000 K	
• Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	

Risks covered	Insurer	Amount	Excess per claim
Study GS-LHON-CLIN 03A in Italy, U.K. and USA:	ALLIANZ		
• ITALY			
– Per victim		€1,500 K	
– Per research protocol		€5,000 K	
• UNITED KINGDOM			
– Per research protocol		£5,000 K	
• UNITED STATES			
– Per research protocol		$5,000 K	
Study GS-LHON-CLIN-03A in Germany	ALLIANZ		
• Per victim		€500 K	
– if up to 1,000 patients participate in this trial		€5,000 K	
– if more than 1,000 patients and up to 3,000 participate in this trial		€10,000 K	
– if more than 3,000 patients participate in this trial		€15,000 K	
Study GS-LHON-CLIN-03B in *France métropolitaine* and DOM-TOM :	HDI Gerling		
• Per victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
• Per research protocol		€6,000 K	
• Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	
Study GS-LHON-CLIN-03B in Italy, U.K. and USA	ALLIANZ		
• ITALY			
– Per victim		€1,500 K	
– Per research protocol		€5,000 K	
• UNITED KINGDOM			
– Per research protocol		£5,000 K	
• UNITED STATES			
– Per research protocol		$5,000 K	
Study GS-LHON-CLIN-03B in Germany	ALLIANZ		
• Per victim		€500 K	
– if up to 1,000 patients participate in this trial		€5,000 K	
– if more than 1,000 patients and up to 3,000 participate in this trial		€10,000 K	
– if more than 3,000 patients participate in this trial		€15,000 K	

Risks covered	Insurer	Amount	Excess per claim
GS-LHON-CLIN-01	**HDI Gerling**		
In mainland France and overseas departments and territories:			
• Per victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
• Per research protocol		€6,000 K	
• Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	
GS-LHON-CLIN-05	**HDI Global SE**		
• FRANCE			
– Per victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
– Per research protocol		€6,000 K	
– Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	
• ITALY	ALLIANZ		
– Per victim		€1,500 K	
– Per research protocol		€5,000 K	
• UNITED KINGDOM	ALLIANZ		
– Per research protocol		£5,000 K	
• UNITED STATES	ALLIANZ		
– Per research protocol		$5,000 K	
• BELGIUM	HDI Global SE		
– Per victim		€650 K	
– Per research protocol		€5,000 K	
• TAIWAN	Allianz GCS		
– Per victim		€500 K	
– Per research protocol		€2,000 K	
• SPAIN	HDI Global SE		
– Per victim		€250 K	
– Per research protocol		€2,500 K	Per protocol and annually
GS010 REGISTRY 001 (REALITY)	**HDI GERLING**		
• FRANCE			
– Per victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
– Per research protocol		€6,000 K	
– Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	

Risks covered	Insurer	Amount	Excess per claim
• ITALY	CNA		
– Per victim		€1,000 K	
– Per research protocol			
• If # subject less than or equal to 50		€5,000 K	
• If # subject more than 50 but less than 200		€7,500 K	
• If # subject more than 200		€10,000 K	
• UNITED KINGDOM	CNA		
– Per victim		£5,000 K	
– Per research protocol		£5,000 K	
• UNITED STATES	CNA		
– Per victim		$1,000 K	
– Per research protocol		$1,000 K	
• SPAIN	CNA		
– Per victim		€250 K	
– Per research protocol		€2,500 K	Per protocol and annually
GS-LHON-CLIN-06			
• FRANCE	HDI Global SE		
– Per victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
– Per research protocol		€6,000 K	
– Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	
• ITALY	CNA		
– Per victim		€1,000 K	
– Per research protocol			
• If # subject less than or equal to 50		€5,000 K	
• If # subject more than 50 but less than 200		€7,500 K	
• If # subject more than 200		€10,000 K	
• UNITED KINGDOM	CNA		
– Per victim		£5,000 K	
– Per research protocol		£5,000 K	
• UNITED STATES	CNA		
– Per victim		$5,000 K	
– Per research protocol		$5,000 K	
• GERMANY	HDI Global SE		
– Per victim (for death)		€50 K for patient of 18 up to 64 €37.5 K for patient of 65 up to 69 €25 K for patient of 70 up to 74	

Risks covered	Insurer	Amount	Excess per claim
– Per victim (for disability)		€100 K for patient of 18 up to 64 €75 K for patient of 65 up to 69 €50 K for patient of 70 up to 74	
GS030-CLIN-001	HARDY		
• UNITED STATES			
– Per claim, per research subject		$5,000 K	
– Per clinical trial		$7,500 K	
– Globally during the period of insurance		$7,500 K	
• FRANCE	HDI Global SE		
– Per victim		€1,000 K	€1,500 per victim capped at €16 K per protocol
– Per research protocol		€6,000 K	
– Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000 K	
• UNITED KINGDOM	CAN/HARDY		
– Per victim		£5,000 K	
– Per research protocol		£5,000 K	

Although we maintain insurance coverage for our clinical trials in the amount of €1 million per victim, €6 million per protocol and €10 million in the aggregate over a one-year period, this insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

3.7 INTERNAL CONTROL AND RISK MANAGEMENT PROCEDURES

As part of its listing on Euronext Paris, the Company has implemented an internal control policy and a certain number of procedures. Over time, the Company seeks to conform to AMF recommendations for small and medium-sized companies with regard to internal control.

The internal control procedures implemented by the Company are intended to:

- ensure control over operations, employee behavior and optimal resource management, in accordance with the framework defined by management, laws and applicable regulations;
- anticipate and control the risks inherent to the Company's activities, whether operational, industrial or financial.

3.7.1 GENERAL INTERNAL CONTROL ORGANIZATION.

Internal control within the Company is handled, *in fine*, by the Board of Directors, assisted by the Audit and Compensation Committees. The Company is managed operationally by two internal committees, the Executive Committee and the Management Committee.

Executive Committee

Upstream of the Board of Directors, and more operationally, an Executive Committee (ComEx) ensures compliance with current procedures. This committee meets once a week, and consists of the chief financial officer, chief medical officer and chief executive officer, who chairs it.

The Executive Committee assists the chief executive officer in the Company's strategic and operational management.

Management Committee

The Executive Committee is supported by a Management Committee (CoDir), which is the operational review body for the Company's projects. The Management Committee meets once a month and consists of the members of the Executive Committee and the Company's principal managers. It meets to monitor performance and adjust the operational orientation, if needed. The Company's Management Committee is a true place for exchange and reflection and plays a role in controlling and coordinating all operational teams. The Management Committee is responsible for meeting the Company's annual corporate objectives.

3.7.2 INTERNAL CONTROL AND RISK MANAGEMENT PROCEDURES.

The procedures implemented by the Company as part of its internal control are reviewed and evaluated by the statutory auditors during their annual reviews of half-year and annual consolidated financial statements. The findings of these tasks are shared with the Company's financial management, allowing it to take corrective measures and improve the Company's internal control. These findings are also shared with the Audit Committee.

3.7.2.1 Financial risk management

Accounting and financial information

The Company's accounting is operated by both the financial department and an independent accounting firm using a dedicated ERP system.

The recording of accounting items, preparation of accounting information, reporting and corporate reports and documentation are provided internally, while the independent firm provides monthly controls, calculation of the research tax credit (CIR) and tax returns.

The work is reviewed and analyzed within the Company's finance department, which prepares quarterly management reports for operations. These reports enable management to assess current expenses, with respect to the budget and various quarterly forecasts, and to take corrective measures if needed.

As of the date of this Universal Registration Document, the Company has implemented the following internal control procedures related to accounting and financial information, as well as the preparation of consolidated financial statements:

- the Company maintains, internally, a separation between the production and the control of financial operations, accounting procedures and the preparation of consolidated financial statements;
- an independent certified public accounting firm provides payroll management, as well as social security and tax returns;
- valuation and assessment of specific financial items, either complex or relying on subjective assumptions, are subcontracted to third-party experts. These items include notably the CIR, the provisions for compensation payable to employees on their retirement and the expense related to share-based payments;
- the Company has implemented an integrated system that provides for book keeping and securing the purchase-to-pay workflow, including electronic approvals, as well as automated entries and payments;
- the Company has implemented monthly closing procedures and key controls (Cut-off entries, Bank statement reconciliations, Manual journal entries review, Payroll reconciliation, etc.) in order to ensure the reliability of the financial information; and
- the Company has also implemented expense-control measures, using an electronic purchase order system. Invoice payments are prepared by the "accounting" function, automatically and electronically transmitted to the bank for payment, and validated by the "controlling" function.

Payroll management

Payroll is also subcontracted in its entirety to an accounting firm. We performed a monthly three-way reconciliation control (reconciliation between the payroll journal, accounting entries and bank statement) over the documentation received by the third-party provider.

3.7.2.2 Operational risk management

Given its stage of development, the Company's operations are primarily:

- preclinical and toxicity studies of drug candidates;
- pharmaceutical and clinical development of drug candidates.

3.7.2.2.1 Preclinical research and toxicity studies of drug candidates

These activities are subcontracted to top-tier, specialized international providers operating in accordance with Good Laboratory Practices (GLP) and certified by AAALAC International, a private non-profit organization that is an international reference in assessing the humane animal treatment in experimentation.

3.7.2.2.2 Pharmaceutical and clinical development of drug candidates

These activities are subcontracted to top-tier, specialized international providers operating in accordance with both Good Laboratory Practices (GLP) and Good Clinical Practices (GCP).

The manufacturing of clinical supply is subcontracted to Contract Manufacturing Organizations (CMOs).

3.7.2.3 Our internal controls, procedures and policies may fail to ensure adherence to applicable regulations

Our internal controls, disclosure controls and procedures and corporate governance policies and procedures are periodically reviewed and updated. Any system of controls, however, is based in part on certain assumptions and can provide only reasonable, rather than absolute, assurances that the objectives of the system are met. Any failure or circumvention of our controls and procedures or failure to comply with regulations related to controls and procedures could have a material adverse effect on our business, financial condition, results of operations and prospects.

INFORMATION ABOUT THE ISSUER

4

INFORMATION ABOUT THE ISSUER

4.1 LEGAL AND COMMERCIAL NAME

Our corporate name is "GenSight Biologics S.A."

4.2 PLACE OF REGISTRATION, REGISTRATION NUMBER AND LEGAL ENTITY IDENTIFIER ("LEI")

We are registered with the Paris Trade and Companies Register under number 751 164 757.

The Company is identified under the Legal Entity Identifier (LEI) 549300NK4AB8OUEX1F54.

4.3 DATE OF INCORPORATION, LENGTH OF LIFE OF THE ISSUER

We were incorporated on April 17, 2012.

The Company's duration is 99 years from the date of its with the Paris Trade and Companies Register except in the event of early dissolution or extension.

4.4 DOMICILE, LEGAL FORM, LEGISLATION, COUNTRY OF INCORPORATION, ADDRESS, TELEPHONE NUMBER AND WEBSITE

Our registered office is located at 74, rue du Faubourg Saint-Antoine – 75012 Paris, France (Tel.: +33 (0)1 76 21 72 20).

We are a French limited liability corporation *(société anonyme)* with a Board of Directors, governed by French law, including, in particular, Book II of the French Commercial Code.

Our website address is www.gensight-biologics.com

The information on the website does not form part of this Universal Registration Document unless that information is incorporated by reference into it.

BUSINESS OVERVIEW

5.1 OVERVIEW

We are an innovative clinical-stage gene therapy company with an initial focus on discovering, developing and commercializing novel therapies for severe retinal neurodegenerative diseases. We are developing a pipeline of proprietary product candidates to provide patients with a long-lasting cure for severe inherited retinal diseases for which there are no currently approved treatments. Our current product candidates are designed to be administered in a single treatment to each eye by intravitreal, or IVT, injection. We are leveraging our expertise in ophthalmology, gene therapy and drug development to restore vision by combining a gene therapy-based approach with our proprietary technology platforms of mitochondrial targeting sequence, or MTS, and optogenetics. We believe our technology platforms have broad applicability both within and outside of ophthalmology as well as central nervous system, or CNS, disorders. Our lead product candidate, GS010, is a recombinant AAV2-based gene therapy for the treatment of Leber Hereditary Optic Neuropathy, or LHON, and is currently in Phase III clinical trials. We reported 48-week top-line data from our Phase III clinical trials REVERSE (37 patients) in April 2018 and RESCUE (39 patients) in February 2019, demonstrating sustained efficacy and safety 96 weeks after a single injection in one eye, and clear superiority to published natural history. A third Phase III trial with GS010, REFLECT (98 patients), is ongoing and we expect 78-week top-line data in the first quarter of 2021 under a Special Protocol Assessment with the FDA. Our second most advanced product candidate, GS030, for the treatment of Retinitis Pigmentosa, or RP, is currently in a Phase I/II trial. The first subject was treated in October 2018, and we expect to complete recruitment in the second half of 2020.

GS010 for the Treatment of LHON

LHON is an orphan mitochondrial disease that causes the sudden and dramatic loss of vision, leading to bilateral blindness in less than a year, in teens and young adults and for which we believe there is currently no effective treatment option. LHON is estimated to have a prevalence of between one in 31,000 and one in 40,000 in the United States and the European Union, respectively. LHON originates mainly from mutations in the three NADH dehydrogenase mitochondrial genes: ND1, ND4 and ND6. NADH dehydrogenase is an enzyme that acts on NADH and is the key enzyme in cellular and mitochondrial metabolism, the complex that supplies energy to cells that promote vision. ND4 and ND1 mutations account for approximately 70% and 15% of the LHON populations, respectively.

Our lead product candidate, GS010, is developed using our MTS technology platform and is designed to treat LHON by restoring the function of NADH dehydrogenase resulting from a mutation in the ND4 gene. Our MTS technology platform allows for efficient expression of a mitochondrial gene by active delivery of messenger ribonucleic acid, or mRNA, to polysomes located at the mitochondrial surface. This allows for the synthesis, translocation, internalization and proper localization of the missing mitochondrial protein into the matrix of the mitochondrion. We believe that our MTS technology is the only existing technology that permits missing mitochondrial proteins to be actively shuttled into the mitochondrion, enabling the restoration of mitochondrial function necessary to effectively treat LHON.

GS010 has received orphan drug designation for the treatment of LHON in the United States and the European Union, and is being evaluated in our ongoing Phase III clinical trials. We reported top-line data from our first Phase III clinical trial REVERSE in April 2018, highlighting the favorable safety and tolerability profile of GS010, and showing a clinically meaningful improvement of visual acuity of +11 ETDRS letters in treated eyes at 48 weeks as compared to baseline in all 37 patients. A similar improvement was reported in untreated eyes, and caused the trial not to meet its primary endpoint, defined as a difference of improvement in visual acuity in GS010-treated eyes compared to sham-treated eyes at 48 weeks. We reported additional results at 72 and 96 weeks in October 2018 and May 2019, showing a clinically meaningful improvement of visual acuity from baseline of +15 ETDRS letters in treated eyes, and of +13 ETDRS letters in untreated eyes at Week 96, sustained from Week 72. The trial also demonstrated a statistically significant relative preservation of the structure of the retina in treated eyes, specifically the volume of the retinal ganglion cells and the thickness of the nerve fiber layers, while untreated eyes continued to deteriorate. We also reported increasing improvements in quality of life at both 48, 72 and 96 weeks. In addition, we also observed that 68% of REVERSE subjects achieved a Clinically Relevant Recovery (CRR) from baseline compared to 15% in a natural history study conducted by Santhera . We reported similar top-line results from our second Phase III trial RESCUE in February 2019, showing visual acuity in GS010-treated eyes and sham-treated eyes evolving with similar trajectories, worsening to a low point, or nadir, before beginning to improve by Week 48. We reported additional results at 72 and 96 weeks in April and September 2019, showing sustained recovery from nadir. By Week 96, GS010-treated eyes improved by +26 ETDRS letters from nadir, sustained from Week 72, compared to the Week 48 improvement of +13 ETDRS letters. This recovery at Week 96 could not yet completely offset deterioration from baseline through the acute phase: GS010-treated eyes were still below baseline by -9 ETDRS letters, compared to -19 ETDRS letters at Week 48. The strength of the bilateral recovery shifted the mean BCVA in both sets of eyes from being off-chart at Week 48 to on-chart at Week 72 and 96. In addition, 61% of GS010-treated eyes improved by a clinically meaningful difference of +15 ETDRS letters from nadir. Similarly,

71% of GS010-treated eyes improved by a clinically meaningful difference of +10 ETDRS letters from nadir. We also reported that 63% of REVERSE subjects achieved a CRR from nadir compared to 28% in a natural history study conducted by Santhera[(1)]. In addition, we conducted a non-clinical study to further investigate the bilateral effect observed in both REVERSE and RESCUE trials. In this study, we reported positive proof of GS010 DNA transfer from one eye to the other eye following unilateral intravitreal injection of primates. Indeed, tissue samples from the non-injected eye of monkeys that had been unilaterally injected with GS010 were found to contain GS010 DNA three months after injection, indicating the expression of the therapeutic gene in the contralateral eye. With these results from REVERSE and RESCUE, we intend to meet with the FDA and apply for Fast Track Designation, which if granted, would allow us to file a BLA and seek priority review, and/or Regenerative Medicines Advanced Therapies designation (RMAT) allowing, in addition to priority review, for a rolling submission and eligibility for accelerated approval, while we continue to conduct our ongoing REFLECT trial pursuant to a special protocol assessment with the FDA. In addition, we expect that the complete results at 96 weeks of our Phase III REVERSE trial and RESCUE trial will be sufficient to support filing for marketing authorization in the European Union. We believe that the benefits of GS010 treatment may prevent further vision loss and/or restore vision, leading to increased autonomy and overall quality of life for affected individuals. We have completed a Phase I/II trial for GS010 in France in 15 subjects with long-standing vision loss from LHON with the ND4 gene mutation. Results of this trial were published in *Ophthalmology*, the journal of the American Academy of Ophthalmology. This trial demonstrated that GS010 was well tolerated, with no unexpected treatment-emergent adverse events, no serious adverse events related to the treatment or procedure, and no suspected unexpected serious adverse reactions. We believe that GS010 has the potential to be the first therapy approved by the FDA for the treatment of LHON.

RESCUE enrolled LHON patients with an onset of vision loss of less than six months in duration, while REVERSE enrolled patients with an onset of vision loss between 6 and 12 months. REFLECT enrolled patients with an onset of vision loss of less than 12 months. For more information on clinical trials protocols, see Section 5.2.2 "Our Lead Product Candidate: GS010 for the Treatment of LHON", of this Registration Document.

GS030 for the Treatment of RP

We are developing GS030 for the treatment of diseases of photoreceptor degeneration that include RP and dry age-related macular degeneration, or AMD, with and without geographic atrophy, or GA. We initially focused our studies on the treatment of RP, which is an orphan family of diseases caused by multiple mutations in over 100 genes involved in the visual cycle. On average, RP patients begin experiencing vision loss as young adults, eventually becoming blind around the age of 40 to 45. RP is the most widespread hereditary cause of blindness in developed nations, with a prevalence of about 1.5 million people throughout the world. In Europe and the United States, the prevalence of RP is approximately one in 3,500 and one in 4,000 and the incidence of new patients each year is 15,000 and 20,000. There is currently no existing treatment for RP.

GS030 utilizes our novel optogenetics technology platform. Optogenetics is a biologic technique that involves the transfer of a gene that is encoding for a light-sensitive protein to cause neuronal cells to respond to light stimulation. Our platform of optogenetics targets retinal ganglion cells, or RGCs, and modifies them into true photoreceptors. This allows us to confer a photoreceptive function to the healthy and preserved RGCs independent of any specific underlying genetic mutation. Light stimulation, which activates the protein, is amplified and enhanced by an external wearable device designed as goggles. We developed these goggles to amplify the light stimulation upon the transduced neuronal cells and expand vision restoration. We believe our technology would be immediately transferable to any disease in which photoreceptors are lost while RGCs remain, such as dry AMD and GA. Approximately 15 million people are affected with AMD in the United States, with a global prevalence of 170 million, and dry AMD accounts for approximately 80% of all cases of late-stage AMD. Given this, we expect to initiate clinical trials of GS030 for the treatment of dry AMD and GA.

GS030 has received orphan drug designation for the treatment of RP in the United States and the European Union and advanced therapy medicinal product, or ATMP, classification for the treatment of RP in the European Union. Our preclinical proof-of-concept studies have demonstrated that GS030 can restore light sensitivity in the retina of blind mice and non-human primates. In other preclinical studies, we have also restored visual behaviors *in vivo* in blind rats using GS030 with demonstrable effects upon their visual cortex. We received approval in December 2017 from the UK's Medicines and Healthcare Products Regulatory Agency, or MHRA, followed by the French *Agence nationale de sécurité du médicament et des produits de santé*, or ANSM, in May 2018 and the US FDA in August 2018, to conduct a Phase I/II clinical trial in severely affected RP subjects and treated the first subject in October 2018. We expect to complete recruitment in the second half of 2020.

(1) In a natural history study conducted by Santhera, 15% of subjects with the ND4 (11778A) mutation achieved the following definition of "clinically relevant recovery" (CRR) from baseline in at least one eye: (i) improved by at least 10 ETDRS letters from their on-chart visual acuity, or (ii) improved from an off-chart level of visual acuity to being able to read at least 5 ETDRS letters (on-chart) ; Silva *et al* (2019), "Natural History of Leber's Hereditary Optic Neuropathy (LHON): Findings from a Large Patient Cohort", Poster presented at NANOS March 16-21, 2019; Poster Session II: Scientific Advancements; Poster: 163.

Our Technology Platforms and Other Applications

We believe our integrated technology, which combines gene therapy with our core MTS and optogenetics technology platforms, has the potential to replace or restore the function of retinal cells, either RGCs or photoreceptors that have degenerated in order to regain vision for patients, thereby improving the quality of their lives. Beyond our initial product candidate, GS010 for the treatment of LHON, we believe that our MTS technology platform can be applied to treatments for LHON caused by other single mutations, including our second LHON product candidate, GS011, to treat LHON due to mutation in the ND1 gene. Similarly, we believe that GS030 using our optogenetics platform can address any disease of photoreceptor degeneration regardless of the etiology and be entirely transferable to dry AMD or GA, offering a meaningful benefit to these diseases that have significant unmet medical needs.

In addition, our MTS and optogenetics technologies have potential applicability outside of our initial focus on severe retinal diseases. We believe our MTS technology platform, given its unique ability to actively shuttle mitochondrial proteins into the mitochondrion, enables the development of treatments for the many indications involving defects of the mitochondrion, including such rare diseases as Kearns-Sayre syndrome and Alpers disease, and possibly more common disorders such as Parkinson's disease and amyotrophic lateral sclerosis, or ALS. Similarly, we believe this gene therapy approach of our optogenetics platform that permits the introduction of proteins sensitive to light stimulation has broad applicability to indications outside ophthalmology that are receptive to light stimulation, such as congenital deafness, pain treatment and vagus nerve stimulation.

We own or have exclusively in-licensed all intellectual property rights covering our MTS and optogenetics platform technologies and our current product candidates. In addition, we hold worldwide commercialization rights to our technology platforms, product candidates and development programs. Because of the orphan nature of LHON and RP, we believe a limited and targeted sales and marketing organization would be able to reach specialized ophthalmology centers and their patients.

Our Management and Scientific Team

We believe that we have a significant competitive advantage as a result of the collective experience of our management and scientific team in the biotechnology industry, specifically in the areas of ophthalmology and gene therapy. Our Chief Executive Officer and co-founder, Bernard Gilly Ph.D., has over 20 years of experience in the pharmaceutical sector and as an entrepreneur. Other members of our executive management team have significant experience in the discovery and development of gene therapy and ophthalmology drug products. Our co-founder, José-Alain Sahel M.D. Ph.D., is the Director of *Institut de la Vision* and Chairman of Departments of Ophthalmology at the *Centre Hospitalier National d'Ophtalmologie des XV-XX* and the Rothschild Ophthalmology Foundation in Paris, France. Since July 2016, Dr. Sahel has also been appointed Chairman of the Department of Ophthalmology at the University of Pittsburgh Medical Center. Such experience plays a critical role in our core MTS and optogenetics technology platforms and reflects substantial cross-disciplinary knowledge.

5.2 OUR PRODUCT DEVELOPMENT PIPELINE

Our pipeline is comprised of two lead product candidates for the treatment of sight-threatening retinal degenerative diseases, together with preclinical development programs targeting ophthalmic and neurodegenerative diseases. Below is a table summarizing our development programs:

Technology	Product Candidate	Indication	Research	Preclinical	Phase I/II	Phase III	Registration	
MTS platform	GS010 (FDA & EMA Orphan Drug Designation)	LHON ND4	→	→	→	→		REVERSE: Phase III top-line data reported in Apr (48w) & Oct (72w) 2018 and in May 2019 (96w)
								RESCUE: Phase III top-line data reported in Feb (48w), Apr (72w) and Sep (96w) 2019
								REFLECT*: Phase III recruitment completed in July 2019, top-line data expected in Q3 2020
	GS011	LHON ND1	→	→				Initiate preclinical studies following GS010 Phase III clinical data
	Undisclosed Mitochondrial Target	Undisclosed	→	→				
Optogenetics	GS030 (FDA & EMA Orphan Drug Designation)	RP	→	→	→			PIONEER: Second cohort ongoing in PIONEER Phase I/II clinical trial. Report interim data one year after last subject treated
	GS030	Dry AMD & Geographic Atrophy	→	→				

*Conducting this trial under a special protocol assessment with the FDA

Subject to the successful completion of clinical trials, we currently expect to file for regulatory approval for GS010 in Europe in the third quarter of 2020, and in the United States in the second half of 2021. Depending on the progress of our interactions with regulatory authorities, GS010 could then potentially be in a position to be approved in Europe in 2021, and in 2022 in the United States, subject however to a variety of factors, including changes in regulatory requirements, evolutions in guidance from the FDA, the EMA or other European regulatory authorities, and the occurrence of unexpected events in the approval process, preparation for commercialization or otherwise, any of which could impact our anticipated timeline and our ability to obtain regulatory approval and commercialize GS010. For a description of such factors, see Section 3 "Risk Factors" of this Universal Registration Document.

5.2.1 GENE THERAPY IN THE EYE: A WELL-VALIDATED APPROACH

The eye is a validated target organ for gene therapy due to its accessibility, small size, compartmentalization and relative immune privileged status. In addition to having a validated manufacturing process, vectors based on adeno-associated virus, or AAV, are believed to be especially well suited for treating severe retinal diseases because AAV is a small, replication-deficient virus that is non-pathogenic and has a well-documented safety profile. The vectors can be directly injected into the diseased tissue and their effects can be non-invasively observed for efficacy and safety. The blood-ocular barrier prevents the widespread dissemination of locally administered vectors throughout the body. Given the small volume of the eye, the amount of vector needed to achieve a therapeutic effect is low, reducing the amount of vector required to be administered to the patient and reducing potential systemic side effects or immune response. In addition, the reduced volume requirement provides us with the advantage of small-scale manufacturing requirements for clinical trials and potential commercialization.

Our Gene Therapy Approach

Building on our scientific expertise and clinical experience of our team, we have developed two proprietary technology platforms, MTS and optogenetics. These technologies are combined with a gene therapy-based approach and have the potential to reverse vision loss, thereby improving the quality of their lives.

- *Our MTS technology platform* allows for efficient expression of a mitochondrial gene by active delivery of mRNA to polysomes located at the mitochondrial surface. This allows for the synthesis, translocation, internalization and proper localization of the mitochondrial protein into the matrix of the mitochondrion. We believe that our MTS technology is the only existing technology that permits missing mitochondrial proteins to be actively shuttled into the mitochondrion, to enable the restoration of mitochondrial function necessary to potentially treat a variety of diseases involving defects of the mitochondrion.
- *Our novel optogenetics technology platform* permits the introduction of proteins sensitive to light stimulation and may have broad applicability to indications within ophthalmology and others that are receptive to light stimulation, such as congenital deafness, pain treatment and vagus nerve stimulation.

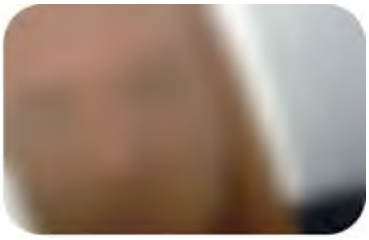
5.2.2 OUR LEAD PRODUCT CANDIDATE: GS010 FOR THE TREATMENT OF LHON

We are leveraging our MTS technology platform to develop GS010 as a treatment for LHON due to a mutation in the ND4 gene, a rare mitochondrial genetic disease that leads to blindness in teens and young adults. We believe that GS010 has the potential to be the first therapy approved by the FDA for the treatment of LHON. We have received orphan drug designation for GS010 in the United States and the European Union. GS010 is currently being studied in Phase III clinical trials. We reported top-line data from our Phase III clinical trials REVERSE in April 2018 and RESCUE in February 2019.

LHON Overview

LHON is a rare maternally inherited disease caused by defects in mitochondrial genes encoding for proteins called NADH dehydrogenase. LHON causes sudden and dramatic loss of vision, leading to bilateral blindness in less than a year, which reduces patients' autonomy and greatly alters the patient's ability to perform daily life activities, including recognizing facial features and expressions. In addition, LHON causes patients and their families trauma socially, emotionally and financially, and the quality of life of patients with LHON is generally poor. The onset of vision loss due to LHON typically occurs between 15 and 35 years of age. The following images are representative of the early onset of vision loss due to LHON, as described by patients.





LHON is caused by defects in mitochondrial genes encoding for proteins called NADH dehydrogenase. These proteins are part of a large enzyme complex known as the respiratory chain complex I, or complex I, which is active in the mitochondrion. Complex I is one of several enzyme complexes necessary for the creation of adenosine triphosphate, or ATP, which is the main energy source within the cell. Three different genes encoding for three NADH dehydrogenases have been linked to LHON and are considered to be the primary mutations for the disease to manifest: ND1, ND4 and ND6.

Although the genetic mutation is present throughout the body, LHON symptoms are almost uniquely limited to retinal ganglion cells, or RGCs. RGCs receive visual information from photoreceptors, and collectively transmit visual information from the retina to the brain *via* the optic nerve. Over the months after onset, LHON is associated with a significant thinning of the RGC layer. Once the RGCs degenerate, signals can no longer be transmitted to the brain.

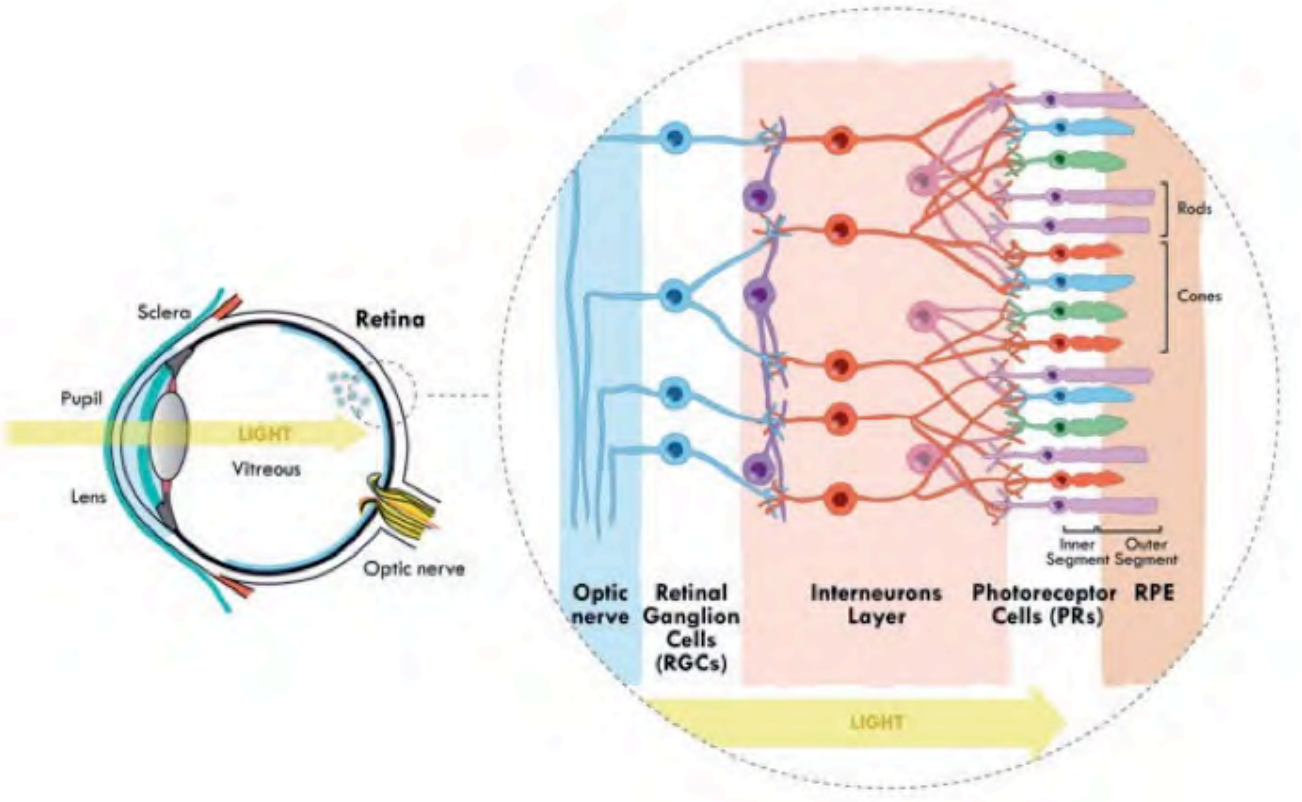
Patients with LHON typically suffer vision loss over a period of weeks and overwhelmingly both eyes are ultimately affected.

Commonly, vision loss is sequential, although some patients report simultaneous bilateral onset. Within 6 months after onset, there is atrophy of the optic nerve. Although maintaining some small element of peripheral vision, the majority of patients with the ND4 mutation become legally blind. For most patients with the ND4 mutation, vision is not recovered.

For ND4 patients, the delay between the first affected and second affected eye averages 1.8 month and the duration of progression of vision loss averages 3.2 months. The mean Early Treatment Diabetic Retinopathy Study, or ETDRS, score at 12 months is 14.4 letters in patients. The normal visual acuity score is 20/20 or 20/25, equivalent to an ETDRS score of 85 and 80 letters, respectively.

For patients with the most severe vision loss, specifically those who cannot count the fingers of the examiner held very close to their face, even small improvements such as going from off-the ETDRS chart to on the-chart or an improvement by five to 10 ETDRS letters can have a positive impact on functionality and quality of life.

The following close-up image depicts a cross-section of the human retina:



The layers of the retina are visible in the right panel, and the left panel is a cross-section of the eye including unlabeled viral particles.

No Effective Existing Therapies for the Treatment of LHON

No treatments for LHON have been approved in the United States. In the European Union, the European Medicines Agency, or EMA, granted Marketing Authorization, or MAA, for Raxone/Idebenone under "exceptional circumstances" as a treatment for LHON in September 2015, though no clinically significant effect of this agent has been demonstrated or studied in randomized clinical trials. A MAA under exceptional circumstances is when comprehensive data cannot be provided, and therefore the MAA is reviewed annually to re-assess the risk-benefit balance, in an annual re-assessment procedure.

Market Opportunity for LHON

LHON is the most common illness caused by mitochondrial DNA mutations. We estimate the incidence of LHON to be approximately 1,400 to 1,500 new patients who lose their sight every year in the United States and Europe. LHON is estimated to have a prevalence of between one in 31,000 and one in 40,000 in Northern Europe. European and North American studies of LHON patients indicate that the ND4 mutation accounts for up to 70% of LHON cases. In Asian countries, the proportion of ND4 mutation is higher, ranging from 80% to 85%.

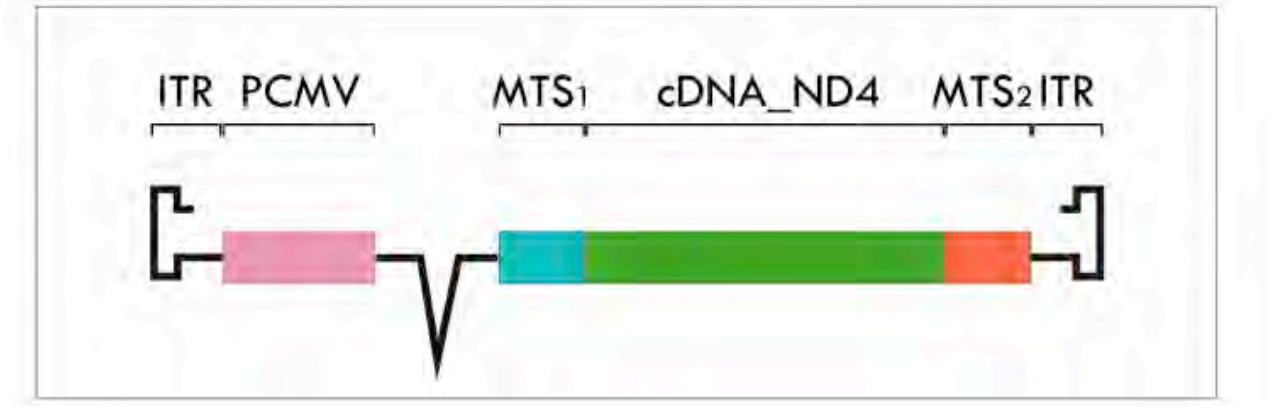
Our Solution: GS010 for the Treatment of LHON

GS010 is developed through our MTS technology platform and is designed to restore the function of NADH dehydrogenase and therefore improves vision. Our GS010 product candidate is a recombinant AAV vector, serotype 2, or AAV2, containing the human wild-type mitochondrial ND4 gene combined with our proprietary MTS technology. We are developing GS010 for the treatment of LHON due to the ND4 gene mutation with visual loss of less than one year.

Our novel, proprietary MTS platform technology has enabled us to develop GS010 with potential advantages, including:

- IVT administration, a straightforward and common approach well-accepted by ophthalmologists, in contrast to subretinal injections;
- use of the AAV2 vector, which is the most studied of all AAVs, with a demonstrated safety profile and validated manufacturing process; in addition, there are currently no IP rights attached to AAV2 and thus no royalty payments associated with its use;
- small viral load administered, decreasing the risk of systemic immunologic response;
- injection of small volumes, reducing the likelihood of ophthalmic complications; and
- small required volumes, resulting in ease of manufacturing.

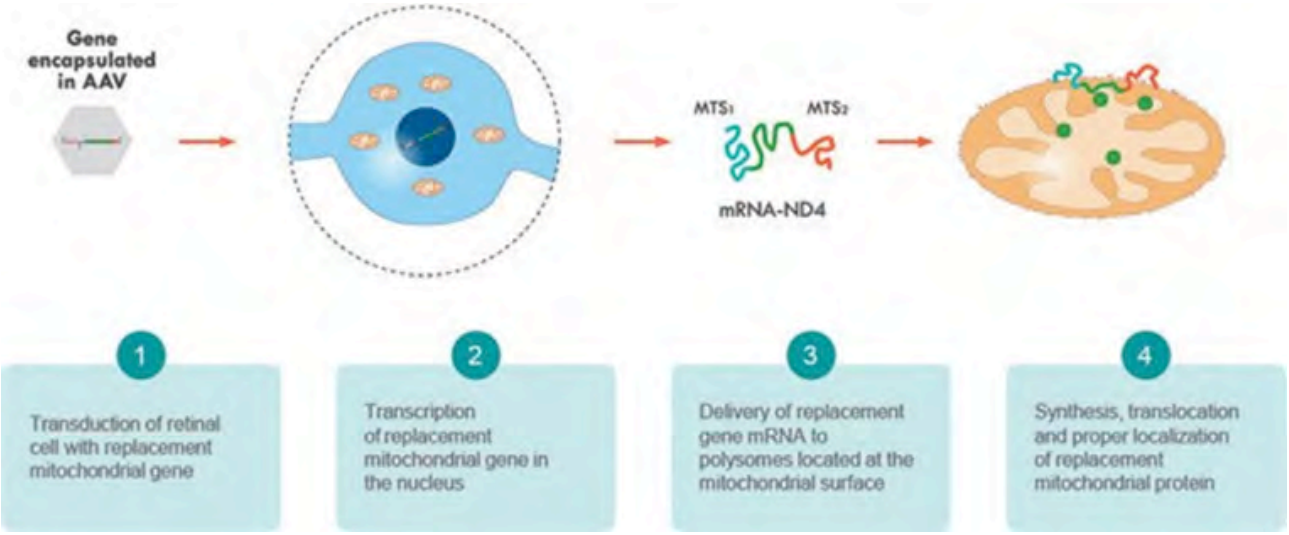
The following image depicts the schematic design of GS010, which includes the steps listed below the image. GS010 allows an efficient expression in the cell nucleus of a mitochondrial wild-type ND4 gene, encoding for a protein which is normally produced in the mitochondrion.



ITR: Inverted Terminal Region; PCMV: Promoter cytomegalovirus; cDNA: complementary DNA; ND4: NADH Dehydrogenase Subunit 4

- The ND4 transgene is flanked by two oligonucleotide sequences, referred as MTS1 and MTS2 in the above diagram.
- MTS2 allows the ND4 mRNA to be addressed to polysomes that are attached to the outer mitochondrial membrane, where it is translated into ND4 protein.
- MTS1, in turn, allows the ND4 protein to be transported through the mitochondrion membrane into the matrix where it integrates the complex I of the respiratory chain in order to restore normal function.

Our construction of GS010, that includes the two MTSs and the functional transgene, is what actively drives this into the mitochondrial matrix, and characterizes the unique nature of our MTS platform, as depicted in the following image.



Clinical Development Program for GS010

We have completed a Phase I/II clinical trial for GS010 and our two most advanced Phase III clinical trials, RESCUE and REVERSE, reported top-line results in 2018 and 2019. Both of these Phase III trials are designed as randomized, double-masked, sham-controlled, multi-center clinical trials in Europe and the United States, of LHON subjects with the ND4 mutation with vision loss. RESCUE has enrolled 39 subjects with an onset of vision loss of less than 6 months in duration and REVERSE has enrolled 37 subjects with an onset of vision loss between 6 and 12 months. Based on our regulatory interactions, subjects as young as 15 are included in our Phase III clinical trials.

Time since onset of vision loss is considered a major factor in the ability to intervene therapeutically due to the neuro-degenerative nature of LHON and the cell death of the RGCs. We have therefore chosen to evaluate two subject groups in these two Phase III clinical trials based on the onset of vision loss of less than one year. This will allow us to define the efficacy of GS010 in early affected populations of subjects at different stages of the disease and to compare an otherwise homogeneous patient population.

Our Phase III clinical trials are intended to determine if GS010 is an effective treatment in halting or reversing vision loss associated with LHON due to the ND4 mutation. A dose level of 9E10 vg/eye was administered once by IVT injection in both trials to a randomly chosen single eye of each subject. The dose level of GS010 in our Phase III clinical trials was determined based on outcomes of the safety and tolerability in our Phase I/II clinical trial.

The primary endpoint of the RESCUE and REVERSE clinical trials is based on Best Corrected Visual Acuity, or BCVA, as measured with the ETDRS at 48 weeks post-injection relative to baseline. The patients' log of the Minimal Angle of Resolution, or logMAR, scores, which are derived from the number of letters they read on the ETDRS chart, will be used for statistical analysis. Both trials have been adequately powered to evaluate a clinically relevant difference of at least 15 ETDRS letters between treated and untreated eyes adjusted to baseline.

The secondary efficacy endpoints compare the best seeing eyes that received GS010 to those that received sham, and compare worse seeing eyes that received GS010 to those that received sham. We will evaluate the proportion of subjects who maintain vision (< ETDRS 15L loss), the proportion of subjects who gain 15 ETDRS letters from baseline, and the proportion of subjects with Snellen acuity of > 20/200. Complementary vision metrics will include automated visual fields, optical coherence tomography, or OCT, and color and contrast sensitivity, in addition to quality of life scales, bio-dissemination and the time course of immune response.

REVERSE : Results at 48, 72 and 96 weeks

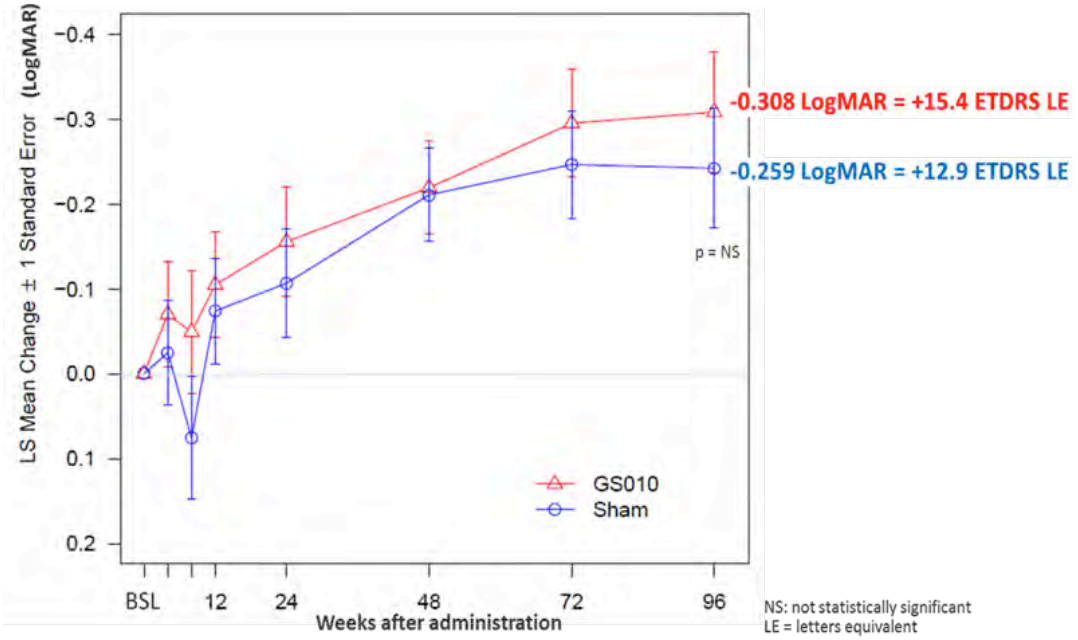
In April 2018, we reported top-line results from REVERSE, our first Phase III clinical trial evaluating the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 37 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) commenced between 6 and 12 months prior to study treatment.

Top-line results highlight the favorable safety and tolerability profile of GS010, and demonstrate a clinically meaningful improvement of +11 ETDRS letters (-0.218 LogMAR) in treated eyes at 48 weeks as compared to baseline in all 37 patients. Unexpectedly, untreated contralateral eyes (treated with a sham injection) show a similar improvement of +11 ETDRS letters (-0.211 LogMAR). Due to this improvement in untreated eyes, the trial did not meet its primary endpoint, defined as a difference of improvement in visual acuity in GS010-treated eyes compared to sham-treated eyes at 48 weeks.

We reported additional results at 72 weeks in October 2018 and 96 weeks in May 2019, showing a continued clinically meaningful improvement of visual acuity of +15 ETDRS letters (-0.308 LogMAR) in treated eyes, and of +13 ETDRS letters (-0.259 LogMAR)(1) in untreated eyes. This improvement, which extends the positive trend that had been reported at Weeks 48 and 72, points to a sustained functional outcome for the trial subjects.

The improvement of visual acuity in sham-treated eyes was unexpected based on the natural history of LHON, for which limited partial spontaneous recovery is reported in only 8 to 22% of patients with the G11778 ND4 mutation (Lam *et al.* 2014, Riordan-Eva et al. 1995).

The graph below shows the mean change from baseline in visual acuity, in both treated (GS010) and untreated (sham) eyes, over time in LogMAR:



Continued bilateral improvement was also observed in contrast sensitivity as determined by Pelli-Robson low-contrast testing. At 96 weeks, GS010-treated eyes and sham-treated eyes gained on average +0.22 LogCS and +0.12 LogCS versus baseline, respectively.

In a natural history study conducted by Santhera(2), 15% of subjects who had the 11778A mutation achieved the following definition of spontaneous "clinically relevant recovery" (CRR) from baseline in at least one eye:

- Improved by at least 10 ETDRS letters from on-chart visual acuity, or
- Improved from off-chart visual acuity to being able to read at least 5 ETDRS letters.

By comparison, 68% of REVERSE subjects achieved this definition of CRR in at least one eye at Week 96, with GS010-treated eyes significantly more likely to achieve this than sham-treated eyes (62% vs. 43%, p = 0.0348).

The objectively measured endpoints were the effects of GS010 on parameters measured with high resolution Spectral-Domain Optical Coherence Tomography (SD-OCT). The trial demonstrated relative preservation of the structure of the retina in both treated and untreated eyes, specifically the volume of the retinal ganglion cells and the thickness of the nerve fiber layers. The critical secondary endpoint of the change in retinal ganglion cell macular volume measured from baseline to Week 96 demonstrated a reduced loss of volume of -0.018 mm^3 for GS010 eyes and -0.031 mm^3 for Sham eyes.

The secondary endpoint of change in thickness of the papillo-macular bundle of the retinal nerve fiber layer from baseline to Week 96 demonstrated preservation of retinal nerve fibers GS010-treated eyes showing a change in thickness of +1.3 µm and sham eyes showing change in thickness equal to +0.6 µm. The change in thickness of the temporal quadrant of the retinal nerve fiber layer from baseline to Week 96 demonstrated reduced loss

(1) Efficacy Endpoint was assessed using a mixed model of analysis of covariance (ANCOVA), with change from baseline at week of interest as the response, and subject, eyes of the subject as random factor, treatment and the baseline LogMAR value as covariates.
(2) Silva *et al* (2019), "Natural History of Leber's Hereditary Optic Neuropathy (LHON): Findings from a Large Patient Cohort", Poster presented at NANOS March 16-21, 2019; Poster Session II: Scientific Advancements; Poster: 163.

of retinal never fibers, with GS010 eyes showing a change in thickness of -1.5 µm and sham eyes –2.4 µm.

In May 2019, we reported continued quality of life improvements at 96 weeks. All 37 patients in REVERSE were asked to complete the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25), a reliable and valid vision-specific quality-of-life instrument that measures patients' perception of their ability to perform daily activities requiring high-acuity vision and their general sense of well-being. The test defines sub-scales for functions such as near-distance vision and vision-related dependency as well as measures of well-being such as ocular pain and vision-related mental health. These sub-scale scores are aggregated into a composite score, excluding the general health rating question.

Well-accepted as a source of patient-reported measures of vision-related function, the questionnaire has been used in many clinical trials. A study in neovascular AMD – which, like LHON, leads to loss of central vision – showed that a clinically meaningful 15-letter change in BCVA was associated with a 4- to 6-point change in the NEI VFQ-25 composite score and in sub-scores in three pre-specified areas (near activities, distance activities, and vision-specific dependency).

At Week 96, REVERSE patients reported mean improvement from baseline for NEI VFQ-25 scores in domains important to patients with loss of central vision: near activities, distance activities, vision-specific dependency and composite score. An improvement had already been observed at Week 48, confirming sustained enhancement of ability to perform activities of daily living. In addition, large improvements were also noted in other domains relevant to LHON patients: role difficulties, general vision, and overall mental health. Again, the improvements observed at Week 48 were sustained at Weeks 72 and 96. The relevant comparison in REVERSE is against patients' own baseline, because the NEI VFQ-25 is assessed by patient; by design, all REVERSE patients received an injection in one eye.

NEI VFQ-25 Results from REVERSE

Mean change from baseline (absolute score and percent)

	Composite Score**	Near Activities	Distance Activities	Dependency	Role Difficulties	General Vision	Mental Health
Week 48	+7.2	+10.4	+9.6	+12.4	+14.5	+10.3	+11.2
	23.2%	*65.1%*	*49.8%*	*100.6%*	*65.0%*	*50.9%*	*81.9%*
Week 72	+8.1	+9.5	+8.2	+18.9	+15.2	+11.9	+15.2
	25.2%	*58.1%*	*42.5%*	*130.2%*	*70.9%*	*54.1%*	*105.6%*
Week 96	+9.5	+13.3	+10.7	+18.5	+15.9	+6.5	+16.1
	+28.8%	*+78.1%*	*+47.4%*	*130.2%*	*+78.9%*	*+32.4%*	*+108.2%*
Clinically relevant difference*	+3.90 to +4.34	+4.67 to +6.06	+5.15 to +5.38	+4.72 to +4.98	+3.31 to +4.70	+4.38 to +4.82	+4.70 to +4.88

* Suñer *et al.* (2009): clinically relevant score differences based on a clinically significant 15-letter BCVA improvement at 12 months.

** The composite score is an average of the vision-targeted sub-scale scores, excluding the general health rating question.

RESCUE : Results at 48, 72 and 96 weeks

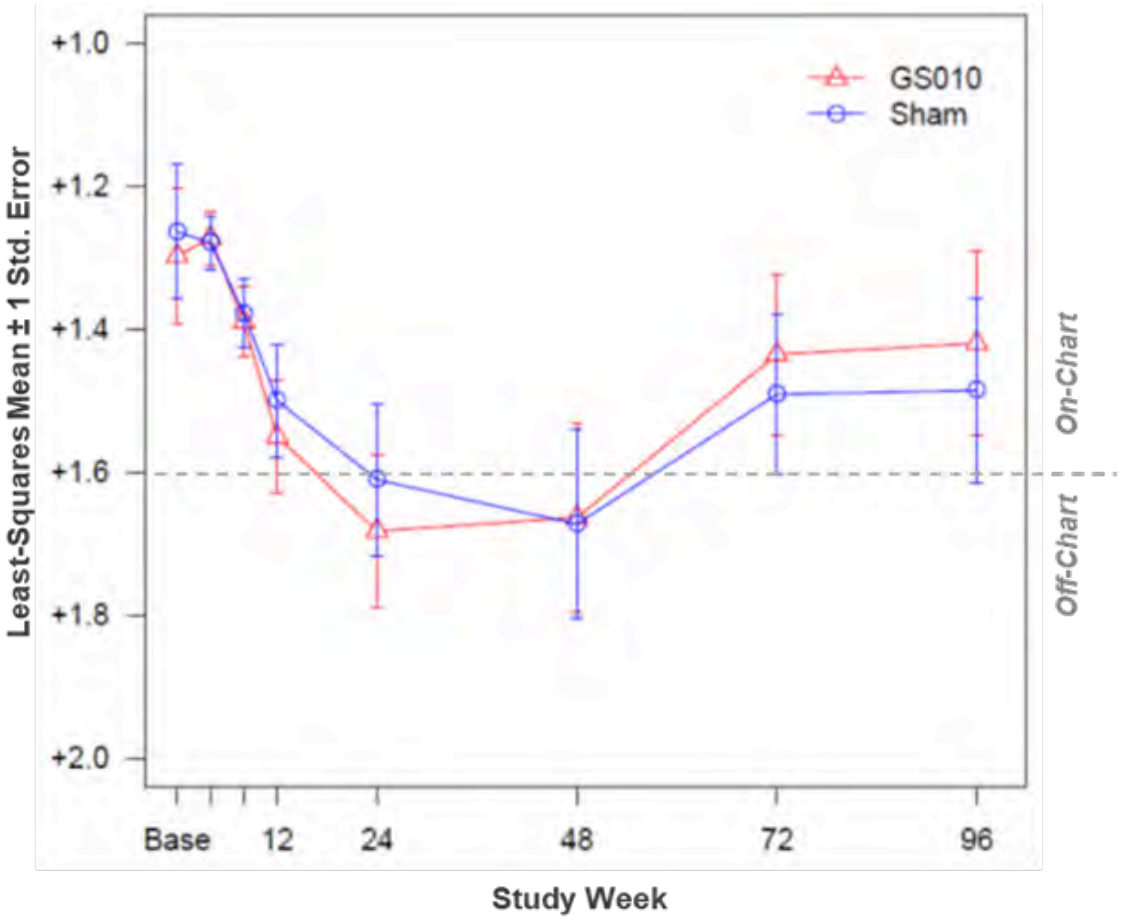
In February 2019, we reported top-line results from RESCUE, our second Phase III clinical trial evaluating the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) commenced up to 6 months prior to study treatment.

Visual loss in LHON usually progresses such that vision reaches a nadir in 3 to 5 months, before stabilizing; the duration and severity of this progression to nadir varies from patient to patient. In RESCUE, mean best-corrected visual acuity (BCVA) of GS010-treated eyes and sham-treated eyes evolved with similar trajectories, worsening to a low point before showing an improvement at Week 48. At Week 48, change from baseline for GS010-treated eyes was +0.380 LogMAR (-19 ETDRS letters), while that for sham-treated eyes was +0.392 LogMAR (-20 ETDRS letters). These figures incorporate a recovery from the nadir of vision loss for drug- and sham-treated eyes: mean improvement from nadir was +13 ETDRS letters equivalent in GS010-treated eyes and +11 ETDRS letters equivalent in sham-treated eyes. Due to this bilateral improvement, the primary efficacy endpoint, defined as a +15-letter difference in visual acuity improvement for GS010-treated eyes compared to sham-treated eyes at 48 weeks, was not met.

Planned analysis of other visual functions and anatomic measures showed results broadly consistent with the direction of BCVA evolution: similar trajectories for GS010-treated and sham-treated eyes with the difference in change from baseline not being statistically significant at Week 48.

We reported follow-up results at 72 weeks in April and 96 weeks in September 2019, showing sustained recovery from the lowest point, or nadir, experienced in the acute phase of the disease. By Week 96, GS010-treated eyes improved by -0.526 LogMAR (+26 ETDRS letters) from nadir, compared to the Week 48 improvement of -0.257 LogMAR (+13 ETDRS letters) and the Week 72 improvement of -0.413 LogMAR (+21 ETDRS letters). This sustained at Week 96 could not yet completely offset deterioration from baseline through the acute phase: GS010-treated eyes were still below baseline by 0.178 LogMAR (-9 ETDRS letters), compared to 0.380 LogMAR (-19 ETDRS letters) at Week 48. The U-shaped curve thus closely matched that of GS010-treated eyes, so a statistically significant difference in visual acuity between GS010- and sham-treated eyes could not be shown.

Time Course of Best-Corrected Visual Acuity (BCVA) in LogMAR



The strength of the bilateral recovery shifted the mean BCVA in both sets of eyes from off-chart values at Week 48 to on-chart values at Weeks 72 and 96. In addition, 61% of GS010-treated eyes improved by a clinically meaningful difference of -0.3 LogMAR (+15 ETDRS letters) from nadir. Similarly, 71% of GS010-treated eyes improved by a clinically meaningful difference of -0.2 LogMAR (+10 ETDRS letters) from nadir.

Contrast sensitivity (CS), a second visual function, evolved in a manner similar to BCVA: while values for GS010-treated eyes and sham-treated eyes remained below baseline, CS also recovered so that the gap to baseline diminished at Weeks 72 and 96 compared to Week 48. The two sets of eyes closely matched each other, so that the difference between their CS values was not statistically significant.

In a natural history study conducted by Santhera[1], 28% of subjects who had the 11778A mutation achieved the following definition of spontaneous "clinically relevant recovery" (CRR) from nadir in at least one eye:

- Improved by at least 10 ETDRS letters from on-chart visual acuity, or
- Improved from off-chart visual acuity to being able to read at least 5 ETDRS letters.

By comparison, 63% of REVERSE subjects achieved this definition of CRR in at least one eye at Week 96, with GS010-treated eyes as likely to achieve this as sham-treated eyes (58% vs. 45%, p = 0.0956).

Change from in Best-Corrected Visual Acuity (LogMAR and ETDRS Letter Equivalents)

	Change from BASELINE								
	Week 48			Week 72			Week 96		
LS Mean (SE) [a]	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent
GS010 Eyes	37	-0.218 (0.055)	+11	37	-0.294 (0.063)	+15	37	-0.308 (0.068)	+15
Sham Eyes	37	-0.211 (0.055)	+11	37	-0.246 (0.063)	+12	37	-0.259 (0.068)	+13

	Change from BASELINE								
	Week 48			Week 72			Week 96		
LS Mean (SE) [a]	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent
GS010 Eyes	34	+0.380 (0.129)	-19	34	+0.192 (0.104)	-10	34	+0.168 (0.132)	-8
Sham Eyes	34	+0.392 (0.129)	-20	33	+0.216 (0.104)	-11	34	+0.238 (0.132)	-12

(a) Efficacy Endpoint was assessed using a mixed model of analysis of covariance (ANCOVA), with change from baseline at week of interest as the response, and subject, eyes of the subject as random factor, treatment and the baseline LogMAR value as covariates.

	Change from NADIR[a]								
	Week 48			Week 72			Week 96		
Mean (SD) [b]	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent
GS010 Eyes	37	-0.487 (0.426)	+24	37	-0.553 (0.444)	+28	37	-0.566 (0.450)	+28
Sham Eyes	37	-0.432 (0.462)	+22	37	-0.478 (0.498)	+24	37	-0.490 (0.480)	+24

	Change from NADIR[a]								
	Week 48			Week 72			Week 96		
Mean (SD) [b]	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent	n	LogMAR	ETDRS Letters Equivalent
GS010 Eyes	34	-0.287 (0.377)	+14	34	-0.509 (0.496)	+25	34	-0.526 (0.479)	+26
Sham Eyes	34	-0.238 (0.325)	+12	33	-0.452 (0.495)	+23	34	-0.457 (0.485)	+23

(a) Nadir was defined as the lowest Visual Acuity value from baseline up to Week of interest. LP/NLP vision was not included in the analysis.
(b) Mean change from nadir was calculated using observed values (no data were imputed).

(1) Silva *et al* (2019), "Natural History of Leber's Hereditary Optic Neuropathy (LHON): Findings from a Large Patient Cohort", Poster presented at NANOS March 16-21, 2019; Poster Session II: Scientific Advancements; Poster: 163.

REVERSE and RESCUE Safety

REVERSE and RESCUE studies demonstrated a consistent safety read-out: GS010 was well-tolerated over 96 weeks. There were no serious adverse events in GS010-treated eyes, and no discontinuations due to ocular events. Most frequently seen ocular adverse events in the therapy group were mainly related to the injection procedure, except for the occurrence of intraocular inflammation, likely related to GS010, and responsive to conventional treatment and without sequelae. There were neither systemic serious adverse events nor discontinuations that were related to study treatment or study procedure.

Non-Human Primate Study

We conducted a non-clinical study in non-human primates to further investigate the bilateral effect observed in both REVERSE and RESCUE trials. In this study, we reported positive proof of GS010 DNA transfer from one eye to the other eye following unilateral intravitreal injection of primates.Tissue samples from the non-injected eye of monkeys that had been unilaterally injected with GS010 were found to contain GS010 DNA three months after injection, indicating the expression of the therapeutic gene in the contralateral eye.

GS010 is currently being investigated in an additional ongoing Phase III trial, REFLECT, while patients in REVERSE and RESCUE continue to be followed for a total period of 5 years.

REFLECT

REFLECT is a multi-center, randomized, double-masked, placebo-controlled Phase III study to evaluate the safety and efficacy of bilateral injections of GS010 in subjects with LHON due to the NADH dehydrogenase 4 (ND4) mutation.

REFLECT is conducted under a Special Protocol Assessment with the FDA on request of the Agency.

The trial planned to enroll 90 patients with vision loss up to 1 year in duration and will be conducted in multiple centers in Europe and in the U.S.

In the active arm, GS010 will be administered as a single intravitreal injection to both eyes of each subject. In the placebo arm, GS010 will be administered as a single intravitreal injection to the first affected eye, while the fellow eye will receive a placebo injection.

The primary endpoint for the REFLECT trial is the BCVA reported in LogMAR at 1.5-Year post-treatment in the second-affected/not-yet-affected eye. The change from baseline in second-affected/not-yet-affected eyes receiving GS010 and placebo will be the primary response of interest. The secondary efficacy endpoints include: BCVA reported in LogMAR at 2-Years post-treatment in the second-affected/not-yet-affected eye compared to both placebo and the first-affected eye receiving GS010, OCT and contrast sensitivity and quality of life scales.

The first subject was treated in March 2018, and enrolment was completed in July 2019, ahead of schedule.

With these results from REVERSE and RESCUE, we intend to meet with the FDA and apply for Fast Track Designation, which if granted, would allow us to file a BLA and seek priority review, and/or Regenerative Medicines Advanced Therapies designation (RMAT) allowing, in addition to priority review, for a rolling submission and eligibility for accelerated approval, while we continue to conduct our ongoing REFLECT trial pursuant to a special protocol assessment with the FDA. In addition, we expect that the complete results at 96 weeks of our Phase III REVERSE trial and RESCUE trial will be sufficient to support filing for marketing authorization in the European Union.

Based on the data from our Phase III trials, we plan to initiate preclinical studies of GS011, our product candidate for the treatment of LHON subjects with the ND1 mutation with vision loss.

Phase I/II Dose-Escalation Safety Trial for GS010

In 2014, we initiated a 15 subject Phase I/II safety trial of GS010 (CLIN-01), which was designed to test the safety and tolerability profile of GS010 with ascending doses in subjects with LHON due to the ND4 mutation. Each subject received a single IVT injection of GS010 in the more severely affected eye. Subjects enrolled were required to have severe vision loss, with acuities of less than 20/200. The trial included four ascending dose cohorts each comprised of three subjects: 9E9 vector genome per eye, or vg/eye in cohort 1, 3E10 vg/eye in cohort 2, 9E10 vg/eye in cohort 3 and 1.8 E11 vg/eye in cohort 4. Once the maximum tolerated dose was established, according to the protocol, we included three additional subjects in the trial.

Overall, GS010 was well tolerated with no unexpected treatment-emergent adverse events, no serious adverse events related to the treatment or procedure, and no suspected unexpected serious adverse reactions. The most common ocular side effects were elevated intraocular pressure, or IOP, and ocular inflammation. These side effects were mostly mild, transient and, when required, treatment responsive to standard therapies, without vision loss.

The secondary endpoints included immuno-monitoring and vector bio-dissemination, visual acuity, color and contrast vision as well as structural tests such as OCT and electrophysiological tests related to the functioning of the RGCs and the optic nerve.

The results of our Phase I/II clinical trial, which were released in June 2016, demonstrated that:

- all 15 subjects completed 48 weeks of follow-up;
- consistent with the protocol requiring treatment of the worst functioning eye, baseline mean logMAR, visual acuity was worse in the treated eyes than non-treated fellow eyes;

- the magnitude of the treatment effect was impacted by disease duration and baseline vision status at the time of treatment;
- a greater magnitude of treatment effect was observed when disease duration was less than two years compared to greater than two years; and
- the magnitude of treatment effect was greater when the baseline vision status was relatively better.

After talks with consultants, we designed our ongoing Phase III trials to target a more homogeneous patient population, with more recently diagnosed (less than 12 months) vision loss, to maximize the benefits and efficacy of treatment.

Visual Function Evolution: Trends of Improved Acuity at 2.5 Years of Follow-up

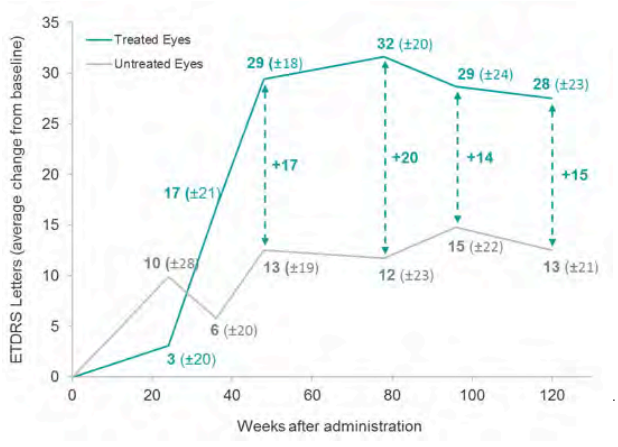
In December 2017, we reported results in 14 subjects after 2.5 years of follow-up (one subject withdrew its consent after 48 weeks of follow-up). As described in the following table, we continued to observe a greater magnitude of treatment effect when the disease duration was less than two years as compared to a disease duration that was greater than two years.

ETDRS letters (LogMAR) Visual Acuity change from baseline **Δ Treated Eye vs Untreated Eye**	**1.0 year**	**1.5 year**	**2.0 years**	**2.5 years**
All subjects (n = 14)	+3 letters (-0.06)	+8 letters (-0.16)	+0 letters (-0.00)	+7 letters (-0.14)
Subjects with ≤ 2y disease duration (n = 5)*	+17 letters (-0.34)	+20 letters (-0.40)	+14 letters (-0.28)	+15 letters (-0.30)

Note (*) Excludes "hand motion" subjects, in accordance with the Phase III protocol.

In the following chart, five letters correspond to one line on the ETDRS chart. Therefore, a difference of 15 letters is equivalent to three lines on the ETDRS chart, the widely recognized standard of clinically significant improvement.

Evolution of visual acuity in the treated eye vs. untreated eye at 2.5 years of follow-up in subjects with vision loss duration ≤ 2 years and Baseline LogMAR ≤ 2.79 (n = 5)



(*i.e.*, excludes "hand motion" subjects, in accordance with the Phase III protocol).

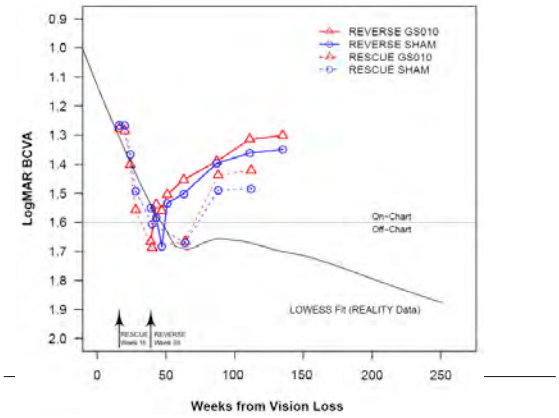
Additional Studies

REALITY

REALITY is a retrospective and cross-sectional observational study of subjects with LHON, conducted in centers across Spain, Italy, France, United Kingdom, and the United States. The objective is to generate insights about the natural history of the disease based on an approach that would facilitate comparisons with REVERSE and RESCUE. The study seeks to enroll 50 subjects by the second quarter of 2020.

Interim analysis of REALITY reported in December 2019, based on the fifteen subjects with the ND4 mutation who were at least 15 years old at onset and who had enrolled in the study as of September 2019, shows the dramatic and usually irreversible decline in visual acuity that is the typical outcome for ND4 LHON patients. Unlike in subjects enrolled in REVERSE and RESCUE, who all received a unilateral injection of LUMEVOQ™, mean visual acuity in REALITY subjects did not recover after the initial decline. The results confirm LHON experts' observations from their clinical practice.

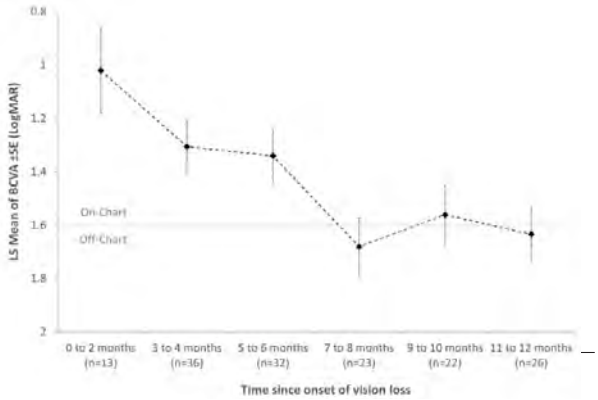
Figure 1. LHON Natural History from Interim Analysis of REALITY vs. Time Course of Visual Acuity from REVERSE and RESCUE



Note: BCVA = best-corrected visual acuity. The LOWESS line for REALITY (n=15 subjects) is based on a series of polynomial regressions around each data point. The regressions use a limited look back and look forward and give distant points less weight. The time course of BCVA for REVERSE and RESCUE uses the least-squares mean based on a mixed model ANCOVA analysis. The starting points of the curves are set to the average time from onset to time of treatment (16 weeks for RESCUE, 39 weeks for REVERSE).

A second set of results, derived from a pooled dataset of baseline readings from the REVERSE and RESCUE patient populations, shows that eyes farther along the progression of the disease, as measured by time since onset, had worse visual acuity.

Figure 2. Best-Corrected Visual Acuity (BCVA) Prior to Injection Among REVERSE and RESCUE Patients, by Time Since Onset



Note: Eyes of REVERSE and RESCUE patients were categorized according to the time between onset of vision loss and baseline reading (one day before injection). The n's represent the number of eyes in each time grouping. By design, the maximum value for onset in the pooled data is 12 months. The average for each group represents the least-squares mean of BCVA values in LogMAR. The y-axis shows an inverted LogMAR scale to represent worse vision with lower vertical positions.

The picture of visual decline is based on cross-sectional data, yet remains consistent with the pattern revealed by the interim analysis for REALITY.

Non-clinical mechanistic study in primates

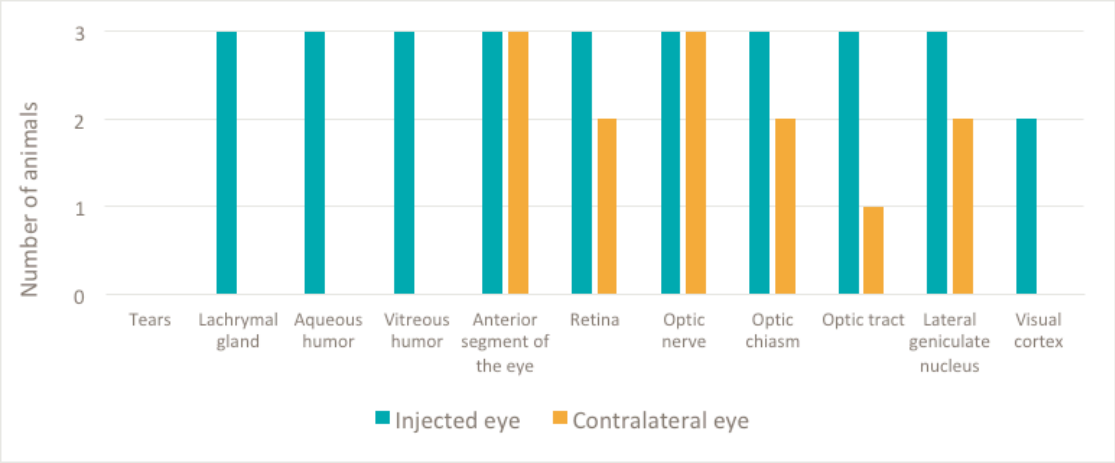
In 2019, we conducted a non-clinical study to investigate the local biodistribution of GS010. Tissue samples from the non-injected eye of monkeys that had been unilaterally injected with GS010 were found to contain GS010 DNA three months after injection, indicating the expression of the therapeutic gene in the contralateral eye.

Performed by CiToxLAB France, a leading CRO for preclinical research, the study was initiated by GenSight to investigate potential mechanisms behind the unexpected contralateral effect seen in two of GS010's Phase III trials, REVERSE and RESCUE. Both trials documented sustained bilateral improvements in LogMAR mean visual acuity. The contralateral effect did not conform to expectations for gene therapies administered to only one eye.

The CiToxLAB study used a purpose-bred species of monkeys, which is favored by scientists and accepted by regulatory bodies due to physiological similarities with humans. For testing at three months, a control monkey was given an intravitreal injection of saline solution in its right eye and was not injected in its left eye. Three test monkeys were given an intravitreal injection of GS010 in their right eyes and not injected in their left eyes. The dosage of GS010 was calibrated to be the allometric equivalent of that used in the GS010 Phase III trials. Three months after the injection, tissues from the right and left eyes were sampled and tested using a qPCR test which had been validated in a dedicated prior study. The highly sensitive and accurate test contains a protocol that specifically targets a portion of the GS010 DNA and can detect the GS010 DNA matrix.

As expected, the qPCR test did not detect the GS010 DNA in any of the tissue samples from the control monkey unilaterally injected with saline solution. Also as expected, the test was able to detect, and in many cases, quantify the presence of GS010 DNA in tissue samples from GS010-injected right eye. Remarkably the qPCR test was also able to detect, and even quantify, viral DNA vector in the contralateral eye, which had received no injection.

Presence of GS010 DNA in the visual and cerebral systems of test monkeys



Note: qPCR test used to detect GS010 DNA was validated in a dedicated study conducted prior to the monkey study. The graph depicts the number of monkeys whose tissues contained DNA that were within the sensitivity of the test to detect. In some cases, the levels were above the quantifiable threshold.

DNA was detected and quantified in the anterior segment, the retina, as well as the optic nerve of the non-injected contralateral eye. In addition, DNA was detected and quantified in the optic chiasm, suggesting that the anatomic route taken by the viral vector DNA from the treated eye to the non-treated eye could be *via* the optic nerves and chiasm.

Regulatory Interaction for GS010

In October 2014, we initiated our first discussions with the FDA regarding the prerequisites for future initiation of clinical trials in the United States. In June 2015, we submitted an application in the United States, which was cleared by the FDA on August 19, 2015.

Following our meetings with the FDA in April and December 2016, the FDA made recommendations with respect to our RESCUE and REVERSE studies, as well as the bilateral treatment of LHON subjects. Based on these recommendations, a special protocol assessment, or SPA, of a bilateral clinical protocol was submitted to the FDA in July 2017 for subjects with vision loss due to the ND4 mutation. The design and planned analysis of the REFLECT protocol (GS-LHON-CLIN-05) testing the efficacy and safety of bilateral injections of GS010 has been agreed to with FDA. Based on REVERSE data and *post-hoc* analyses, we plan on meeting with the FDA to ensure that the GS010 clinical development plan continues to meet their expectations to support a regulatory submission. Based on results of RESCUE and REVERSE, if compelling, we intend to meet with the FDA and apply for Fast Track Designation, which if granted, would allow us to file a BLA and seek priority review and rolling submission, and/or Regenerative Medicines Advanced Therapies designation (RMAT) allowing, in addition to priority review, eligibility for accelerated approval, while we continue to conduct our ongoing REFLECT trial pursuant to a special protocol assessment with the FDA. In addition, we expect that the complete results at 96 weeks of our Phase III REVERSE trial and RESCUE trial will be sufficient to support filing for marketing authorization in the European Union.

In December 2019, the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM), granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*. Dr Catherine Vignal, who as the prescribing physician originated the request, will be able to use LUMEVOQ™ to treat a patient recently affected by Leber Hereditary Optic Neuropathy (LHON). GenSight Biologics committed to provide the drug for a bilateral injection.

The temporary authorization is the outcome of a close partnership between physicians and pharmacists from the CHNO of the *Quinze-Vingts*, the *"Ouvrir les yeux"* (Open the eyes) patient advocacy group and GenSight Biologics, to the benefit of patients affected by LHON.

In France, use of pharmaceutical products not yet approved with a Marketing Authorization (AMM) and not recruiting for a clinical trial requires first obtaining an ATU from the ANSM.

Named patient ATUs are granted by the ANSM under the following conditions:

- The product is meant to treat, prevent or diagnose a severe or rare disease,
- No other appropriate treatment is available in France,
- The product's efficacy and safety are presumed in the state of scientific knowledge,
- The ATU is requested by and remains under the responsibility of the prescribing physician when the drug has the potential to benefit the patient.

5.2.3 OUR SECOND PRODUCT CANDIDATE: GS030 FOR THE TREATMENT OF PHOTORECEPTOR DEGENERATION

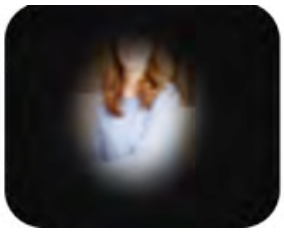
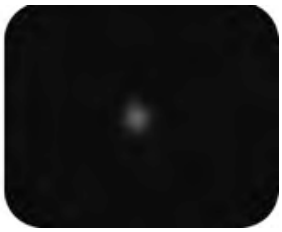
We are leveraging our optogenetics technology platform to develop GS030 for the treatment of diseases of photoreceptor degeneration that include RP, dry AMD and GA. Our most advanced clinical program using our optogenetics platform is for the treatment of RP, which is an orphan family of diseases caused by multiple mutations in over 100 genes involved in the visual cycle. There is currently no existing treatment for RP. GS030 has received orphan drug designation for the treatment of RP in the United States and the European Union and advanced therapy medicinal product, or ATMP, classification for the treatment of RP in the European Union. We are currently conducting a Phase I/II clinical trial in end stage, non-syndromic RP subjects. The first subject was treated in October 2018, and we expect to complete enrollment in the third quarter of 2020. We anticipate receiving interim data within one year after the last subject is treated. Upon evidence of clinical proof of concept in RP and demonstration of our approach, we believe this technology would be immediately transferable to any disease in which photoreceptors are lost while RGCs remain, such as dry AMD and GA. Given this, we expect to initiate clinical trials of GS030 for the treatment of dry AMD and GA.

RP Overview

RP is the leading cause of hereditary blindness in developed countries. RP represents a group of related genetic eye disorders that clinically manifest in visual disability. The mutations that cause RP are heterogeneous and include recessive, dominant and X-linked forms of more than 100 genes.

RP causes progressive vision loss due to degeneration of rod photoreceptors resulting in the loss of peripheral vision followed by degeneration of cone photoreceptors resulting in loss of central vision. The first symptom of RP is usually difficulty with night vision, which may occur as early as childhood. The disease progresses over a period of years or decades and often ultimately leads to complete loss of vision. Some patients become blind as early as age 30, and the majority of patients become legally blind before the age of 60. RP reduces patients' autonomy and greatly alters the patients' ability to perform daily life activities. The following images illustrate a representation of the deterioration of normal vision to blindness in RP.



No Existing Therapies for the Treatment of RP

No treatments for RP have been approved in the United States or the European Union. Other gene therapy approaches under development to treat vision loss due to RP are focused on specific mutations and these therapies, if approved, would be limited to specific patient subpopulations. Another alternative to treat vision loss from RP involves medical devices in the form of retinal implants, certain of which products have received marketing approval in Europe and the United States. Retinal implants have proven to restore some visual perception in patients and are intended for patients with advanced RP who have lost their photoreceptors. Therefore, treatment of RP is considered a significant unmet medical need.

Market Opportunity in RP

RP is the leading cause of hereditary blindness in developed countries, with a prevalence of about 1.5 million people throughout the world. In Europe and the United States, about 265,000 to 350,000 patients suffer from RP, and every year an estimated 10,000 to 15,000 patients with RP lose their sight. Some studies of prevalence rates of RP may underestimate the number of severely visually impaired patients with RP because they are based on patients with active follow-up care in ophthalmology clinics. We believe that many patients stop seeing ophthalmologists within a few years after reaching blindness because of a perceived lack of treatment and difficulty in traveling to medical centers.

Our Solution: GS030 for the Treatment of Photoreceptor Degeneration

GS030 is developed through our optogenetics platform and is designed to confer light sensitivity to normally light insensitive retinal neurons, specifically RGCs, in order to restore vision. While there is significant loss of photoreceptor cells in these diseases, RGCs are preserved.

Our novel, proprietary optogenetics platform technology has enabled us to develop GS030 with potential advantages over other therapies currently in development, including:

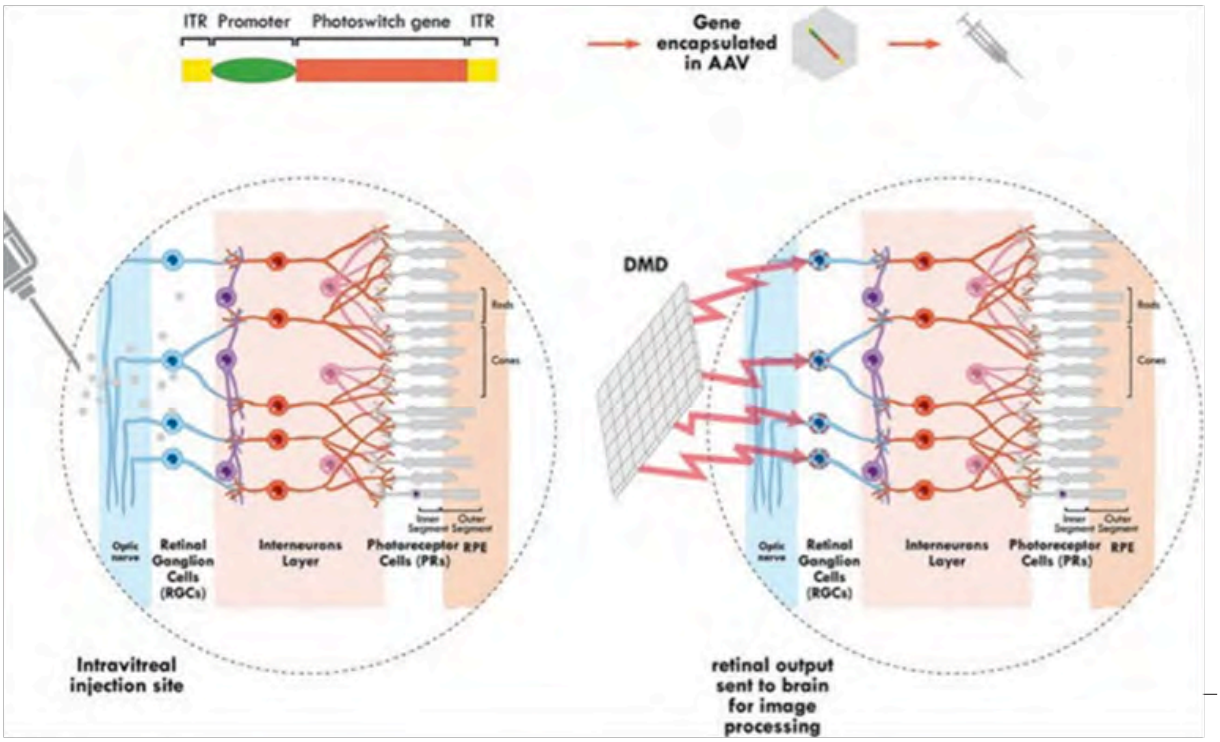
- potential to address any photoreceptor degenerative disease independent of genotype;

- IVT administration, a straightforward and common approach well-accepted by ophthalmologists, in contrast to subretinal injections;
- small viral load administered, decreasing the risk of systemic immunologic response;
- injection of small volumes, reducing the likelihood of ophthalmic complications; and
- small required volumes, resulting in ease of manufacturing.

Our primary optogenetics strategy consists of introducing ChrimsonR, a light-sensitive protein belonging to the channel rhodopsin family into normally light insensitive cells present in the inner retinal layer, particularly RGCs, *via* a gene therapy product injected into the vitreous of an affected eye. Upon light stimulation, the ChrimsonR protein is activated leading to an electrical response of the cell, which in turn carries electrical signals encoding visual information through the optic nerve into the visual cortex of the brain. This process mimics the natural function of the retina without the need for the initial step of the transduction cascade, which normally occurs in the outer segments of the cone. By stimulating RGCs, partial restoration of retina performance allowing daily life tasks is expected.

The figure below illustrates our optogenetics strategy aimed at restoring vision in retinal degenerative diseases, which includes the following steps:

- The photoswitch gene (gene encoding for ChrimsonR protein) is packaged into an AAV2 7m8 vector.
- The AAV2 7m8 carries the transgene into RGCs, resulting in synthesis of ChrimsonR protein within the membrane of the RGCs.
- When appropriate light (590nm wavelength) is shed onto the RGCs expressing ChrimsonR, it results in a depolarization of the cells, creating an action potential which is then transmitted to the visual cortex by the optic nerve.
- The visual cortex will then assemble the signals to form a useful image.



Because cells expressing optogenetic protein are less light sensitive than normal photoreceptors, vision under regular daylight conditions is unlikely to be possible. However, amplifying the light source and mimicking the normal retinal activity of capturing visual information will then amplify the light signal at the appropriate wavelength to enable vision restoration.

Product Structure for GS030

GS030 consists of two components:

- a gene therapy product comprising a gene encoding a photoactivatable channelrhodopsin protein, ChrimsonR, delivered *via* a modified AAV2 known as AAV2 7m8; and

- an external wearable device in the form of biomimetic goggles that stimulate the engineered retinal cells. The images are projected by a light source that uses a specific wavelength onto the retina.

Development Program of GS030 for the Treatment of RP

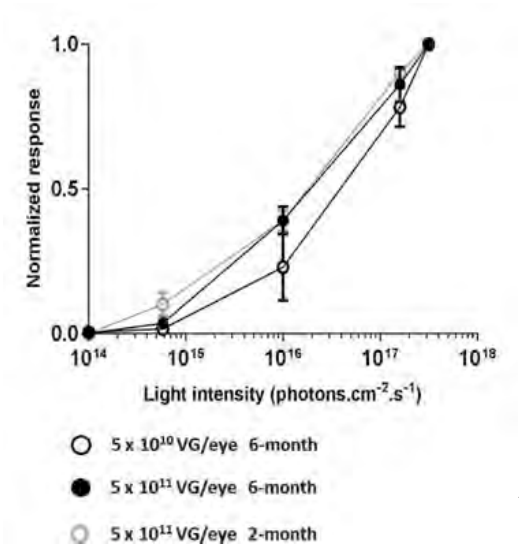
We have conducted numerous preclinical studies including a local tolerance study in mice and a long-term toxicity and biodistribution study in monkeys. GS030 for the treatment of RP is currently in an ongoing Phase I/ II trial. The first subject was treated in October 2018, and we expect to complete enrollment in the second half of 2020.

Preclinical Studies of GS030 in Non-Human Primates

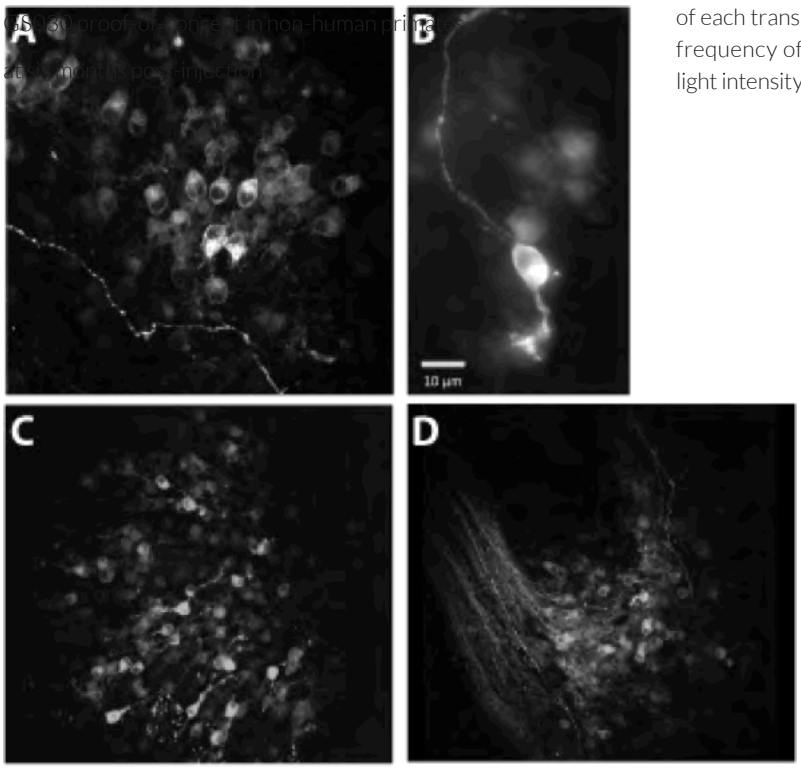
GS030 was injected intravitreally in both eyes of monkeys. After two months, the retinas were dissected and connected to a multi-electrode array system to record the electrical activity of RGCs. At regular intervals (two months and six months) the firing activity of the transduced RGCs was measured upon light activation at the appropriate wavelength and at varying intensities. The results demonstrate that two months post-injection, the RGCs of non-human primates are active, and have the ability to transmit visual information as normal RGCs would.

We conducted a confirmatory study in monkeys to assess the activity of GS030 at various doses and at six months post-injection.

GS030 proof-of-concept in non-human primates at six months post-injection



In healthy retinas, RGCs fire electric spikes to the visual cortex at frequencies that are proportional to light intensity, which is referred to as irradiance. In this experiment, monkeys are treated with GS030 and their retina is sampled after one month. Retina are put on a multielectrode array and 590nm light is then shed onto the retina at increasing intensity. As irradiance increases, the electrodes are measuring the increase of the firing frequency of each transduced RGC. As shown in the chart above, the firing frequency of the RGCs increases almost proportionally to the light intensity, which is what one would expect in a normal eye.



These photographs above show microscopic views of monkey retinas after receiving treatment with GS030. (A) and (C) show that GS030 achieves efficient transfection of the central part of the retina (fovea and peri-fovea region). (B) shows a magnification of one RGC showing that the protein is in the cytoplasm and in the membrane of the cell, as confirmed in (D) with the view of the RGCs and their axons.

This study confirmed the initial data and supports the expression of ChrimsonR in the retina of monkeys.

GLP Toxicity Studies to Assess Phototoxicity

This study assessed the phototoxicity of three levels of light intensities following GS030 injection of rd1 mice, a relevant model of RP. One dose level of GS030, which was the highest dose, was combined to a single two-hour exposure to 600nm light at three levels of intensity in order to cover the intended use in our Phase I/II clinical setting. The purpose of the study was to determine the local tolerability of light exposure on transduced RP retinas based on the following endpoints: histopathology of the retina, outer layer thickness, number of RGCs, cell viability and/or apoptosis.

GLP Toxicity Study to Evaluate Toxicity and Biodistribution

This study evaluated the toxicity, biodistribution and shedding of viral particles as well as immunogenicity of GS030 vector and ChrimsonR protein after IVT injection in non-human primates. Two dose levels of GS030 were injected bilaterally. The study allowed us to evaluate and confirm at three and six months the safety and local tolerability of the vector and protein, the biodistribution and shedding of the vector in tissues and fluids, as well as systemic and local ocular immunogenicity.

Proof-of-Concept Study Showing Restoration of Retinal Electrical Activity in a Mouse Model of RP

An rd1 mouse is affected by the degeneration of rods followed by the degeneration of cones, leading to the loss of vision five to six weeks after birth. When the retinas of such mice are dissected post-mortem and connected to a multi-electrode array, an electrical response to light is not detected. Using the same method with the retinas from rd1 mice that have received an IVT injection of GS030, an electrical response to light is produced and detected with the multi-electrode array and this response is a function of light intensity.

A New Generation of Channelrhodopsin-Based Gene Therapy

An Optimized Optogenetic Protein

We have conducted proof-of-concept studies with channelrhodopsin-2, or ChR2, which when introduced into RGCs, has proven to restore vision in a murine model of RP. However, activation of ChR2 requires high-intensity blue light at 470nm wavelength which has been shown to be toxic for the retina and is not practical for clinical use.

We have therefore developed a novel channelrhodopsin protein, known as ChrimsonR, which responds to light at near-red wavelength, where light scattering decreases and absorption by endogenous chromophores is reduced, meaning that long-term safety should be significantly improved compared to other channelrhodopsins.

A Powerful Gene Delivery Vector

Since RGCs are the cells closest to the vitreo-retinal surface, they are amenable to AAV infection with IVT injection, a major advantage from a surgical standpoint given the relative ease of administration. Our AAV is an AAV2 modified in its capsid with an inserted 7m8 sequence. Experiments have demonstrated that AAV2 7m8 has markedly improved expression in RGCs and other retinal cells compared to AAV2 in both rodents and non-human primates.

Optoelectronic External Wearable Medical Device: The Biomimetic Goggles

The natural range of light sensitivity of human photoreceptor cells is broader than that of channelrhodopsins. To achieve adequate stimulation of transduced RGCs, we combine our gene therapy-based treatment with an external wearable medical device, which allows the amplification of the image at specific optimal wavelength of the selected opsin.

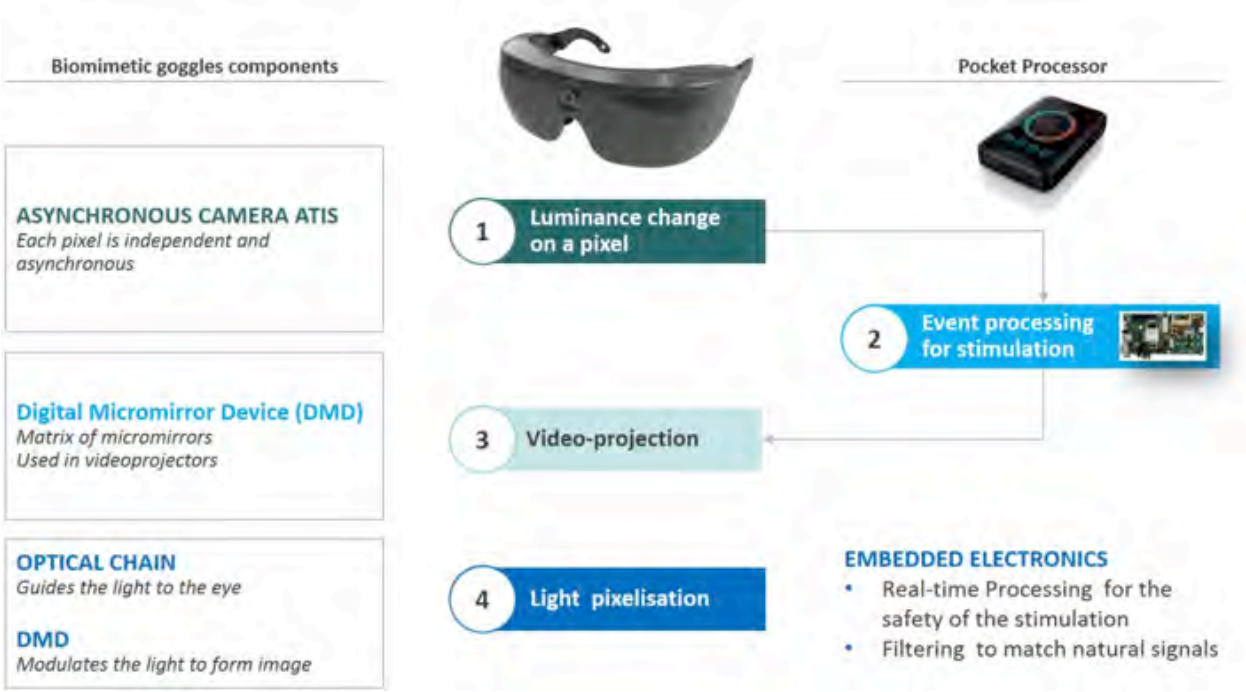
We are developing an external wearable medical device composed of:

- a visual interface integrating an asynchronous time-based image sensor, or ATIS (also called a neuromorphic video camera), and a digital micromirror array, or DMD, driven by a microprocessor, that convey the visual information signal and light to the macula; and
- a pocket processor connected to an optoelectronic stimulation device that processes the visual information and controls a light source in order to encode and amplify corresponding light signals at a specific narrowband wavelength of 580-610nm.

Software is provided to medical centers that allows the tuning and definition of parameters to optimize the patient response.

The figure set forth below presents the components of the external wearable medical device:

External Wearable Medical Device Components



We determined the necessary specifications for the external wearable medical device to optimize the specific light wavelength for activation of the ChrimsonR proteins while taking into account the particular anatomy of the eye. Our team is developing the algorithms necessary to operate the device in close collaboration with the Laboratory of Mathematics Applied to Vision of the Université Pierre et Marie Curie, or UPMC, in Paris, France. We have designed a prototype that will be further developed in advance of Phase III clinical trials and commercialization.

Preclinical Development of GS030 for RP

We have also conducted several studies in order to support the clinical Phase I/II CTA submission.

Preliminary Toxicity Study Showing Safety of GS030 in Non-Human Primates

We conducted an exploratory ocular histopathology study in non-human primates to investigate potential ocular toxicity following single bilateral IVT administration of GS030. No ophthalmological signs of intolerance or toxicity, structural modifications or inflammation of the retina were observed up to six months post-injection. A slight and transient increase in the serum anti-AAV2 immunogenicity, or neutralizing antibodies, was observed. GS030 was thus locally and systemically well tolerated up to six months.

We submitted a request for a non-clinical scientific advice recommendation from the EMA in April 2016, as well as a request for a Type C meeting with the FDA in December 2016, to validate the non-clinical program and future requirements for the device. Both the EMA and the FDA have agreed with our strategy in principle to evaluate toxicity in a rodent disease model and in non-human primates, and we therefore initiated the studies during the fourth quarter of 2016.

Clinical Development Program of GS030 for RP

We have initiated a Phase I/II, open-label, multi-center trial to evaluate the safety and tolerability of GS030 and the external wearable medical device in RP subjects. Our CTA was authorized in the United Kingdom in December 2017, in France in May 2018 and our IND was released in August 2018 in the United States. The trial includes secondary endpoints that could serve to demonstrate proof of concept of the efficacy of our optogenetics approach in RP patients. Restoration of visual perception would serve as a proof-of-concept for the combination of GS030 treatment with the use of biomimetic goggles.

We plan to enroll up to 18 subjects across up to four cohorts. The first subject was treated in October 2018 at the Moorfields Eye Hospital in London, United Kingdom, and we expect to complete recruitment in the third quarter of 2020. The initial three cohorts will undergo dose escalation to determine the maximum tolerated or feasible dose of GS030. In the fourth cohort, either the maximum tolerated or maximum feasible dose will be administered for safety analysis and proof-of-concept data collection. We anticipate receiving interim data within one year after the last subject is treated.

The trial is planned to include adult subjects with documented diagnosis of RP. The initial cohorts will enroll RP subjects with virtually no light perception or limited to light perception. Pending safety outcomes, RP subjects with higher levels of visual acuity may be considered for inclusion in the fourth cohort. As RP is a disease of photoreceptor degeneration, the restoration of vision sense will require some level of intactness of the downstream components of the visual apparatus, including the neuronal elements of the retina, RGCs, optic nerve and primary visual cortex. We believe that subjects with higher degree of visual acuity would derive greater benefit from treatment with our GS030 product candidate by virtue of their visual apparatus being better preserved.

The trial is planned to encompass the testing of traditional ophthalmic parameters, such as visual acuity tests and also functional vision tests, such as avoiding obstacles or moving in unfamiliar or changing environments. We plan to carry out subject evaluation prior to GS030 administration with and without the biomimetic goggles to establish baseline parameters. Subsequent to IVT injection of GS030, a visual rehabilitation program will ensue, comprising a training period for learning to use the biomimetic goggles in a controlled laboratory environment, including in fixed and mobile simulations and subsequently in common indoor and outdoor environmental conditions.

Baseline ophthalmological testing will be completed before and after IVT injection of GS030 with and without biomimetic goggles. Given the varied levels of disease state, it is not expected that all subjects will show improvement in all secondary outcome measures. Furthermore, use of the biomimetic goggles will require training and, therefore, we expect that the learning period will vary among subjects. As a result, the time point of demonstrating efficacy may vary among subjects. Improvement will be assessed by whether a subject can perform a visual task with "goggles on" when light-induced activation of the optogenetic protein is expected to occur compared to baseline and also compared to "goggles off" when no or insufficient photo-activation of the optogenetic protein should take place.

Regulatory Interaction for GS030

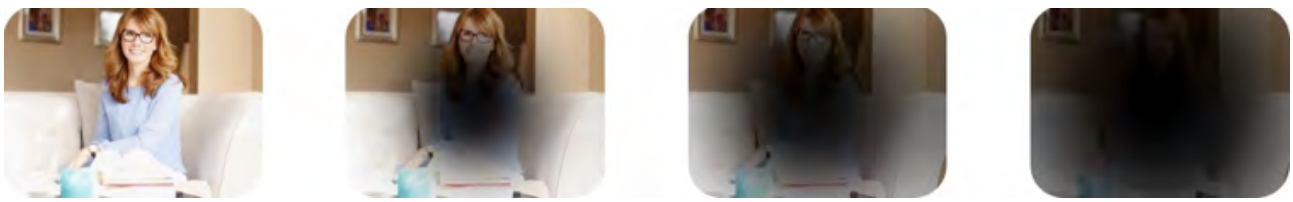
In April 2016, we requested the EMA's Committee for Advanced Therapies, or CAT, to issue a recommendation on the classification of our GS030 product, which is constituted of the biological product, in the form of gene therapy, and an external wearable medical device, in the form of biomimetic goggles. We sought the same advice at the FDA's Office of Combination Products. GS030 has been classified as a combination product whose primary mode of action is provided by the gene therapy part of GS030-DP, and the Center for Biologics Evaluation and Research, or CBER, is the jurisdiction in charge of evaluation. The regulatory pathway is based on the following classification: an IND will be necessary for clinical trial initiation, and a BLA will be required at the time of marketing authorization. In order to validate the adequacy of our non-clinical toxicology and safety program designed to support the first-in-man study, we submitted a request for non-clinical scientific advice from the EMA in April 2016 and an early Type C meeting with the FDA. Both the EMA and FDA have agreed with our strategy in principle to evaluate toxicity in a rodent disease model and in non-human primates, and we completed these toxicology studies in 2017.

In order to obtain agreement on the adequacy of the data presented to support initiation of an IND in the United States, a formal Type B Pre-IND meeting was held with the FDA in December 2017. During this meeting, the FDA agreed in principle with our Phase I/II clinical trial design, as well as CMC and medical device aspects to support an IND.

Market Opportunity for GS030 in Dry AMD and GA

AMD is a degenerative disorder characterized by loss of the photoreceptors and preservation of the RGCs, and is driven by genetic and environmental factors. Central vision, which is essential to read, perform precise tasks and recognize faces, is lost. Peripheral visual field is usually preserved. Macular degeneration typically occurs in patients over the age of 55. The early form of AMD is called dry AMD and can evolve over time to late AMD. Late AMD can take two forms, either wet AMD or GA. Dry AMD is six times more prevalent than wet AMD. Approximately 15 million people are affected with AMD in the United States, with a global prevalence of 170 million, and dry AMD accounts for approximately 80% of all cases of late-stage AMD. The prevalence of AMD increases significantly in those older than 75, reaching 22% in the population over 90.

The following image illustrates the deterioration of normal vision to blindness in AMD:



GS030: Our Planned Strategy for the Treatment of Dry AMD and GA

We believe that our optogenetics technology platform could be used for the treatment of dry AMD or GA. Because GS030 uses optogenetics and can address diseases of photoreceptor degeneration regardless of the type of mutation, we believe that GS030, if successful in the treatment of RP, would be entirely transferable to the dry form of AMD and would offer enormous benefit to a common disease currently unamenable to therapy. Although RP and GA have very different origins, both diseases are characterized by the degeneration of the photoreceptor cells in the patient's retina. Upon evidence of clinical proof-of-concept in RP, we may initiate clinical trials of GS030 for the treatment of dry AMD and GA.

5.2.4 LEVERAGING OUR PLATFORMS TO ADDRESS CENTRAL NERVOUS SYSTEM DISORDERS

We have established an integrated development platform to replace or restore the function of retinal cells that have degenerated in order to regain quality of sight for patients, thereby transforming their lives. We intend to pursue the application of our integrated development platform to other indications beyond ophthalmology, in particular, for degenerative diseases of the central nervous system.

5.2.5 PHARMACO-ECONOMICS OF BLINDNESS AND VISUAL IMPAIRMENT

Blindness and visual impairment impact not only the individual but also the family, caregivers, and the community, leading to significant societal costs. The total annual cost of vision disorders and blindness in the United States was estimated to be $139 billion in 2013, and the total cost of blindness alone in the European Union was estimated at €32 billion, or up to €60,000 per patient per year. These figures include direct costs such as medical treatment, medical visual prostheses, adaptations and assistance devices, and special training and assistance programs, as well as indirect costs resulting from impaired vision, the loss of productivity and the need for supportive care, long-term care and the costs of social programs. These conditions also can have significant, multidimensional effects on patients' quality of life, including their physical and emotional well-being.

5.3 IMPORTANT EVENTS IN THE DEVELOPMENT OF THE COMPANY

April 2012	Incorporation of the Company on the basis of a collaborative effort involving renowned academic institutions.
March 2013	Series A private round raising €19.7 million through Novartis Venture Fund, Abingworth, Versant Ventures, Vitavest S.à r.l. and Bpifrance (FBIMR).
February 2014	Initiation of a Phase I/II clinical trial to assess safety and tolerability of GS010 in Leber's Hereditary Optic Neuropathy, or LHON.
June 2015	Positive interim safety report of the Phase I/II clinical trial confirming safety and tolerability of GS010 in LHON.
July 2015	Series B private round raising €32.1 million (or €30.8 million net proceeds) through our Series A investors joined by Fidelity Management & Research Company, Perceptive Advisors, Jennison Associates, HealthCap and Sphera Global HealthCare Fund.
December 2015	Initiation of two Phase III clinical trials to demonstrate efficacy of GS010 in LHON.
July 2016	Listing of our shares on Euronext Paris which allowed the Company to raise approximately €45.2 million (or €41.4 million net proceeds).
January 2017	U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to the Company's product candidate GS030 for the treatment of Retinitis Pigmentosa.
April 2017	Creation of the first subsidiary, GenSightBiologics Inc., registered and located in the Unites States of America.
June 2017	Capital Increase which allowed to raise €22.5 million (or €20.7 million net proceeds), by means of a private placement reserved to a category of persons, U.S. and European institutional investors specialized in healthcare and biotechnology.
December 2017	Positive long-term visual acuity gains and safety results from Phase I/II Study of GS010 for the treatment of Leber Hereditary Optic Neuropathy.
December 2017	GenSight Biologics received MHRA approval to initiate Phase I/II PIONEER clinical trial of GS030 gene therapy in Retinitis Pigmentosa.
April 2018	Top-line data at 48 weeks of the REVERSE Phase III clinical trial with GS010 in LHON.
October 2018	Top-line data at 72 weeks of the REVERSE Phase III clinical trial with GS010 in LHON.
October 2018	Treatment of first subject in first-in-man PIONEER Phase I/II clinical trial of GS030 combining gene therapy and Optogenetics for the treatment of Retinitis Pigmentosa.
December 2018	Additional data reporting sustained quality of life improvements at Week 72 of the REVERSE Phase III clinical trial with GS010 in LHON.

February 2019	Topline data at 48 weeks of the RESCUE Phase III clinical trial with GS010 in LHON.
February 2019	Completion of an €8 million capital increase without discount subscribed entirely by Sofinnova.
April 2019	Topline data at 72 weeks of the RESCUE Phase III clinical trial with GS010 in LHON.
May 2019	Topline data at 96 weeks of the REVERSE Phase III clinical trial with GS010 in LHON.
July 2019	GenSight Biologics completes enrollment of GS010 REFLECT Phase III trial in the treatment of LHON ahead of schedule.
September 2019	Topline data at 96 weeks of the RESCUE Phase III clinical trial with GS010 in LHON.
October 2019	Reporting of evidence of GS010 DNA transfer to contralateral eye of primates unilaterally injected with GS010 Gene Therapy.
December 2019	First Temporary Authorization for Use (ATU nominative) granted to the National Eye Hospital of the *Quinze-Vingts* in Paris by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM)
December 2019	Interim analysis of 15 patients in REALITY natural history study supporting REVERSE and RESCUE efficacy results
December 2019	GenSight Biologics obtains €15 million in financing through a bond issuance from Kreos Capital and a reserved capital increase from Sofinnova and 3SBio

5.4 STRATEGY AND OBJECTIVES

Our goal is to transform the lives of patients suffering from severe degenerative diseases of the eye and central nervous system through the development and commercialization of novel therapies by combining gene therapy-based approaches with our proprietary MTS and optogenetics technology platforms. The key elements of our strategy are the following:

- **Complete clinical development and obtain regulatory approval for our lead product candidate, GS010, for the treatment of LHON.**

We reported top-line results of our two most advanced ongoing Phase III clinical trials of GS010 for the treatment of LHON, RESCUE and REVERSE, in 2018 and 2019. We intend to meet with the FDA and apply for Fast Track Designation, which if granted, would allow us to file a BLA and seek priority review and rolling submission, and/or Regenerative Medicines Advanced Therapies designation (RMAT) allowing, in addition to priority review, eligibility for accelerated approval, while we continue to conduct our ongoing REFLECT trial pursuant to a special protocol assessment with the FDA. In addition, we expect that the complete results at 96 weeks of our Phase III REVERSE and RESCUE trials will be sufficient to support filing for marketing authorization in the European Union. GS010 has received orphan drug designation for the treatment of LHON in the United States and the European Union. We believe that GS010 has the potential to be the first FDA-approved therapy for LHON.

- **Advance clinical development of our second most advanced product candidate, GS030, using our optogenetics technology for the treatment of RP.**

GS030 has demonstrated that it can restore light sensitivity in the retina in animal models. In late 2017, we received MHRA approval to conduct a Phase I/II clinical trial of GS030 in blind RP subjects. We treated the first subject in October 2018 and expect to complete recruitment in the second half of 2020. We anticipate receiving interim data within one year after the last subject is treated. GS030 has received orphan drug designation for the treatment of RP in the United States and the European Union. We believe that due to its ability to introduce a gene encoding for light-sensitive protein into target cells, GS030 has the potential to be the first therapy that partially or fully restores sight to RP patients.

- **Expand our pipeline by leveraging our proprietary MTS technology platform.**

Mitochondrial defects are associated with several severe degenerative diseases of the optic nerve as well as diseases of the central nervous systems. We believe our discovery capabilities and clinical experience will allow us to pursue the preclinical and clinical development of treatments using our MTS technology platform to more broadly target degenerative diseases such as other forms of LHON or diseases of the central nervous system. For example, while our later stage Phase III LHON trials are designed to treat subjects with the mutation in the ND4 gene, we plan to initiate preclinical development for GS011 using our MTS technology to treat LHON due to mutation in the ND1 gene. In addition, our MTS technology platform has the potential to address neurodegenerative diseases of the central nervous system caused by mitochondrial defects, such as Kearns-Sayre syndrome, Alpers disease, Parkinson's disease and ALS.

- **Pursue preclinical development of other indications using our optogenetics technology platform.**

The initial focus of our optogenetics technology platform using GS030 is for disorders of the photoreceptor cells, in particular RP. However, because GS030 can address diseases of photoreceptor degeneration regardless of the type of mutation, we believe that GS030 may be extended to address patients suffering from dry AMD and GA, both areas of significant unmet medical need. We plan to explore other indications outside of ophthalmology where we are able to use light to stimulate the neurons, such as congenital deafness, pain treatment and vagus nerve stimulation.

- **Directly commercialize our lead product candidate, GS010, in key geographies and retain the option to commercialize GS030 by ourselves.**

We hold worldwide commercialization rights to our platform technologies, product candidates and development programs. If approved, we intend to commercialize GS010, initially in the United States and the European Union, ourselves. Due to the orphan nature of LHON, we believe a targeted sales and marketing organization would be able to reach specialized ophthalmology centers and their patients. We have built, and continue to expand upon, key relationships with ophthalmic experts and patients of severe retinal neurodegenerative diseases around the globe, since we anticipate that a large majority of patients suffering from this disease will be referred to a limited number of large, well-equipped centers with neuro-ophthalmologists and retina specialists in each country. Due to the broad patient populations that GS030 may address, we may enter into strategic partnerships to maximize commercial value of our product candidate.

- **Acquire or in-license complementary technologies and product candidates.**

In addition to our current product candidates, we will evaluate acquisition or in-licensing opportunities with the potential to expand and diversify our pipeline in ophthalmology and other neurodegenerative disorders. We believe that our management team's expertise in the gene therapy field and the broad applicability of our proprietary technology platforms provide us with a competitive advantage in evaluating product opportunities.

5.5 RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

5.5.1 OVERVIEW

We engage in substantial research and development efforts to develop innovative product candidates. Research and development expenses consist primarily of:

- sub-contracting, collaboration and consultant expenses, that primarily include the cost of third-party contractors such as CROs, who conduct our non-clinical studies and clinical trials;
- personnel costs, including salaries, related benefits and share-based compensation, for our employees engaged in scientific research and development functions;
- licensing and intellectual property costs, including upfront payment for exclusive licensing;
- purchases, real-estate leasing costs and rental income received from sublease agreements, as well as conferences and travel costs; and
- depreciation and amortization.

Our research and development expenses in the periods presented, and for the current period to date, mainly relate to the following activities:

- **GS010:** Our Phase I/II dose-escalation safety study for GS010 was initiated in 2014, recruitment was completed in April 2015 and a follow-up study is currently ongoing. GS010 entered into two parallel Phase III trials, RESCUE and REVERSE, in the fourth quarter of 2015, following the release of our IND application by the FDA. The trials are designed as a double-masked, sham-controlled, multi-center, multi-country clinical trial in Europe and the United States. We completed enrollment of all 37 patients for REVERSE in February 2017, and completed the enrollment of 39 patients for RESCUE in July 2017. A third Phase III trial was initiated in the fourth quarter of 2017, REFLECT. This trial is designed as a randomized, double masked, placebo-controlled, multi-center clinical trial. The recruitment was completed in July 2019.
- **GS030:** In 2015, we conducted preclinical, proof-of-concept studies with different molecules that led to the definition of GS030. We initiated GLP, toxicology studies on non-human primates. We obtained the approval to initiate Phase I/II PIONEER clinical trials from MHRA in December 2017. The first patient was treated in October 2018 in the United Kingdom.

Our direct research and development expenses consist principally of external costs, such as manufacturing expenses, non-clinical studies, startup fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, acquiring and manufacturing clinical study materials and costs related to collaborations, which we allocate to our specific research programs. In addition, we allocate personnel-related costs, depreciation and other indirect costs to specific programs.

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates and pursue later stages of clinical development of other product candidates.

A change in the outcome of any of these variables with respect to the development of GS010, GS030 or any other product candidate that we are developing could mean a significant change in the costs and timing associated with the development of such product candidates. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct non-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in enrollment in any clinical trials,

we could be required to spend significant additional financial resources and time on the completion of clinical development. For a discussion on the risks associated with completing the development projects on schedule, see Section 3.2, "Risks Related to the Discovery and Development of and Obtaining Regulatory Approval for Our Product Candidates" of this Universal Registration Document.

5.5.2 RESEARCH AND DEVELOPMENT EXPENDITURES

From 2018 to 2019, the total amount spent by us for research and development activities slightly decreased from €29.0 million to €28.7 million, respectively.

Our research and development expenses for the periods presented, and for the current period to date, mainly relate to GS010 and GS030, see Section 7.3, "Results of Operations – Comparisons for the Twelve Months Ended December 31, 2018 and 2019 – Research and Development Expenditures" of this Universal Registration Document.

Our research and development expenses consist principally of external costs, such as manufacturing expenses, non-clinical studies, startup fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, costs related to acquiring and manufacturing clinical study materials and costs related to collaborations, which we allocate to our specific research programs. In addition, we allocate personnel-related costs and other indirect costs to specific programs.

The following table sets forth the cost for our research and development for the fiscal years ending December 31, 2018 and 2019:

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	4,691	3,458
Sub-contracting, collaborations and consultants	21,288	23,027
Licensing and intellectual property	752	383
Office costs	727	32
Travel and entertainment expenses	760	774
Allowance for amortization	270	554
Others	543	482
Total research and development expenses	**29,031**	**28,710**

(1) Includes €950 K and €385 K related to share-based compensation expense as of December 31, 2018 and 2019 respectively.

5.5.3 MEDICAL AND SCIENTIFIC COMMITTEE

In addition to our own research and development teams, we have a Scientific Advisory Board comprised of seven renowned scientists from different countries who are opinion leaders in their Specialties and key assets to our business. The function of the Scientific Advisory Board is to identify new technological advances that may be of interest for our business.

Since our inception, our Scientific Advisory Board has been comprised of the following members:

- **Dr. Botond Roska (Chairman of our Scientific Advisory Board)** is senior group leader at the Friedrich Miescher Institute in Basel, Switzerland. Dr. Roska was educated at the University of California Berkeley, Harvard University and Harvard Medical School as well as at Semmelweis Medical School. Dr. Roska's group studies the structure and function of the retina and pioneered retina cell type specific optogenetic vision restoration.
- **Professor José-Alain Sahel (Vice-Chairman of our Scientific Advisory Board)** chairs the *Institut de la Vision*, a center of excellence in ophthalmology assembling scientific teams (UPMC, INSERM and CNRS) as well as the French National Eye Hospital, featuring access to cohorts of well-diagnosed patients and a state-of-the-art Clinical Investigation Center.
- **Professor Jean Bennett (Vice-Chairman of our Scientific Advisory Board)** is Professor of Ophthalmology and Cell and Developmental Biology and a Senior Investigator in the F. M. Kirby Center for Molecular Ophthalmology at the University Of Pennsylvania School Of Medicine. Professor Bennett also has an appointment as a Senior Investigator at the Center for Cellular and Molecular Therapeutics, The Children's Hospital of Philadelphia.
- **Luk H. Vandenberghe**, Ph.D., is Assistant Professor at Harvard Medical School and runs an active research laboratory at the Massachusetts Eye and Ear Infirmary and the Schepens Eye Research Institute. He directs the Grousbeck Gene Therapy Center which is focused on the biology of somatic gene transfer, the development of enabling technologies in gene therapy and the translation of clinical programs with a particular emphasis on vision and hearing restoration.

- **Professor Ernst Bamberg** is Professor of Biophysical Chemistry at University of Frankfurt, and Director of the Department of Biophysical Chemistry of the Max Planck Institute für Biophysik in Frankfurt. Pr. Bamberg is the inventor of the optogenetics approach and has been at the fore front of this technology since its discovery.
- **Professor Connie Cepko** is Professor at Harvard Medical School. Professor Cepko works on the mechanisms that direct development of the central nervous system of vertebrates and, in particular, on the vertebrate retina. Professor Cepko has produced seminal works in the mechanisms that lead to the death of photoreceptors in the many inherited forms of human blindness.
- **Dr. Serge Picaud,** Ph.D., is director of research at the *Institut de la Vision* in Paris. Over the last 15 years, Dr. Picaud has developed many cellular and animal models of different retinal diseases for assessing the efficacy of neuroprotection or other therapeutic strategies. Dr. Picaud thus developed the culture of *post-mortem* human retinal tissue, which provides the means to test AAV vectors efficacy on human retinal neurones.

To our knowledge, as of the date of this Universal Registration Document, there are no conflicts of interest between the position of Dr. Botond Roska and Professor José-Alain Sahel in the Company and their position in FMI and *Institut de la Vision*, respectively.

5.5.4 COLLABORATION, PARTNERSHIP AND RELATED AGREEMENTS

To our knowledge, as of the date of this Universal Registration Document, there are no conflicts of interest between the duties of our directors and officers and their personal interests, as they have no interest of any kind in the companies that are parties to the collaboration, partnership and related agreements mentioned below.

Our main collaboration, partnership and related agreements include the following as of this Universal Registration Document:

Agreements Relating to GS010

Genethon

Partnership Agreement Relating to the Research, Development and Commercialization of GS010

- Object:

In February 2013, we entered into a partnership agreement with Genethon. Under the terms of this agreement, Genethon is free to exploit the data, know-how, materials and inventions, whether patentable or not, developed or generated in the course of performing a given research and development project that relate to the processes, materials and assays used to manufacture biological products for any purpose without further obligation or payment to us. We may exploit the data, know-how, materials and inventions, whether patentable or not, developed or generated in the course of performing a given research and development project that relate to a product being developed by the parties pursuant to a given research and development project for any purpose at our own discretion, subject to the payment to Genethon of any milestone payments and royalties negotiated and agreed in a product addendum.

- Obligations of GenSight:

Under the terms of the partnership agreement, we are primarily responsible for (i) the performance of all *in vitro* and *in vivo* preclinical studies and for all clinical activities and, as sponsor, for the initiation, conduct and management of all clinical trials to be conducted in the context of the research and development project, and (ii) all regulatory affairs matters related to the development of the product(s) (other than matters specific to product manufacturing) with support from Genethon.

- Obligations of Genethon:

Genethon is primarily responsible for (i) the development of the processes to manufacture product(s) and for the manufacture of product(s) required for preclinical and clinical studies; and (ii) all regulatory affairs matters related to the manufacture of the product(s), including the elements of clinical trial and marketing authorization submissions that relate to the manufacture of the product(s).

- Financial obligations:

Costs are shared between us and Genethon in accordance with certain principles set forth in the partnership agreement. Each party bears its own internal costs incurred in the performance of preclinical activities. We are responsible for all external costs incurred by the parties in the performance of preclinical activities. Genethon is responsible for all internal and external costs incurred to manufacture research quality grade batches of the products in the context of preclinical activities. Genethon also assumes the internal and external costs incurred to manufacture all batches, whether GMP or not, of products used for regulatory preclinical toxicology studies, and one GMP batch for the initial Phase I clinical studies. We are responsible for all internal and external costs incurred by the parties in the performance of clinical activities. In addition, we bear all internal and external costs for the manufacture of all GMP batches of products other than any GMP preclinical toxicology batches, and the initial GMP both for Phase I clinical studies, the costs of which are borne by Genethon. Genethon bears all internal costs associated with activities of regulatory support in connection with manufacturing a product, while all such external costs are borne by us.

- Proprietary rights:

Under the terms of the partnership agreement, Genethon is free to exploit the data, know-how, materials and inventions, whether patentable or not, developed or generated in the course

of performing a given research and development project that relate to the processes, materials and assays used to manufacture biological products for any purpose without further obligation or payment to us. We may exploit the data, know-how, materials and inventions, whether patentable or not, developed or generated in the course of performing a given research and development project that relate to a product being developed by the parties pursuant to a given research and development project for any purpose at our own discretion, subject to the payment to Genethon of any milestone payments and royalties negotiated and agreed in a product addendum.

- Term and termination:

The partnership agreement will continue in full force and effect for the longer of (i) a period of 10 years; or (ii) until the expiration/termination of the last project addendum duly executed between us and Genethon, unless otherwise terminated under the terms of the partnership agreement.

Sight Again Program

Consortium Agreement Relating to the Research and Development of Complimentary Therapeutic Remedies for GS030

- Object:

In July 2014, we entered into a consortium agreement with Pixium Vision S.A., a company based in France that develops vision restoration systems and Fondation Voir et Entendre, or FVE, a scientific foundation that funds scientific programs in the field of ophthalmic diseases. This consortium agreement, known as "Sight Again," or the Program, aims to further unlock technology hurdles in the development of new therapeutic approaches to restore sight to legally blind patients suffering from differing stages of RP. Sight Again is part of *Programme d'Investissement d'Avenir*, a major investment initiative launched and organized by the French Government. Under the agreement, we, in conjunction with Pixium Vision and FVE, are focusing on two complementary therapeutic remedies: an optogenetic gene therapy developed by us, GS030, and a vision restoration system comprising a sub-retinal implant developed by Pixium Vision, PRIMA, designed to deliver improved visual perception. Both therapeutic remedies require a visual stimulation device, comprising a visual interface, a mobile processor and software.

During the collaboration period, the Program is governed by a joint steering committee, or JSC, consisting of representatives of the parties to the collaboration agreement. The JSC is responsible for, among other things, monitoring and assessing the progress of collaboration activities, validating the results and information provided by working groups, modifying or suspending the program in whole or in part and approving amendments to the agreement.

- Obligations of GenSight:

Under the terms of this agreement we are responsible for conducting all research and development activities in relation to our product candidates, from proof of concept to request for marketing authorizations.

- Proprietary rights:

Under the terms of the agreement, results obtained become the property of the party responsible for carrying out the research. In the case of joint research, results become the property of the parties involved with the research on a *prorata* basis in accordance with their respective contributions. We may freely use our own and joint results, except for research benefiting third-parties. We may be granted an operating license should we need specific knowledge of results of another party, and a free use of rights of products developed by FVE under the Program as well as a right of first review on any of the results of FVE. We and Pixium Vision have been granted a joint-exclusive operating license, each in our respective fields, on joint results obtained within the program.

- Financial obligations:

In consideration for this joint exclusivity, we and Pixium Vision pay royalties to FVE, calculated as a percentage of net sales generated by the joint results and joint patents. Such royalties may not exceed 0.6 percent of revenues generated by the commercial use of the patent, and an annual threshold of €50 K per Company, and shall expire when the cumulated amount of royalties paid reaches a total of €500 K.

- Term and termination:

The term of the agreement is five years and six months, subject to prior termination.

Master Agreement Relating to the Sight Again Program

In December 2014, we entered into a master agreement relating to the Program with Bpifrance Financement, Pixium Vision and FVE setting forth the characteristics of the Program, to fix the amount and conditions for awarding funding granted by Bpifrance Financement as well as to clarify the principles and arrangements for monitoring the implementation of the Program by Bpifrance Financement.

Financial Aid Agreement Relating to the Sight Again Program

In December 2014, we entered into a financial aid agreement relating to the Program with Bpifrance Financement setting forth the amounts and conditions upon which Bpifrance Financement shall grant financial aid to the Program. We will benefit from approximately €6.8 million, of which €1.1 million is available as subsidies and approximately €5.7 million as repayable advances. The approximately €5.7 million repayable advances and any interest thereon will only be repayable if and when the product hits the market. Should we, within two years following the

termination of this financial aid agreement, reach cumulated revenues of €80.0 million (excluding taxes) for a period of 15 years from the first year of repayment we shall be required to make an additional payment to Bpifrance Financement of a maximum aggregate amount of approximately €2.7 million. The financial aid from Bpifrance Financement is intended to cover both industrial research and experimental development.

Amendments Relating to GS030

The terms of the consortium agreement, master agreement and financial aid agreement originally applied to the development of the optogenetics product candidate targeting RP known as GS020, a precursor to GS030. The parties have supplemented the agreements to include provisions relating to the development of GS030.

Agreements Relating to GS010 and GS030

Specific Research Agreements Under the Framework Agreement Relating to Research and Development in Ophthalmic Diseases (GS010 and GS030)

In October 2014, as a part of the framework agreement, we entered into a specific agreement with UPMC, *Institut National de la Santé et de la Recherche Médicale* and *Centre National de la Recherche Scientifique* for the development and evaluation of the visual stimulation goggles, for a duration of 24 months. This agreement terminated on October 2016.

In November 2014, as a part of the framework agreement, we entered into a specific research agreement with UPMC, *Institut National de la Santé et de la Recherche Médicale* and *Centre National de la Recherche Scientifique* for a program aiming to restore high acuity vision with optogenetic therapy, and defining the technical means required and the milestones to be achieved.

In June 2015, as a part of the framework agreement, we entered into a specific research agreement with UPMC, *Institut National de la Santé et de la Recherche Médicale* and *Centre National de la Recherche Scientifique* for a program aiming to develop and approve clinical prototypes of glasses for the stimulation of an optogenetically transfected retina.

5.5.5 INTELLECTUAL PROPERTY

To our knowledge, as of the date of this Universal Registration Document, there are no conflicts of interest between the duties of our directors and officers and their personal interests as they have no interest of any kind in the companies that are parties to the in-license agreements mentioned below.

We rely on licenses granted by third-parties to develop our product candidates. We have rights to use and exploit certain issued patents and pending patent applications under license from certain third-parties.

Our main in-license agreements include the following:

Agreements Relating to GS010

Inserm Transfert

License Agreement for Patents Relating to GS010

- Object:

On October 12, 2012, we entered into a license agreement with Inserm Transfert S.A. (acting as delegatee of Inserm). Under the license agreement, Inserm Transfert and Inserm granted us (i) an exclusive, royalty-bearing worldwide license under certain patent rights and biological material in the treatment of ocular diseases in humans (including mitochondrial diseases of the ocular area), (ii) a non-exclusive, royalty-bearing worldwide license under certain patent rights and biological material in the treatment of mitochondrial diseases in humans together with (iii) a non-exclusive, royalty-bearing worldwide license under certain know-how, to develop, make, have made, use, and sell or otherwise distribute certain products, in the treatment of mitochondrial diseases and ocular diseases in humans, with a limited right to grant sublicenses.

- Proprietary rights:

Inserm Transfert and Inserm reserved the right on their behalf and that of all other non-profit academic research institutions to practice and use the patent rights and biological material in the treatment of ocular diseases in humans (including mitochondrial diseases of the ocular area) (i) for any academic purposes as well as (ii) for the performance of research programs performed in the frame of industrial partnerships and (iii) with our prior written approval on the clinical protocol, for certain non-profit clinical research. Inserm Transfert reserved (a) the right to practice and use the know-how for any purposes and (b) the right to practice and use as the patent rights and biological material for any purposes outside the treatment of ocular diseases in humans. Under the agreement, we have the first right of negotiation for exploitation rights of any results that may issue from such non-profit clinical research in the treatment of ocular diseases in humans (including mitochondrial diseases of the ocular area) and under certain conditions.

- Obligations of GenSight:

We are required to use our best efforts to develop the products in compliance with a certain development plan and to use our reasonable efforts to introduce the product into the commercial market, in each case, as soon as practicable, consistent with reasonable business practices. Under the agreement, we manage the prosecution, defense and maintenance of the licensed patent rights, at our own cost and in consultation with Inserm Transfert.

- Financial obligations:

Upon entering into the license agreement we paid an upfront license fee and reimbursed Inserm Transfert for all expenses incurred by it prior to entry into the license agreement in connection with the filing, prosecution, defense and maintenance of the patent rights. We are responsible for the payment of all future fees and costs relating to the prosecution, defense and maintenance of the patent rights during the term of the license agreement. In addition, we are required to make certain milestone payments to Inserm Transfert upon the achievement of certain development, regulatory and commercial milestone events. Under the terms of the license agreement, we also are required to pay Inserm Transfert low-to mid-single-digit royalties on incremental annual worldwide net sales of the product.

- Term and termination:

The license agreement will continue in full force and effect until the later of (i) the expiration of the last to expire patent right covering the manufacture, use or sale of the licensed product in any country of the world and (ii) ten years after the first commercial sale of the licensed product in a country in which a royalty is paid, unless otherwise earlier terminated under the terms of the license agreement. Inserm Transfert may at its sole discretion convert the license in the treatment of ocular diseases in humans into a non-exclusive license or terminate the agreement if (a) we have not timely met any of the development milestones in the development plan and fail to cure within 60 days of written notice from Inserm; (b) we interrupt certain development activities in respect of any licensed product for more than nine months; (c) we interrupt commercialization of a licensed product for more than 12 months after a first commercialization of such product in a country; (d) there is no commercialization of a licensed product within two years following the obtaining of its commercialization approval in a country; (e) we have not put the licensed product into commercial use and are not keeping the products reasonably available to the public within ten years of the effective date of the agreement; or (f) if we cease business operations or become the subject of a petition in bankruptcy.

Association Française contre les Myopathies

License Agreement for Scientific Data Relating to GS010

- Object:

On December 2, 2013, we entered into a license agreement for use of scientific data with the *Association Française contre les Myopathies*, or AFM, the French Muscular Dystrophy Association, Genethon and Inserm Transfert, acting as a delegate of Inserm and on behalf of the UPMC, or UPMC collectively, the licensors. Under the agreement, the licensors granted us a worldwide, exclusive, royalty-bearing license, with a limited right to grant sublicenses, for the use of certain scientific data and information developed, owned or controlled by the licensors, to develop, make, have made, use, and sell or otherwise distribute certain products, including to obtain authorization to develop and commercialize products for the treatment of mitochondrial diseases and ocular diseases in humans as described in our license agreement with Inserm Transfert. The scientific data are defined as data needed to obtain agencies authorizations.

- Obligations of GenSight:

We are required to use all commercially reasonable efforts to develop the products in compliance with the development plan set forth in our license agreement with Inserm Transfert and to use our reasonable efforts to introduce the product into the commercial market, in each case, as soon as practical, consistent with our reasonable business practices.

Under the license agreement, we have committed to achieving certain milestones relating to the development, manufacture and commercialization of the licensed products, including certain regulatory, clinical and commercial objectives. Under certain circumstances, such as the imposition of government regulation restricting the implementation of the development program or requiring changes thereto, unforeseen results in preclinical experiments or clinical trials or technical constraints, we and Inserm Transfert may reasonably extend the development plan.

- Financial obligations:

We paid the licensors a one-time license fee of €10 K. We also are obliged to make milestone payments ranging from €13 K to €375 K upon the achievement of certain development, regulatory and commercial milestone events. We have paid the residual licensors €187 K in connection therewith. Under the terms of the license agreement, we are required to pay to the licensors low single-digit royalty payments on annual worldwide net sales.

- Term and termination:

The license agreement will continue in full force and effect until the later of (i) the expiration of the patent rights licensed to us under our license agreement with Inserm Transfert and (ii) ten years after the first commercial sale of the product in a country in which a royalty is paid, unless otherwise earlier terminated under the terms of the license agreement. Inserm Transfert may at its sole discretion convert the exclusive license under the agreement into a non-exclusive license or terminate the agreement if (a) we have not timely met any of the development milestones in the development plan; (b) we interrupt certain development activities in respect of any product for more than nine months; (c) we have not put the product into commercial use and are not keeping the products reasonably available to the public within ten years of the effective date of the agreement; or (d) if we cease business operations to become the subject of a petition in bankruptcy.

President and Fellows of Harvard College

License agreement for the use of Harvard Master Cell Bank relating to GS010

- Object:

On June 18, 2019, we entered into a license agreement with President and Fellows of Harvard College ("Harvard"). Under the license agreement, Harvard granted us a non-exclusive, worldwide, royalty-bearing license, non-transferable without its prior consent , with right to grant sublicenses, for the use of biological material (an Harvard proprietary Master Cell Bank) to develop, have developed make, have made, market, offer for sale, sell, have sold, promote, have promoted, import and/or export any licensed products (including GS010), for the prevention and/or the treatment of ocular diseases.

- Obligations of Harvard:

Harvard is required to deliver us a reasonable supply of the biological material as soon as practicable and to the extent reasonably request by ourselves.

- Obligations of GenSight:

We are required to use commercially reasonable efforts to develop, market and commercialize the licensed products and we are subject to reporting obligations.

- Financial obligations:

We paid Harvard a non-refundable license issuance fee of $25 K. In addition, we agreed to pay an annual license maintenance fee as from the first commercial sale of a licensed product ranging from $25 K to $75 K (creditable against running royalties), a milestone payment of $25 K upon achievement of marketing authorization for the first licensed product in any country, and a running royalty of less than 1% on net sales for a period of 15 years from the date of the first commercial sale (on a licensed product by licensed product basis).

- Term and termination:

The license agreement will continue in full force and effect until the expiration of the payment obligations, unless earlier terminated. We also have the right to terminate the agreement at any time and for any reason upon 90 days' prior written notice.

Upon termination, we will have a perpetual, fully paid-up, non-exclusive, worldwide, non-transferable license to use Harvard's Master Cell Bank to make, have made, market, offer for sale, sell, have sold, import and/or export any licensed products, including GS010 for the prevention and/or the treatment of ocular diseases.

Agreements Relating to GS030

Adverum Biotechnologies (formerly Avalanche Biotechnologies)

License Agreement for Patents Relating to GS030

- Object:

On February 23, 2014, we entered into a non-exclusive license agreement with Adverum. Under the license agreement, Adverum granted us a worldwide non-exclusive royalty-bearing sublicense, with a limited right to grant further sublicenses, under certain patents and patent applications to which Adverum has obtained certain rights from the Regents of the University of California, or the Regents, to use, make, have made, import, sell, and offer for sale products and services that comprise a recombinant adeno-associated virus serotype 2 7m8 vector, or AAV2 7m8, to deliver any of three genes (channelrhodopsin, halorhodospin or rod-derived cone viability factor) for the treatment of ocular diseases in humans.

- Obligations of GenSight:

Under our license agreement with Adverum, we are obliged to use commercially reasonable efforts to develop, manufacture and commercialize the licensed products at our own cost and expense in accordance with a specific development plan under the Adverum agreement and are obligated to achieve certain specified milestones, including regulatory approvals, by certain target dates. If we fail to achieve any of these milestones by its target date, we have the option to extend the target date by 12 months upon the payment of $50 K to Adverum for each such extension.

- Financial obligations:

We paid Adverum a one-time license fee of $30 K in addition to $145 K as reimbursement for past costs for preparing, filing, prosecuting and maintaining the licensed patent rights. Under the terms of the license agreement, we also are required to reimburse Adverum for all such present and future costs up to a maximum of $30 K per year, together with an annual license maintenance fee of $30 K (minus the patent expenses paid in the prior year). Further milestone payments on a product-by-product basis will be due, upon the achievement of certain milestone events.

Further, upon the sale of any products or services licensed under the Adverum agreement, we are required to pay to Adverum low- to mid-single-digit royalties on annual worldwide net sales of such licensed products and services. Our royalty payment obligations to Adverum endure on a country-by-country and product/service-by-product/service basis for so long as at least one valid claim of any patent sublicensed from Adverum covers the manufacture, use or sale of a given product/service in a given country.

- Obligations of Adverum:

Adverum is responsible for and retains sole control over the prosecution, filing, maintenance and enforcement of all patents licensed to us under the agreement.

- Term and termination:

The license agreement will continue in full force and effect on a country-by-country basis until there are no remaining royalty obligations in any country, at which time the agreement shall expire in such country, unless otherwise terminated by the parties in accordance with the terms of the license agreement. We may

terminate the agreement at any time upon 90 days' prior written notice to Adverum, and Adverum may terminate the agreement in part or its entirety upon written notice to us if we assign the agreement in violation of its terms or fail to timely meet any of our specified development or milestones achievement obligations.

Upon the termination of the license agreement between Adverum and Regents, our license agreement with Adverum will survive, provided that, among other things, we will be required to make any monetary payments that Adverum would have been required to make under its agreement with Regents had it not been terminated.

Massachusetts Institute of Technology

License Agreement for Patents Relating to GS030

- Object:

On January 6, 2016, we entered into a license agreement with the Massachusetts Institute of Technology, or M.I.T., upon exercising an option right granted under the patent option agreement between M.I.T. and us, dated January 9, 2015. Under this license agreement, M.I.T. granted to us a royalty-bearing, license to certain patent rights jointly owned by M.I.T. and the University of Alberta, for use of the ChrimsonR or photoactivatable halorhodopsin protein (known as Jaws) gene expression sequences, in the retina for the prevention and treatment of blindness in humans. The license is exclusive but subject to the rights of M.I.T., the University of Alberta and any other non-profit research institute to practice under the patent for research, teaching and educational purposes, the U.S. government's royalty-free, non-exclusive, non-transferrable license to practice the patent, and certain mandatory third-party sublicensing requirements.

- Financial obligations:

Under the terms of this license agreement, we agreed to pay a license issue fee of $45 K, license maintenance fees up to $100 K per year and variable payments up to $7.3 million depending on the achievement of milestone events. We also agreed to pay running mid-single-digit royalties on future net sales.

This license agreement has been amended in April 2017, under which we will provide the M.I.T. with a written research and development plan no later than July 1, 2018.

This license agreement has been amended a second time in May 2018, under which we will provide the M.I.T. with a written research and development plan no later than July 1, 2019.

This license agreement shall remain in effect until the expiration or abandonment of all issued patents and patent applications under this license agreement, unless earlier terminated. We have the right to terminate this license agreement, for any reason, upon at least six months prior written notice to M.I.T., and upon payment of all amounts due to M.I.T. under the agreement. M.I.T. has the right to terminate this license agreement (i) immediately upon written notice if we cease to carry on our business related to the agreement, or (ii) if we fail to pay any amounts due and payable within 30 days.

Sorbonne Université, CNRS, Inserm and SATT Lutech

License agreements for Patents relating to GS030

- Object:

On May 6, 2019, we entered into a license agreement with Sorbonne Université, CNRS, Inserm and SATT Lutech. Under this license agreement, we are granted an exclusive, worldwide, royalty-bearing license, non-transferable without the licensors' prior consent and with right to grant sublicenses, to certain patents to develop, have developed, manufacture, have manufactured, own, supply, use, register, have registered, promote, distribute, have distributed, import, have imported, export, have exported, market and have marketed the product, a light stimulating device of photosensitive cells, part of GS030, for the treatment of vision disorders by optogenetic therapy.

- Proprietary rights:

Sorbonne Université, CNRS and Inserm reserved the right (i) to use the patent rights for any academic purposes and research programs performed by themselves or in the frame of partnerships with third parties, including in the field of treatment of vision disorders by optogenetic therapy, (ii) to grant any rights in the patents to third parties for any purposes outside the treatment of vision disorders by optogenetic therapy.

- Obligations of GenSight:

We are required to use commercially reasonable efforts to develop, market, promote and commercialize the product in the field of the treatment of vision disorders by optogenetic therapy. If we fail, without cause, to use such efforts to obtain at least a marketing authorization (MA) or biological license application (BLA) for a product by certain target dates or to develop product sales thereafter, SATT Lutech, on behalf of Sorbonne Université, CNRS and Inserm, will have the right to convert the exclusive license into a non-exclusive license.

- Financial obligations:

We paid the licensors a one-time license upfront payment of €30 K. We are also obliged to pay milestone payments upon achievement of certain development and regulatory milestone events. After the grant of a MA or BLA for the product, we are required to pay a fixed royalty fee for each first use of a product on a patient who has received the associated gene therapy treatment. In addition, we are required to pay an annual license maintenance fee creditable against the total paid amount of fixed royalty fee due on the same year.

We are responsible for the payment of all future fees and costs relating to the prosecution, defense and maintenance of the patent rights during the term of the license agreement unless i) we expressly refused the generating step and industrial property costs associated during the consultation phase with the licensors, in which case the patent right in question will automatically be excluded from the patents covered by the license, ii) Satt Lutech has granted a license on the patents to one or more third party outside the field of the treatment of vision disorders by optogenetic therapy in which case the costs will be shared equally, iii) the license has been converted into a non-exclusive license, in which case we will pay at most 50% of the industrial property costs due after the conversion (weighted, if relevant, by application of ii)). If we decide to cease bearing the industrial property costs, in full or part, the corresponding patent(s) will automatically be excluded from the scope of the license and the licensors will have the right to license said patent rights to third parties including in the field of treatment of vision disorders by optogenetic therapy.

- Obligation of the SATT Lutech

SATT Lutech, on behalf of Sorbonne Université, CNRS and Inserm, is responsible for and retains sole control over the management of the licensed patents, in consultation with us and, if relevant, with the third party licensed outside the field of the treatment of vision disorders by optogenetic therapy.

- Term and termination:

The license agreement will remain in force until the expiration of the last valid claim of the patent rights, on a country-by-country and product-by-product basis. We also have the right to terminate the agreement at any time and for any reason upon six months' prior written notice.

5.5.5.1 Our Intellectual Property Estate Patents

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business, including seeking, maintaining and defending certain patent rights licensed from third-parties. We also rely on trade secrets and know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the fields of allogeneic transfer, optogenetics, gene therapy and specific optics and algorithms that may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. See Section 9, "Regulatory environment" of this Universal Registration Document.

Our future commercial success may depend, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business; defend and enforce our in-licensed patents and any patents that we may own in the future; preserve the confidentiality of our trade secrets and proprietary know-how; and operate without infringing the patents and proprietary rights of third-parties. Our ability to stop third-parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights, either owned or in-licensed, under valid and enforceable patents, trade secrets or other know-how that cover these activities. In some cases, these rights may need to be enforced by third-party licensors.

Our rights to intellectual property, whether in-licensed, owned or co-owned are generally directed to methods of treatment or prevention of clinical indications important for our development programs, allotopic expression, mitochondrial trafficking, optogenetics, AAV vectors, transferring genetic material into cells, processes to manufacture and purify our product candidates, optics and other proprietary technologies and processes related to our product candidates. We also possess significant know-how and trade secrets relating to our product candidates.

In-licensed Patent Rights

As of the date of this Document, we in-licensed at least 10 U.S. and foreign patent applications and at least 22 U.S. and foreign patents, that have been filed by or on behalf of our licensors.

Product candidate	Owner	Title	Patent Term	Countries	Current status
LHON (GS010)	Inserm	Expression of mitochondrial protein by an enhanced allotopic approach	2026	United States European Union	European Union: granted, no opposition filed United States: one patent granted and one divisional pending
RP (GS030)	University of California (Adverum)	Adeno-associated virus virions with variant capsid and methods of use thereof	2032	Australia, Canada Singapore, Israel, China (3x), European Union (2x), Korea, Japan, United States (4x), Russia, Mexico, South Africa	Granted in US, EP, JP, CN, MX, RU, ZA and AU

Product candidate	Owner	Title	Patent Term	Countries	Current status
RP (GS030)	M.I.T.	Channelrhodopsins for optical control of cells	2032	Korea, United States, European Union, Hong Kong	United States: one patent issued and one application pending Granted in Europe and Korea
RP (GS030)	Sorbonne Univ. CNRS INSERM	Method and device for controlling a device for aiding vision	2032	Australia, Canada, Hong Kong, China, European Union, Korea, Japan, United States	Granted in US, EP, JP, CN, KR, AU, HK
RP (GS030)	Sorbonne Univ. CNRS INSERM	Display control precedent and device for implementing the method		European Union, United States	Granted in EP and US
RP (GS030)	Sorbonne Univ. CNRS INSERM	Method for downsampling a signal outputted by anasynchronous sensor		European Union, United States	United States: allowed Granted in Europe

With regard to the GS010 product candidate, as discussed above, we have in-licensed a patent family from Inserm Transfert that relates to an expression vector for the delivery of a protein into the mitochondrion of a mammalian cell and the uses thereof. This patent family contains one issued U.S. patent, one pending U.S. application and one granted European patent. The granted European patent and the pending U.S. application, if issued, are expected to expire in 2026, subject to possible patent term extensions.

With regard to the GS030 product candidate, as discussed above, we have exclusively in-licensed from M.I.T. patent applications pending in the United States, Hong Kong and South Korea and a granted European patent directed to ChrimsonR. The granted European patent and pending applications, if issued, are expected to expire in 2032, subject to possible patent term extensions. In addition, as discussed above, we have non- exclusively in-licensed from Adverum a patent family that relates to the AAV2 7m8 vector, with patents granted in the U.S., Europe, China, Australia, Mexico, Russia, South Africa and Japan, and patent applications pending in China, United States, Europe, Canada, Israel, South Korea, Singapore and Brazil, where the granted patents and pending applications, if issued, are expected to expire in 2032, subject to possible patent term extensions.

Product candidate	Owner	Title	Patent Application Number	Filing date	Countries	Current status
RP (GS030)	GenSight Biologics UPMC CNRS INSERM	Optogenetic visual restoration using ChrimsonR	US62/329692	29/04/2016	United States, European Union, China, Japan, Korea, Canada, Australia, Hong Kong	Pending
RP (GS030)	GenSight Biologics UPMC CNRS INSERM	Device for illuminating an object with a controlled light intensity and associated method	EP16305741.7	17/06/2016	United States, European Union, China, Japan, Korea, Canada, Australia	Pending
RP (GS030)	GenSight Biologics UPMC CNRS INSERM	Medical device intended to be worn in front of the eyes	EP16306005.6	02/08/2016	United States, European Union	Pending in the US Allowed in EP
RP (GS030)	GenSight Biologics UPMC CNRS INSERM	Objective, camera and system adapted for optogenetics	EP17305805.8	28/06/2017	United States, European Union, China, Japan, Korea, Canada, Australia	Pending

Product candidate	Owner	Title	Patent Application Number	Filing date	Countries	Current status
RP (GS030)	GenSight Biologics	Method and device for processing asynchronous signals generated by an event-based light sensor	EP 18305020.2	11/01/2018	PCT	International phase
LHON (GS010)	GenSight Biologics	Recombinant AAV2 vectors and methods of using the same	US62/683,501	11/06/2018	PCT	International phase
RP (GS030)	GenSight Biologics	Method for controlling an optogenetic device using a command law for the radiant power of a light source and associated devices	EP19305135.6	05/02/2019		International phase
RP (GS030)	GenSight Biologics	Method for controlling an optogenetic device using filtering and associated devices	EP19305136.4	05/02/2019		International phase
RP (GS030)	GenSight Biologics	Viewing apparatus and method for projecting a light signal	EP19305561.3	03/05/2019		Priority filing

Trademarks

GenSight is a registered Community Trademark covering 26 member states of the European Union (including UK).

The brand name chosen for GS010, as approved by the EMA for use in the MAA, is LUMEVOQ (lenadogene nolparvovec). LUMEVOQ is a registered Community Trademark (including UK), and is also registered in the US. Upon regulatory approval, GenSight intends to commercialize GS010 under LUMEVOQ trademark.

The brand name chosen for GS030 is LUMOVI. An International Trademark covering EU (Community Trademark) and US, and claiming the French trademark priority, has been filed. Upon regulatory approval, GenSight intends to commercialize GS030 under LUMOVI trademark.

We may, in the future, file additional applications to register GenSight, LUMEVOQ and/or LUMOVI in other territories and/or file applications for new trademarks covering current or future products and/or services in certain markets of interest. See Section 3.5, "Legal Risks and Risks Related to our Intellectual Property — Our trademarks and trade names may not be adequately protected and we may not be able to build name recognition in our markets of interest" and Section 18.6, "Legal and Arbitration Proceedings" of this Universal Registration Document.

5.6 COMPETITION

The biopharmaceutical industry, including the gene therapy field, is characterized by rapid scientific technological changes and significant competition. Any product candidates that we successfully develop and commercialize will have to compete with therapies that may become available in the future. We face competition from pharmaceutical and biotechnology companies, as well as from academic institutions, governmental agencies and public and private research institutions.

We are aware of a number of companies focused on developing gene therapies in various indications, including Adverum Biotechnologies, Inc., Ultragenyx Pharmaceutical, Inc., Applied Genetic Technologies Corporation, Asklepios BioPharmaceutical, Inc., Audentes Therapeutics, Inc., bluebird bio, Inc., GlaxoSmithKline, Biogen, Inc., Spark Therapeutics, Inc., uniQure N.V. and Voyager Therapeutics, Inc., as well as several companies addressing other methods for modifying genes and regulating gene expression. Any advances in gene therapy technology made

by a competitor may be used to develop therapies that could compete against any of our product candidates.

For our specific retinal gene therapy products, the main competitors include:

- **GS010 for the Treatment of LHON:** The Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine in the United States has enrolled the first five participants in its Phase I trial of virus-based gene transfer for this mitochondrial disorder. The Huazhong University in China, which completed Phase I/II studies in 2013 using gene therapy, recently published data with nine months follow-up and the evaluation of both safety and some visual acuity outcomes. The purpose of these studies is exclusively academic and, to our knowledge, Huazhong University is not currently developing any drug candidates. We are aware of other companies and institutions focused on developing therapies in the LHON space that do not involve gene therapy, including: Santhera Pharmaceuticals Holding AG using a chemical entity, Idebenone, approved under exceptional circumstances in Europe; and Stealth Biotherapeutics Inc. using an antioxidant agent known as Ocuvia, which is currently in Phase II clinical trials.
- **GS030 for the Treatment of RP:** To our knowledge, we are the only Company in the Clinic with a technology that utilizes light at near-red wavelength with goggles. RetroSense Therapeutics, LLC, or RetroSense, is developing a ChR2-based optogenetic product that is in Phase I studies that will have to utilize blue light to stimulate the ChR2 without goggles. Retrosense was acquired by Allergan plc in September 2016. Applied Genetic Technologies Corporation, or AGTC, is partnering with Bionic Sight to develop an optogenetic therapy combining a ChR-based gene therapy and a neuro-prosthetic device using an algorithm for retinal coding. This program is still in preclinical development. In addition, the only approved non-therapeutic treatment for RP is retinal implants.
- **GS030 for the Treatment of GA:** No approved therapy currently exists for GA. Most major clinical- stage therapeutic treatments for GA are in the field of cell therapy, including lampalizumab, an anti-Factor D, the development of which F. Hoffmann-La Roche Ltd. terminated post unsuccessful Phase III data. GlaxoSmithKline plc's anti-amyloid beta monoclonal for patients with GA is in Phase II clinical trials. Novartis' LFG-316 C5 monoclonal antibody for patients with GA is in Phase II clinical trials. Apellis Pharmaceuticals, Inc. is currently developing a C3 inhibitor, which has completed Phase II and initiated Phase III clinical trials. Gyroscope Therapeutics, Ltd, started in 2019 a Phase I/II FOCUS study of a gene therapy (GT005) coding for an inhibitor of the Complement System, in patients with geographic atrophy due to dry AMD.
- **GS030 for the Treatment of Dry AMD:** No approved therapy currently exists for dry AMD. Ophthotech Corporation's Zimura, a complement C5 inhibitor, is currently in a Phase IIb clinical trial. Johnson and Johnson is developing Palucorcel, which utilizes human embryonic stem cells that recently completed a Phase I/II trial. Similarly, Astellas Pharma Inc. is developing a stem cell treatment currently in Phase II. BioTime, Inc. is developing OpRegen, a dry AMD-targeted therapy that replaces missing retinal pigment epithelium cells with OpRegen cells and is currently in a Phase I/IIa dose escalation study. Regenerative Patch Technologies requires a subretinal implant of stem cells and is in a Phase I/II trial.

Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

5.7 INVESTMENTS

5.7.1 HISTORICAL INVESTMENTS

Our historical investments since 2015 involve mainly the acquisition of property, plant and equipment, and intangible assets. The following table sets forth our net cash used in investing activities as of December 31, 2018 and 2019:

	As of December 31,	
In thousands of euros	2018	2019
Cash flows from investment activities		
Acquisitions of property, plant and equipment	(789)	(69)
Acquisitions of intangible assets	(2)	(7)
Acquisitions of non-current financial assets	8	(26)
Acquisitions of current financial assets	120	—
Net cash flows from investment activities	**(663)**	**(102)**

5.7.2 FUTURE PLANNED INVESTMENTS

As of the date of this Universal Registration Document, we do not have any material commitments to make investments in the future.

5.7.3 JOINT VENTURE

N/A

5.7.4 ENVIRONMENTAL ISSUES

In accordance with legal and regulatory requirements of Grenelle II Law and its implementing decree, we have published for the 2017 fiscal year an annual social and environmental responsibility report annexed to the management report of the Board of Directors, such report having been completed by a report issued by an independent expert. Since the fiscal year beginning January 1, 2018, we are no longer required to publish such a report.

5.8 MANUFACTURING

We have chosen to outsource manufacturing to specialized contract manufacturing organizations, or CMOs. As part of this strategy, we have hired experienced chemistry, manufacturing and controls, or CMC, and quality assurance personnel in order to (i) assess potential CMO partners, (ii) conduct the necessary audits and due diligence in connection with partner CMOs, (iii) oversee, review and audit the CMC process to be used for all regulatory submissions and (iv) oversee, review and control all the methods and protocols used to ensure that the final product meets our quality specifications.

We partner with leading CMOs in gene therapy manufacturing, including BrammerBio to produce non-clinical and clinical drug products for clinical development and future commercialization. We have made significant efforts to scale up and optimize the manufacturing process with a view to the delivery of commercial batches.

Our AAV-based gene therapy products are produced using transient triple transfection process for GS010 and the baculovirus process for GS030. Production is carried out in compliance with current good manufacturing practices, or cGMP, by CMOs that have been certified by national regulatory authorities.

Manufacturing Process Using Transient Triple Transfection for GS010

The transient triple transfection-based production process uses adherent HEK293 cells amplified in multi- tray cell-culture systems. Cells are co-transfected with three independent plasmids. Transfected cells are harvested and cell lysate is then clarified in order to eliminate cellular debris.

Purification of the AAV vector is then achieved by immunoaffinity and filtration in the final formulation buffer, leading to drug substance.

The concentration of the drug substance is adjusted to a defined concentration, before being sterile filtered and filled into individual vials, to eventually become the drug product. Drug product is stored at <-60°C.

Batches for the ongoing Phase III trials were produced at the Henogen S.A., which was acquired by Groupe Novasep, facility in Belgium in compliance with cGMPs. In anticipation of our commercial needs and process validation, we implemented the transfer of the manufacturing process to the BrammerBio facility in Cambridge, Massachusetts in October 2017, to ensure commercial supply for the European Union and the United States. For each batch production, a series of quality control tests are performed during the process and at release to assess product strength, quality, purity and safety under controlled and validated standard operating procedures in accordance with cGMP.

Manufacturing Process Using Baculovirus Production for GS030

The AAV is produced in SF9 insect cells using two recombinant baculovirus vectors. One vector carries the viral genome, and the other carries elements for the expression of functions required for replication of the AAV genome and assembly of the viral capsids.

The SF9 cells are cultivated in suspension in a serum-free medium in single-use bioreactors. Production of AAV by the SF9 insect cells/baculovirus method has proven to be an efficient and scalable means of recombinant AAV production.

During the manufacturing process, the AAV vector is isolated from lysed, harvested cells by affinity chromatography. The vector is further purified by ion-exchange chromatography to create the bulk drug substance, or BDS. To produce the drug product, the BDS is adjusted to a defined concentration with formulation buffer, then sterile filtered before being filled into individual vials. Drug product is stored at <-60°C.

Manufacturing Process for the GS030 Medical Device

The goggles will be manufactured and tested at an established ISO13485-certified site in France, under the control of our Quality Assurance team. The devices will be certified to initially meet European and U.S. requirements, and will be extended to other countries *via* the international MDSAP program.

5.9 SALES AND MARKETING

We hold worldwide commercialization rights to our platform technologies, product candidates and development programs. If approved, we intend to commercialize GS010, initially in the United States and the European Union, ourselves. Due to the orphan nature of LHON, we believe a targeted sales and marketing organization would be able to reach specialized ophthalmology centers and their patients. We have built, and continue to expand upon, key relationships with ophthalmic experts and patients of severe retinal neurodegenerative diseases around the globe, since we anticipate that a large majority of patients suffering from this disease will be referred to a limited number of large, well-equipped neuro-ophthalmologists and retina specialists in each country. Due to the broad patient populations that GS030 may address, we may enter into strategic partnerships to maximize commercial value of our product candidate.

ORGANIZATIONAL STRUCTURE

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ORGANIZATIONAL STRUCTURE

On April 28, 2017, the Company incorporated its first subsidiary, Gensight Biologics Inc., a Delaware corporation, registered and located in the United States of America. This U.S-based subsidiary is wholly owned by GenSight Biologics S.A.

OPERATING AND FINANCIAL REVIEW

The following information concerning our financial condition and results of operations is derived from our consolidated financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2019 and should be read in conjunction with our consolidated financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2019 included in Section 18.1.1, "Company's Annual Consolidated Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2019" to this Universal Registration Document.

Our consolidated financial statements were prepared in accordance with IFRS as adopted by the European Union for the fiscal years in question. Deloitte & Associés and Becouze have audited our consolidated financial statements as of and for the fiscal year ended December 31, 2019. The report of our Statutory Auditors for the consolidated financial statements included in this Universal Registration Document is included in Section 18.1.2.

The main differences between IFRS as adopted by the European Union and French GAAP affecting the financial position and results of operations of the Company are broken down as follows for the year ended December 31, 2019:

In thousands of euros	*As of December 31, 2019*
Statutory net loss under French GAAP	***(29,323)***
GenSight Inc. result (loss)	*(803)*
Share-based payments	*(1,307)*
Net impact of IFRS 16	*(106)*
Financial provisions	*603*
Impact of the valuation of convertible Bonds under IFRS 9	*127*
Intangible assets	*(18)*
Employee benefits	*(36)*
Net (gain) / loss from the sale of Treasury Stocks	*78*
Unrealized gains on financial assets	*75*
Net loss under IFRS	***(30,710)***

Share-based payments

Under French GAAP, share-based compensation related to the grant of equity instruments is not recognized in the income statement. Under IFRS, the cost of the transactions paid with equity instruments is recognized as an expense in exchange for an increase in the shareholders' equity.

Financial provisions

Under French GAAP, a provision related to the current account with the subsidiary has been booked for a total amount of €603 K.

Impact of the valuation of Convertible Bonds under IFRS

Under IFRS, the issuing company must separately identify the liability and equity components of convertible bonds and treat them accordingly in the financial statements.

Initially, the liability component is calculated by discounting the future cash flows of the bonds (interest and principle) at the rate of a similar debt instrument without the conversion option. The value of the equity component is the difference between the present value of the liability component of the convertible bond (as mentioned above) and the total proceeds from the issue of bonds.

Subsequently, Interest is charged to the income statement based on the effective interest rate, which is usually higher than the nominal rate, to reflect the true opportunity cost of the financial liability.

Intangible assets

Under IFRS, an intangible asset was recognized and amortized in the context of a license agreement. The acquisition of this license has resulted in the issuance of ordinary shares as consideration paid for the license.

Leases

IFRS 16 – Leases has become effective as of January 1, 2019. This new standard replaces existing standards for leases, including IAS 17 – Leases, IFRIC 4 "Determining whether a agreement contains a lease agreement, "SIC-15" Advantages in Operating Leases "and SIC-27" Assessment of the Substance of Transactions Taking the Legal Form of a Lease".

The objective of IFRS 16 is to report information that (a) faithfully represents lease transactions and (b) provides a basis for users of financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. To meet that objective, a lessee should recognize assets and liabilities arising from a lease.

IFRS 16 introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. A lessee is required to recognize a right-of-use asset representing its right to use the underlying leased asset and a lease liability representing its obligation to make lease payments.

Employee benefits

Under French GAAP, the Company has chosen not to recognize liabilities in relation to long-term employee benefits. Under IFRS, a liability has to be recognized for employee benefits for the defined benefit obligation and is measured as the present value of benefits that have accrued to employees through services rendered up to that date, based on actuarial methods of calculation.

Net (gain) / loss from the sale of Treasury Stocks

Under IFRS, the Net (gain) / loss from the sale of treasury stocks are not recognized in the income statement, but as part of equity, in Consolidation Adjustments.

Unrealized gains on financial assets

Under French GAAP, the Company recorded financial assets at cost, being the acquisition price. Potential loss at year end is recognized through income and unrealized gains are not recognized. Under IFRS, money market funds are measured at fair value, with unrealized gains being recognized through income as the Company has designated these financial assets at fair value through profit and loss.

The table below sets forth the statements of income data as of December 31, 2019 and 2018:

	As of December 31,	
In thousands of euros	2018	2019
Operating income		
Revenues	—	700
Other income	4,346	4,210
Total operating income	**4,346**	**4,910**
Operating expenses		
Research and development	29,031	28,710
General and administrative	7,010	5,736
Sales and marketing	1,350	762
Total operating expenses	**37,391**	**35,208**
Operating profit (loss)	**(33,045)**	**(30,298)**
Financial income	44	95
Financial expenses	(452)	(504)
Financial income (loss)	**(408)**	**(409)**
Income tax	—	(4)
Net income (loss)	**(33,453)**	**(30,710)**
Basic and diluted earnings (loss) per share[1]	**(1.37)**	**(1.08)**
Number of shares used for computing basic and diluted earnings (loss) per share	24,466,559	28,382,184

(1) See Note 23 to our consolidated financial statements as of and for the fiscal year ended December 31, 2019 for further details on the calculation of basic and diluted earnings (loss) per share.

7.1 OVERVIEW

We are an innovative clinical-stage gene therapy Company with an initial focus on discovering, developing and commercializing novel therapies for severe retinal neurodegenerative diseases. We are developing a pipeline of proprietary product candidates to provide patients with a long-lasting cure for severe inherited retinal diseases for which there are no currently approved treatments. Our current product candidates are designed to be administered in a single treatment to each eye by intravitreal, or IVT, injection. We are leveraging our expertise in ophthalmology, gene therapy and drug development to restore vision by combining a gene therapy-based approach with our proprietary technology platforms of mitochondrial targeting sequence, or MTS, and optogenetics. We believe our technology platforms have broad applicability both within and outside of ophthalmology as well as central nervous system, or CNS, disorders. Our lead product candidate, GS010, is a recombinant AAV2-based gene therapy for the treatment of Leber Hereditary Optic Neuropathy, or LHON, and is currently in Phase III clinical trials. We reported top-line results for REVERSE at 48, 72 and 96 weeks in April, October 2018, and May 2019, respectively. Top-line results for RESCUE at 48, 72 and 96 weeks were reported in February, April and September 2019, respectively. Our second most advanced product candidate, GS030, for the treatment of Retinitis Pigmentosa, or RP, is currently in an ongoing Phase I/II trial. We enrolled the first subject in this orphan family of diseases in October 2018.

We have never generated any revenues from marketed product sales. We do not expect to generate material revenue from product sales unless and until we successfully complete development of, and obtain marketing approval for, one or more of our product candidates, which is subject to significant uncertainty. To date, we have financed our operations primarily through private placements of ordinary shares and preferred shares, and through conditional advances and non-refundable subsidies received from Bpifrance Financement, part of Bpifrance, a French public investment bank, and sales of our ordinary shares in connection with the initial public offering of our ordinary shares on Euronext Paris in July 2016.

All of our operating losses resulted from costs incurred in connection with our development programs and from general and administrative expenses associated with our operations.

See Section 3.1, "Financial Risks". We expect to incur substantial losses from operations in the foreseeable future as we continue our research and development efforts, advance GS010, GS030 and other product candidates through preclinical and clinical development, seek regulatory approval and prepare for and, if approved, proceed to commercialization. Specifically, we have incurred and we expect to continue to incur substantial expenses in connection with any Phase III clinical trials, as well as Chemistry Manufacturing and Controls, or CMC, activities that we may conduct for GS010 and our planned preclinical and clinical studies for GS030. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue the development of our product candidates, including planned and future clinical trials;
- seek regulatory approvals for our product candidates;
- prepare for the potential launch and commercialization of our product candidates, if approved;
- establish a sales and marketing infrastructure for the commercialization of our product candidates, if approved; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and operations as a French public company.

Until such time that we can generate substantial revenue from product sales, we expect to finance these expenses and our operating activities through a combination of our existing liquidity and proceeds from any additional future financing. If we are unable to generate revenue from product sales, in particular from GS010, in accordance with our desired timeframes, we will need to raise additional capital. However, we may be unable to raise additional funds or enter into other funding arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant other rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full.

As indicated in Note 2 of our consolidated financial statements for the period ended December 31, 2019, such consolidated financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, issued by the International Accounting Standards Board, or IASB, as adopted by the European Union. IFRS includes the International Accounting Standards, or IASs, approved by the IASB and the accounting interpretations issued by the International Financial Reporting Interpretations Committee, the former Standing Interpretations Committee.

7.2 FINANCIAL OPERATIONS OVERVIEW

7.2.1 OPERATING INCOME

Our operating income consists of revenues and other income.

7.2.2 REVENUES

Revenues as of December 31,2019 solely comes from the named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted by the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) to the CHNO of the *Quinze-Vingts* on December 9, 2019. The price per patient was set at €700 K by the Group (€350 K per eye).

In France, use of pharmaceutical products not yet approved with a Marketing Authorization (AMM) and not recruiting for a clinical trial requires first obtaining an ATU from the ANSM.

GenSight Biologics will be paid a preliminary price by the hospitals. Upon obtaining full marketing authorization and completing pricing negotiations, GenSight may be required to rebate to the foreign government the difference between the preliminary price and the final price.

As of December 2019, payment terms have been established and Gensight reasonably estimated the amount of consideration to which it will ultimately be entitled on the basis of the future negotiations with the National Drug Safety Agency and prices for comparable treatments.

Our ability to keep generating product revenue and become profitable depends upon our ability to successfully develop and commercialize our product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the amount or timing of product revenue. None of our product candidates have completed clinical development. We reported top-line results from our two most advanced Phase III trials for GS010, REVERSE and RESCUE, in April 2018 and February 2019, respectively. Even if we are able to bring GS010 or our other product candidates at earlier stages of development through to commercialization, we may be unable to continue our operations at planned levels and be forced to reduce our operations.

7.2.3 OTHER INCOME

Our other income consists of subsidies and conditional advances and research tax credits.

Subsidies and Conditional Advances

Due to the innovative nature of our product candidate development programs, we have benefited from subsidies and conditional advances from Bpifrance Financement. Bpifrance Financement's mission is to provide assistance and support to

emerging French companies to facilitate the development and commercialization of innovative technologies.

The funds we have received are intended to finance our research and development efforts and the recruitment of specific personnel. Such funding is in the form of non-refundable subsidies and conditional advances.

We account for non-refundable subsidies as other income ratably over the duration of the funded project. Funds are recognized in other income in our statement of income (loss) for the fiscal year in which the financed expenses or expenditures were recorded. Since inception, we have received a grant from Bpifrance Financement of a non-refundable subsidy of €1,147 K (of which €865 K was received in December 2014) in connection with our development of product candidates using our optogenetics technology platform. The received non-refundable subsidy was fully amortized over 2014 and 2015, and we do not expect to receive any additional subsidies.

Funds received from Bpifrance Financement in the form of conditional advances have been recognized as financial liabilities, as we are obligated to reimburse Bpifrance Financement for such conditional advances in cash based on a repayment schedule and are not included in other income.

For more information with respect to the subsidies and conditional advances, see Section 8.3, "Funding Sources" of this Universal Registration Document.

Research Tax Credits

The research tax credit *(crédit d'impôt recherche)*, or CIR is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research and included as other income. Companies demonstrating that they have expenditures that meet the required criteria, including research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause, receive a tax credit that can be used against the payment of the corporate tax due the fiscal year in which the expenditures were made and during the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenditures taken into account for the calculation of the CIR only involve research expenses.

The main characteristics of the CIR are the following:

- the CIR results in a source of cash inflow for us from the tax authorities, since it is used to offset the payment of corporate tax or is paid directly to us for the portion that remains unused for corporate tax;
- a company's corporate tax liability does not limit the amount of the CIR – a company that does not pay any corporate tax can request direct cash payment of the research tax credit; and
- the CIR is not included in the determination of the corporate tax.

As a result, we have concluded that the CIR meets the definition of a government grant as defined in IAS 20 Accounting for Government Grants and Disclosure of Government Assistance and, as a result, it has been classified as other income within operating income in our statement of income (loss).

We requested the reimbursement of the 2017 CIR under the Community tax rules for small and medium-sized companies in compliance with the regulatory texts in effect for the amount of €3.7 million, which was received in September 2018. We have requested the reimbursement of the 2018 CIR in the amount of €4.3 million, which was received in December 2019. We have requested the reimbursement of the 2019 CIR in the amount of €4.2 million, which has not been received as of the date of this Universal Registration Document.

Legislative or regulatory changes relating to CIR or challenges by the French tax authorities with respect to our research expenditures or our eligibility to receive CIR could have a material adverse effect on our ability to operate our business and our financial condition, results of operations and prospects.

7.2.4 OPERATING EXPENSES

Since inception, our operating expenses have consisted primarily of research and development activities and general and administrative costs and since 2017, marketing and sales expenses.

7.2.4.1 Research and Development

We engage in substantial research and development efforts to develop innovative pharmaceutical product candidates. Research and development expenses consist primarily of:

- sub-contracting, collaboration and consultant expenses, that primarily include the cost of third-party contractors such as contract research organizations, or CROs, who conduct our non-clinical studies and clinical trials;
- personnel costs, including salaries, related benefits and share-based compensation, for our employees engaged in scientific research and development functions, and which includes contributions required by French law related to certain share-based compensation, which we refer to as social contributions;
- licensing and intellectual property costs, including upfront payment for exclusive licensing;
- purchases, real-estate leasing costs and rental income received from sublease agreements, as well as conferences and travel costs; and
- depreciation and amortization.

Our research and development expenses in the periods presented, and for the current period to date, mainly relate to the following activities:

- **GS010:** Our Phase I/II dose-escalation safety study for GS010 was completed in 2016 and a follow-up study is currently ongoing. In 2017, we reported additional clinical trial results with the product candidate after two and two and a half years of follow-up in our Phase I/II study. GS010 entered into Phase III trials, RESCUE and REVERSE, in the fourth quarter of 2015, following the release of our investigational new drug, IND, application by the U.S. Food and Drug Administration, or the FDA. The trials are designed as a double-masked, sham-controlled, multi-center, multi-country clinical trial in Europe and the United States. We completed enrollment of all 37 subjects for REVERSE and 39 subjects for RESCUE in February and August 2017, respectively. Top-line results for REVERSE at 48, 72 and 96 weeks were reported in April and October 2018 and in May 2019, respectively. Top-line results for RESCUE at 48, 72 and 96 weeks were reported in February, April and September 2019, respectively. REFLECT, a bilateral Phase III clinical trial conducted pursuant to a special protocol assessment with the FDA, was initiated in 2018. The recruitment was completed in July 2019.
- **GS030:** From 2014 to 2016, we conducted preclinical proof-of-concept studies with different molecules that led to the discovery of GS030. In 2017, we have initiated good laboratory practice, toxicology studies on non-human primates. We received the approval to initiate Phase I/II clinical trials in December 2017. The first subject was treated in the United Kingdom in October 2018.

Our direct research and development expenses consist primarily of external costs, such as manufacturing expenses, non-clinical studies, startup fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, acquiring and manufacturing clinical trial materials and costs related to collaborations, which we allocate to our specific research programs. In addition, we allocate personnel-related costs, depreciation and other indirect costs to specific programs.

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of preclinical and clinical development, primarily due to the increased size and duration of later-stage clinical trials, as well as the ramp-up of CMC and manufacturing activities in preparation for regulatory submission, and ultimately commercialization. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for our product candidates, and complete clinical development and prepare for commercialization of other product candidates.

We cannot determine with certainty the duration or costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of our ongoing, as well as any additional, non-clinical studies, clinical trials and other research and development activities;
- clinical trial and early-stage results;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for GS010, GS030 or any other product candidate that we may develop in the future.

A change in the outcome of any of these variables with respect to the development of GS010, GS030 or any other product candidate that we are developing could mean a significant change in the costs and timing associated with the development of such product candidates. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct non-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in enrollment in any clinical trials, we could be required to spend significant additional financial resources and time on the completion of clinical development. For a discussion on the risks associated with completing the development projects on schedule, see Section 3.2, "Risks Related to the Discovery and Development of and Obtaining Regulatory Approval for Our Product Candidates".

7.2.4.2 General and Administrative

General and administrative expenses consist primarily of personnel costs and share-based compensation for personnel other than research and development or sales and marketing staff. General and administrative expenses also consist of fees for professional services, mainly related to audit, IT, accounting, recruitment and legal services, communication and travel costs, real-estate leasing costs, office furniture and equipment costs, allowance for amortization and depreciation, directors' attendance fees, insurance costs and overhead costs, such as telecommunications expenses.

We anticipate that our general and administrative expenses will increase in the future as we grow our support functions for the expected increase in our research and development activities and the potential commercialization of our product candidates. We also anticipate increased expenses associated with being a public company in France, including costs related to audit, legal, regulatory

and tax-related services associated with maintaining compliance with Euronext Paris listing and AMF requirements, director and officer insurance premiums, and media and investor relations costs.

7.2.4.3 Sales and Marketing

Sales and marketing expenses consist primarily of professional fees, communication and branding fees and personnel costs. If and when we believe that regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations.

In the meantime, we anticipate some increased expenses related to our current activities and pursuing investments, as required.

7.2.4.4 Finance Income (Expense)

Our financial expenses relate to interests expenses related to our convertible bond loan and our conditional advances, to the interest expenses related to the application of the new standard IFRS 16 on Lease expenses as well as to foreign currency losses related to the purchase of services denominated in U.S. dollars.

Our cash and cash equivalents have been deposited only in a non-interest-bearing current account. We expect to follow an investment philosophy whereby our cash and cash equivalents are deposited primarily in savings and money market and time deposit accounts with original maturities of three months or less. We expect our savings and deposit accounts and marketable securities to generate a modest amount of interest income.

7.2.5 CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our consolidated financial statements are prepared in accordance with IFRS. Some of the accounting methods and policies used in preparing our financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. The actual value of our assets, liabilities and shareholders' equity and of our earnings could differ from the value derived from these estimates if conditions change and these changes had an impact on the assumptions adopted. We believe that the most significant management judgments and assumptions in the preparation of our financial statements are described below. See Note 3 to our consolidated financial statements for the period ended December 31, 2019 for a description of our other significant accounting policies.

Licenses Recognized as Intangible Assets

As of December 31, 2013, we recorded an intangible asset relating to exclusive in-licenses for two patent families from Novartis Pharma AG. We issued 670,588 ordinary shares as consideration paid for the exclusive licenses. Given that the fair value of the licenses cannot be reliably estimated, in accordance with IFRS2 *Share-based Payment*, or IFRS2, the amount of the intangible asset being recognized was determined by reference to the fair value of the ordinary shares that we issued based on an independent valuation. The licenses are being amortized over 15 years from February 2013, the date the licenses were entered into, which corresponds to the expected useful life of the licenses.

Conditional Advances

In 2014, we received a grant from Bpifrance Financement of both subsidies and conditional advances in relation to the development of our optogenetics technology platform. The program will be funded according to a specified schedule set forth in the contract, subject to completion of milestones. As the program advances, we will provide Bpifrance Financement with interim progress reports and a final report when the funded project ends. Based on these reports, we are entitled to conditional advances from Bpifrance Financement.

Each award of an advance is made to help fund a specific development milestone. The total amount of the conditional advances initially granted was €5.7 million, of which €678 K was received in December 2014 and €2.3 million was received in July 2016 and recognized as non-current liabilities in our statement of financial position, as this conditional advance is repayable by us according to a repayment schedule.

Our contract with Bpifrance Financement sets forth a repayment schedule that totals a maximum amount of €6.5 million, based on the assumption that we received the €5.7 million for total conditional advances. Following the repayment of the conditional advances, we may be required to make additional payments over a period of two years of up €2.7 million (€1.2 million the first year and €1.6 million the second year), depending on whether we reach cumulative revenues, excluding taxes, of €80.0 million by 2037. Our obligation to repay these amounts is based on the technical and commercial success of the funded program, as determined by the revenue forecasts or revenues deriving from direct or indirect exploitation of the products and results of our optogenetics technology platform. In the event Bpifrance Financement determines that the program is not successful, Bpifrance Financement will meet with us to assess the impact on the repayments and the repayment schedule.

Actual results related to the development of these programs may differ from these estimates in which case the financial liability reflected in our consolidated financial statements for the conditional advances may be reduced. Notably, after review and analysis of the stage of completion of the remaining milestones, level of expenses that have been incurred as of December 31, 2018 and 2019, and given that the term of the initial agreement is set on November 30, 2019; the Group has made the assumption that it would not be able to complete the key milestones on time and therefore should not receive any more conditional advance

from Bpifrance Financement. As a consequence, the remaining conditional advance contractually agreed, representing a total amount of €2,333 K should not be received by the Company.

The current and non-current portions of the financial liability recognized in our consolidated financial statements associated with these conditional advances are determined based on the applicable reimbursement schedules at the end of each reporting period and measured using the effective rate method. The portion of the conditional advances for terms longer than one year are classified as non-current liabilities while the portion for terms of less than one year are classified as current liabilities.

Fair value of the convertible bond

The measurement of the fair value of the liability component of the convertible bond, calculated on the basis of the contractually agreed interest and amortization payments discounted at market interest rates.

Revenue

The estimate of the selling price for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*. The National Drug Safety Agency, granted to GenSight Biologics a Temporary Authorization for Use ("ATU nominative"). Variable consideration under IFRS 15 are required to be estimated at contract inception. The Group assessed individual contracts to determine the estimated variable consideration and related constraints.

Share-Based Compensation

We have granted share-based warrants in the form of share warrants for founders (*Bons de Souscription de Parts de Créateur d'Entreprise*, or BCE) and share warrants (*Bons de Souscription d'Actions*, or BSA), stock options (*Options de souscription ou d'achat d'actions*, or SO) and free shares (*Attributions gratuites d'actions*, or AGA), since January 1, 2016 with the following exercise prices for each of the grant dates reflected below:

Grant date	Number of **warrants granted**	Exercise price per share	Ordinary share fair market value per share at grant date	Per share fair value of warrants granted
July 8, 2013	892,000	€0.025	€1.025	€0.44
July 8, 2013	328,000	€0.025	€1.025	€0.36
April 9, 2014	193,800	€0.025	€1.025	€0.44
April 9, 2014	33,000	€0.025	€1.025	€0.36
December 3, 2014	60,000	€0.025	€2.150	€2.15
July 8, 2015	733,298	€3.275	€7.800	€5.56
July 8, 2015	121,000	€3.275	€7.800	€5.31
July 26, 2016	205,000	€8.080	€8.000	€2.94
July 27, 2017	165,000	€5.040	€5.15	€1.64
September 18, 2018	20,000	€2.22	€3.74	€2.02
July 23, 2019	105,000	€1.45	€2.65	€1.83

Grant date	Number of **stock options** granted	Exercise price per share	Ordinary share fair market value per share at grant date	Per share fair value of warrants granted
July 27, 2017	220,000	€5.04	€5.12	€2.09
December 19, 2017	300,000	€5.55	€5.55	€2.20
March 14, 2018	175,000	€6.98	€6.98	€2.63
September 18, 2018	30,000	€2.19	€2.10	€0.91

Grant date	Number of **free shares granted**	Ordinary share fair market value per share at grant date
July 26, 2016	766,000	€8.00
July 27, 2017	593,500	€5.12
December 19, 2017	72,500	€5.55
September 18, 2018	380,000	€2.10
December 19, 2018	135,000	€4.04
July 23, 2019	610,000	€1.88
January 28, 2020	1,020,000	€3.72

We account for share-based compensation in accordance with IFRS2. Under the fair value recognition provisions of this guidance, share-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Our determination of the fair value of the warrants and ordinary shares is described below:

Fair Value of Our Warrants

We use the Black-Scholes option-pricing model to determine the fair value of warrants. Use of this valuation method requires management to apply judgment and make estimates, including:

- the expected term of our share-based warrants;
- the volatility of our ordinary shares;
- the risk-free rate for a period that approximates the expected term of our share-based warrants;
- the expected dividend yield; and
- the fair value of our ordinary shares on date of grant.

To determine the grant date fair value of share-based warrants, these complex and subjective variables are estimated as follows:

Expected Term. The expected term represents the period that our share-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the warrant awards granted, we have based our expected term on the simplified method, which represents the average period from vesting to the expiration of the award.

Expected Volatility. As we do not have a sufficient amount of trading history for our ordinary shares to make reliable volatility estimates, the expected share price volatility for our ordinary shares was estimated by taking the average historic price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the warrant grants. We did not rely on implied volatilities of traded warrants and options in our industry peers' shares because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own ordinary share price becomes available.

Risk-Free Interest Rate. The risk-free interest rate is based on the yields of France Treasury securities with maturities similar to the expected term of the warrant for each warrant group.

Dividend Yield. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

If any of the assumptions used in the Black-Scholes model changes significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The following table presents the weighted-average assumptions used to estimate the fair value of warrants and stock options granted during the periods presented:

BCE / BSA

	As of December 31,	
	2018	2019
Volatility	58.02%	78.50%
Risk-free interest rate	0.1%	0.1%
Expected life (in years)	4.25 years	4.25 years
Dividend yield	— %	— %

Stock Options

	March 14, 2018	September 18, 2018
Volatility	48.75%	58.02%
Risk-free interest rate	0.1%	0.1%
Expected life (in years)	4.25 years	4.25 years
Dividend yield	— %	— %

Fair Value of Our Ordinary Shares

Since being listed on Euronext Paris in July 2016, the fair value of our ordinary shares generally has been determined by reference to the closing price of a share on the grant date.

Liabilities with one of our key supplier

The Group terminated its contractual relationship with one of its key suppliers during the year. No financial compensation was required. In November 2019 GenSight received two invoices from this supplier for a total amount of USD2.6 million. The Company considers that the main part of services billed by this supplier have not been performed. As of December 31, 2019, discussions between this supplier and GenSight are still ongoing. The Group's legal counsels have advised that they do not consider that the claim has merit, and they have recommended that it be contested. The Company booked a liability for € 2.4 million offset by a credit note to be received for € 2.2 million, considering that only € 0.2 million could be due to this supplier.

7.3 RESULTS OF OPERATIONS

Comparisons for the Twelve Months Ended December 31, 2018 and 2019

Operating Income

We generated operating income of €4.3 million in 2018 and €4.9 million in 2019, an increase of 13.0%.

The revenue reported as of December 31, 2019 solely comes from the named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted by the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) to the CHNO of the *Quinze-Vingts* on December 9, 2019, for a total of €700 K.

Operating Income was mainly generated by our CIR.

	As of December 31,	
In thousands of euros	2018	2019
Revenues	—	700
Other income	4,346	4,210
CIR	4,322	4,210
Subsidies	24	—
Total operating income	**4,346**	**4,910**

As no research and development expenditure is capitalized before obtaining a marketing authorization, the CIR related to a research program is entirely recorded as operating income.

For 2018, we recorded other income related to CIR of €4.3 million, which was reimbursed in cash in December 2019. We requested the reimbursement of the 2019 CIR in the amount of €4.2 million, which has not been received at the date of this Universal Registration Document.

Research and Development Expenditures

From 2018 to 2019, the total amount spent by us for research and development activities remained steady with €28.7 million in 2018 versus €29.1 million as at December 2019.

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	4,691	3,458
Sub-contracting, collaboration and consultants	21,288	23,027
Licensing and intellectual property	752	383
Offices costs	727	32
Travel and entertainment expenses	760	774
Allowance for amortization	270	554
Others	543	482
Total research and development expenses	**29,031**	**28,710**

(1) Includes €1.0 million and €0.4 million related to share-based compensation expense for 2018 and 2019, respectively.

The following significant variations have been observed among the components:

- 8,2% or €1,739 K increase in sub-contracting, collaborations and consultants, that includes the costs of service providers in connection with conducting our clinical trials in 2019, and notably our Phase III trials for GS010, RESCUE, REVERSE and REFLECT, as well as our Phase I/II trial for GS030, PIONEER, as well as the development and manufacturing of the device used in the Phase I/II trial for GS030; totally offset by
- 28.3% or €1,233 K decrease in personnel expenses, explained by:
  - — the decrease of €0.6 million of share-based compensation expenses
  - — The decrease of the average headcount dedicated to Research and Development; from 25 to 20 in 2018 and 2019, respectively
- 95.6% or €695 K decrease of the office costs, mainly explained by the cancellation of the rental costs under the new standard IFRS 16
- 49.1% or €369 K decrease in Licensing and Intellectual Property explained by the achievement in 2018 of the contractual milestone following the enrollment of the first patient in the Phase I trial of GS030.

The table below summarizes our research and development expenses incurred by program:

	As of December 31,	
In thousands of euros	2018	2019
Direct research and development expense by program:		
GS010	18,074	19,667
GS030	4,011	3,229
Total direct research and development expense	**22,085**	**22,896**
Personnel related (including share-based compensation)	4,691	3,458
Indirect research and development expense	2,255	2,356
Total research and development expenses	**29,031**	**28,710**

General and Administrative Expenses

During the period presented, our general and administrative expenses decreased from €7.0 million in 2018 to €5.7 million in 2019.

Our general and administrative expenses are broken down as follows:

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	2,993	2,877
Fees	2,062	881
Communication and travel expenses	1,051	959
Real estate property rental	255	52
Office furniture and small equipment	146	142
Postal and telecommunication expenses	25	26
Allowance for amortization and depreciation	45	401
Directors attendance fees and expenses	150	185
Insurance and banking fees	48	47
Equipment rental	3	2
Others	232	164
Total G&A expenses	**7,010**	**5,736**

(1) Includes €1.1 million and €0.8 million related to share-based compensation expense as of December 31, 2018 and 2019, respectively.

The decrease in our general and administrative expenses (18.2% or €1.3 million) from year to year mainly results from the decrease of €1.2 million in professional fees, related mainly to lawyers and audit fees.

Sales and Marketing Expenses

During the period presented, our sales and marketing expenses decreased from €1.4 million in 2018 to €0.8 million in 2019.

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	658	393
Fees	493	229
Communication and travel expenses	39	66
Office costs	108	2
Depreciation and amortization expenses	—	30
Others	52	42
Total S&M expenses	**1,350**	**762**

(1) Includes €0.3 million and €0.1 million related to share-based compensation expense as of December 31, 2018 and 2019, respectively.

The decrease in Personnel expenses is explained by the decrease of €219 K in share-based compensation expenses as well as a decrease of €40 K in the accrual for social contribution related to the free shares.

The decrease primarily derives from the communication expenses. The Group had initiated pre-launch activities for GS010 in late 2017 and 2018 related to medical and commercial workstreams as well as payer landscape analysis.

Operating Loss

Our operating loss decreased from €(33.0) million in 2018 to €(30.3) million in 2019. As described above, this is mainly due to the €700 K revenue from the Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted by the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) to the CHNO of the *Quinze-Vingts* on December 9, 2019.

In addition, we observed a decrease of €1.3 million in our G&A expenses, due to professional fees, mainly related to lawyers and audit fees occurred in 2018 which have not been reiterated in 2019; as well as a decrease of €0.6 million in Sales and Marketing expenses.

Financial Loss

Our net financial loss remained steady with €(408)K in 2018 versus €(409) K in 2019. Our financial income increased from €44 K in 2018 to €96 K in 2019. We did not invest in securities and cash equivalents in 2019, therefore the financial income only arose from the foreign exchange gains coming from the purchase of services denominated in U.S. dollars. We generated foreign exchange losses of €(43) K in 2018 and €(115) K in 2019, also related to the purchase of services denominated in foreign currencies, primarily in U.S. dollars. Our interest expenses corresponding to accrued interests of conditional advances have decreased from €(408) K to €(191) K. We also booked interest expenses deriving from the first application of the new standard IFRS 16 for €(179) K; as well as interests attached to our bond financing for €(18) K, based on the effective interest rate.

CAPITAL RESOURCES

8.1 OVERVIEW

We have financed our operations since inception primarily through private placements of equity securities and sale of ordinary shares, raising a total of €128.6 million net of transaction-related costs as of December 31, 2019 including, *inter alia*, the sale of Series B preferred shares for which we received net proceeds of €30.8 million in a private placement which occurred on July 2015, the sale of ordinary shares in our initial public offering on Euronext Paris in July 2016 for which we received net proceeds of €41.4 million, the capital increase in June 2017 whose net proceeds amounted to €20.7 million, the capital increase in February 2019, entirely subscribed by Sofinnova, whose net proceeds amounted to €7.9 million, as well as the capital increase in December 2019, subscribed by both Sofinnova and 3Sbio, whose net proceeds amounted to €8.3 million.

8.2 ANALYSIS OF CASH FLOW

The table below summarizes our sources and uses of cash for the years ended December 31, 2018 and 2019:

	As of December 31,	
In thousands of euros	2018	2019
Net cash flows from operating activities	(28,383)	(28,112)
Net cash flows from investment activities	(663)	(102)
Net cash flows from financing activities	(115)	21,245
Net (decrease)/increase in cash and cash equivalents	**(29,160)**	**(6,969)**

Our net cash flows from operating activities were €(28.4) million and €(28.1) million for 2018 and 2019, respectively. During 2019, we pursued our efforts in advancing our research and development programs, mainly GS010, that progressed into three Phase III trials, as well as the ramp-up of CMC and manufacturing activities in preparation for regulatory submission, and ultimately commercialization. Our net cash from operating activities in 2019 consisted primarily of a net loss of €(31.1) million adjusted of non-cash items, including share-based payments of €1.3 million, retirement pension obligations of €35 K, amortization and depreciation of €985 K and other financials items of €371 K.

Changes in working capital amounted to €1,896 K and €(144) K for 2018 and 2019, respectively. The significant items in the change in working capital in 2019 include an increase in the accounts receivable of €844 K relating to the the named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted by the ANSM in December 2019; offset by the decrease in other receivables for €964 K, relating to the decrease of prepaid expenses, mostly related to manufacturing costs, as the development process and related services are being delivered.

Our net cash flows from investment activities were €(663) K and €(102) K in 2018 and 2019, respectively. Regarding 2018, these mainly derived from the purchase of leasehold improvement, furnitures and technical equipment for a total amount of €(789) K, mostly for our U.S. subsidiary. Concerning 2019, these relate to the acquisition of technical and computer equipment for €(69) K.

Our net cash flows from financing activities increased from €(115) K in 2018 to €21.2 million in 2019. In 2019, we received net proceeds of €16.2 million from the issuance of ordinary shares, as well as €5.7 million from bond financing.

8.3 FUNDING SOURCES

During 2016 and 2017, we obtained new financing by both issuance of securities and receipt of conditional advances from Bpifrance Financement. We did not get any new financing in the course of 2018 and completed two capital increases for a total net proceeds of €16.2 million in the beginning in 2019, as well as a bond financing of €6 million.

In thousands of euros	Equity capital	Bond financing	Conditional advances	Subsidies	Total
2014 (including financing and advances received prior to 2014)	19,436	–	678	865	20,979
2015	30,837	–	–	–	30,837
2016	41,439	–	2,279	–	43,718
2017	20,724	–	–	–	20,724
2019	16,182	5,692	–	–	21,874
Total	**128,618**	**5,692**	**2,957**	**865**	**138,132**

On July 7, 2015, we sold 4,624,871 Series B preferred shares for which we received net proceeds of €30.9 million in a private placement.

On July 8, 2015, we issued 1,833,247 warrants for which we received proceeds of €30 K.

On July 13, 2016, we issued 5,000,000 ordinary shares for which we received net proceeds of €36.4 million in our initial public offering on Euronext Paris.

On August 10, 2016, we issued 655,859 ordinary shares for which we received net proceeds of €5.0 million after exercising the overallotment option in connection with our initial public offering on Euronext Paris.

On September 3, 2016, we issued 112,000 ordinary shares for which we received net proceeds of €3 K in connection with the exercise of share warrants.

On October 6, 2016, we issued 32,720 ordinary shares for which we received net proceeds of €4 K in connection with the exercise of share warrants.

On October 31, 2016, we issued 205,000 warrants for which we received proceeds of €133 K.

On June 27, 2017, we issued 3,750,000 ordinary shares for which we received net proceeds of €20.7 million.

On February 25, 2019, we issued 3,921,568 ordinary shares for which we received net proceeds of €7.9 million.

On December 19, 2019, we issued 3,799,701 ordinary shares for which we received net proceeds of €8.3 million.

In December 2019, GenSight Biologics obtained committed financing in the form of a bond financing of up to €12 million from Kreos Capital VI (UK) Limited and issued a drawdown notice thereunder for the first tranche of €6 million, including a €4.2 million straight bond issuance and a €1.8 million convertible bonds issuance.

The financial transaction is structured as follows:

- a capital increase for a total amount of €9 million representing 3,799,071 new shares subscribed for €4 million by Sofinnova Crossover I and for €5 million by Strategic International Group Limited, a wholly owned subsidiary of 3SBio Inc.; and
- subject to the condition precedent of realization of the 3SBio-Sofinnova Transaction, a bond issuance for a maximum amount of €10 million divided in 2 tranches as follows:
  - a first tranche (the "Tranche A") in the form of:
    - a bond issuance subscribed by Kreos Capital VI (UK) Limited for an amount of €6 million including €1.8 million subscribed by Kreos Capital VI (Expert Fund) LP in the form of convertible bonds, and
    - a concurrent issuance of share warrants for an amount the potential exercise of which would represent €1.2 million subscribed by Kreos LP; and
  - a second tranche, exercisable, subject to the realization of a Qualifying Financing, at the Company's option until September 1, 2020, in the form of:
    - a bond issuance subscribed by Kreos UK for an amount of €4 million including a maximum amount of €1.2 million susceptible to be subscribed at its election by Kreos LP in the form of convertible bonds, and
    - a concurrent issuance of share warrants for an amount the potential exercise of which would represent €300,000.

The Company has the option to issue additional bonds similar to the bonds described above (assimilables) to Kreos UK for an amount of €2 million.

We have incurred net losses in each year since our inception. Substantially all of our net losses resulted from costs incurred in connection with our development programs and from general and administrative expenses associated with our operations.

We have not incurred any bank debt.

In 2014, we received a grant from Bpifrance Financement of both non-refundable subsidies and conditional advances in relation to the development of our optogenetics technology platform. The program will be funded according to a specified schedule set forth in the contract, subject to completion of milestones. As the program advances, we provide Bpifrance Financement with interim progress reports and a final report when the funded project ends. Based on these reports, we are entitled to conditional advances from Bpifrance Financement. Each award of an advance is made to help fund a specific development milestone. The total intended amount of the conditional advances initially granted was €5.7 million, of which €678 K was received in December 2014 and €2.3 million received in July 2016, and recognized as non-current liabilities in the statement of financial position, as this conditional advance is repayable by us according to a repayment schedule.

Bpifrance Financement Conditional Advances

The original payment schedule for conditional advances under the program is summarized below:

- €678 K received in December 2014;
- €2.3 million received in July 2016 (initially estimated to be €2.7 million based on the payment schedule and reduced as a result of lower costs incurred by us than anticipated);

- €494 K originally to be received in the second quarter of 2018;
- €853 K originally to be received in November 2018; and
- €986 K originally to be received in November 2019.

The advances bear interest depending on the level of success of the funded program. The repayment schedule for a total amount of €6.5 million, including interest at an annual rate of 1.44%, based on the assumption of the reception of a total amount of €5.7 million of conditional advances, would be as follows:

- €550 K on or before June 30, 2022;
- €1.0 million on or before June 30, 2023;
- €1.5 million on or before June 30, 2024;
- €1.7 million on or before June 30, 2025; and
- €1.7 million on or before June 30, 2026.

Following the repayment of all of the conditional advances, we may be required to make additional payments over a period of two years of up to €2.7 million, depending on whether we reach cumulative revenue, excluding taxes, of €80.0 million by 2037. Our obligation to repay these amounts is based on the technical and commercial success of the funded program, as determined by the revenues forecasts or revenues deriving from direct or indirect exploitation of the products and results of our optogenetics technology platform. In the event Bpifrance Financement determines that the program is not successful, Bpifrance Financement would meet with us to assess the impact on the repayments and the repayment schedule.

After review and analysis of the stage of completion of the remaining milestones, level of expenses that have been incurred as of December 31, 2018 and 2019, and given that the initial agreement was on November 30, 2019, the Group considers that it would not be able to complete the remaining key milestones on time and therefore should not receive any more conditional advance from Bpifrance Financement.

The updated repayment schedule for a total amount of €3,303 K (€2,957 K of cash received + €346 K of capitalized interests) of all of the conditional advances is as follows:

- €550 K on or before June 30, 2022;
- €1,000 K on or before June 30, 2023;
- €1,500 K on or before June 30, 2024; and
- €253 K on or before June 30, 2025;

Following the repayment of all of the conditional advances, the Company may be required to make additional payments over a period of two years of up to €1.4 million (€603 K the first year and €823 K the second year), depending on whether the Company reaches cumulative revenues, excluding taxes, of €80.0 million. These additional repayments should be done within 15 years following the first year of reimbursement, *i.e.* 2037. The obligation to repay these amounts is based on the technical and commercial success of the funded program, as determined by the revenues forecast or revenues deriving from direct or indirect exploitation of those products and results of its optogenetics technology platform. In the event Bpifrance Financement determines that the program is not successful, Bpifrance Financement will meet with the Company to assess the impact on the repayments and the repayment schedule.

Bpifrance Financement non-refundable subsidy

We have been granted a total of €1.1 million in non-refundable subsidies as follows:

- €866 K received in December 2014;
- €173 K originally to be received in November 2018; and
- €111 K originally to be received in November 2019.

In the same way as for the conditional advances, as of December 31, 2019, the Group considers that it would not be able to complete the remaining key milestones on time and therefore the Group did not receive any subsidy in 2019 and should not receive any more non-refundable subsidy from Bpifrance Financement.

The table below summarizes the aggregate amounts of subsidies and conditional advances we have received as of December 31, 2019

In thousands of euros	Entitled	Granted	Repayed	To be granted
Conditional advances	5,686	2,957[1]	–	–
Subsidies	1,147	866	–	–
Total	**6,833**	**3,823**	**–**	**–**

(1) The estimated amount from the initial payment schedule was €2.7 million. The costs occurred by us amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.

8.4 PRINCIPAL USES OF CASH

8.4.1 CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table discloses aggregate information about our material contractual obligations and the periods in which payments are due as of December 31, 2019. Future events could cause actual payments and timing of payments to differ from the amounts set forth below.

In thousands of euros	Total	Less than one year	One to three years	Four to five years	More than five years
Conditional advances	3,633[(1)]	–	550	2,500	583
Corporate Bonds	4,621	889	3,732	–	–
Pension and employee benefits	103	–	–	–	103
G&A and related services	2,187	437	875	875	–
Total	**10,544**	**1,326**	**5,157**	**3,375**	**686**

(1) The estimated amount from the initial payment schedule was €2.7 million. The costs occurred by us amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.

The amounts of contractual obligations set forth in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

8.4.2 OPERATING CAPITAL REQUIREMENTS

Since its incorporation, the Company has funded its activities through several equity financings, grants, conditional advances and Research Tax Credit. To date, the Company has no product revenue, and management expects operating losses to continue for the foreseeable future until, where appropriate, generate revenue from sale of its development drug candidates. As the Company continues to actively prepare for the launch of its GS010 product in Europe and in the United States in 2021, if approved by regulatory authorities, current cash and cash equivalents on hand are not projected to be sufficient to support the Company's current operating plan for a period of 12 months following the date of issuance of the 2019 consolidated financial statements.

The Company has also decided to continue the current development activities of its GS030 product but not to undertake any studies or uninitiated costs to date, focusing primarily on its GS010 product.

The Company expects to seek additional funds, most likely from equity or structured debt financings.

Our present and future funding requirements will depend on many factors, including, among other things:

- the size, progress, timing and completion of our clinical trials for any current or future product candidates, including our lead product candidates, GS010 and GS030;
- the number of potential new product candidates we identify and decide to develop;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims of infringement raised by third-parties;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of the GS010 product candidate and any other current or future product candidates, including GS030 and other product candidates in preclinical development, together with the costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly, or in the form of royalty payments from any future potential partnership agreements, on the GS010 platform or relating to our other product candidates.

For more information as to the risks associated with our future funding needs, see the section of this Universal Registration Document entitled Section 3 "Risk Factors".

8.4.3 CAPITAL EXPENDITURES

Our main capital expenditures in 2018 and 2019 were primarily related to leasehold improvements and office and IT equipment for our headquarters and to license and software fees. Clinical research and development costs are not capitalized until marketing authorizations are obtained.

	As of December 31,	
In thousands of euros	2018	2019
Licenses, software	2	7
Property, plant and equipment	789	69
Non-current financial assets	–	–
Total	791	76

In 2018, our capital expenditures primarily related to acquiring technical equipment and installations €(214 K), leasehold improvement €(355 K), furniture €(192 K) and computer equipment €(28 K).

As of December 31, 2019, we had no material contractual commitments to acquire property, plant or equipment.

8.5 INFORMATION REGARDING THE ANTICIPATED SOURCES OF FUNDS NEEDED

Not applicable.

REGULATORY ENVIRONMENT

We are subject to a variety of laws and regulations in France, the United States and the European Union (or EU). Our product candidates use biological products and medical devices that are subject to laws and regulations regarding testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, export and import, reporting, approval, advertising and other promotional practices.

Clinical Trials on Human Subjects

Before testing any biological product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as non-clinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. Preclinical tests must comply with the laws and regulations and other requirements, including Good Laboratory Practices (GLP), in each jurisdiction in which they are conducted.

Clinical trials involving human beings are typically conducted in three sequential phases that may overlap or be combined:

- **Phase I.** The biological product is initially introduced into healthy human subjects and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- **Phase II.** The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- **Phase III.** Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. These studies are intended to provide an adequate basis for marketing approval. Studies in Phase III may also further explore the dose-response relationship, or explore the drug's use in wider populations, in different stages of disease, or in combination with another drug.

Clinical trials may, at times, be necessary after marketing in order to explain certain side effects, explore a specific pharmacological effect, or obtain additional data that is more precise. A regulatory authorization is required for the conduct of clinical trials.

The regulatory authorities may block the protocols for clinical trials suggested by the companies that apply to test products, suspend them, or require significant modifications in them. Moreover, the patient must be kept informed of the objective, the methodology, and the time period of the research, as well as of the anticipated benefits, constraints, and foreseeable risks resulting from the administration of the products that are the object of the clinical trials. The information communicated is summarized in a written document delivered to the patient prior to any administration of products, and the latter must confirm his or her agreement to participate in the clinical trial by signing an informed consent form.

Government Regulation in the European Union

Regulatory Authorization/Approval Required for the Conduct of a Clinical Trial in the EU

In the EU, requirements for the conduct of clinical trials on medicinal products are currently provided for in the European Directive No. 2001/20/EC of the European Parliament and of the Council of April 4, 2001 relative to the implementation of good clinical practices (or GCP) in the conduct of clinical trials on medicinal products for human use, or Clinical Trials Directive. Each country of the European Union had to implement this Directive into national law by eventually adapting it to its own regulatory framework.

Although the European Directive No. 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 EU, 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, the Clinical Trials Directive has been amended by Regulation (EU) No. 536/2014 of the European Parliament and of the Council of April 16, 2014 on clinical trials on medicinal products for human use, adopted on April 16, 2014 and published in the *Official Journal* of the EU on May 27, 2014 (the "Clinical Trials Regulation").

The Clinical Trials Regulation entered into force on June 16, 2014 and will take effect six months after the publication of the notice referred to in Article 82(3) delivered by the European Commission on the EU clinical trial portal and database. The entry into application of the Regulation is expected to occur at some point in 2020 according to the European Commission's website. To our knowledge, this notice has not been published yet. Until the Clinical Trials Regulation comes into effect, all clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and/or one or more Ethics Committees (or ECs). The authorization and oversight of clinical trials remains the responsibility of each Member State.

Regulatory Authorization/Approval Required for the Conduct of a Clinical Trial in France

General framework. In France, the Clinical Trials Directive has been notably implemented by Act No. 2004-806 of August 9, 2004 relative to the public health policy, as amended, and by Decree No. 2006-477 of April 26, 2006, modifying the title of the French Public Health Code, or PHC, on research involving human beings, this for all categories of products concerned: medicinal products, medical devices, biological products, ATMP, etc.

French Order No. 2016-800 of June 16, 2016 on research involving human beings and Act No. 2012-300 of March 5, 2012 (or *"Loi Jardé"*) related to biomedical research involving human beings have recently adapted French law to the new provisions of Clinical Trials Regulation. France adopted several changes to the laws and regulations on clinical trials since then.

Applicable provisions. The main French provisions applicable to the conduct of clinical trials are the following:

- Decree No. 2017-884 of May 9, 2017 modifying some regulatory provisions on research involving human beings;
- Order of May 3, 2017 establishing the list of researches referred to in Article L.1121-1, 2°, of the French Public Health Code;
- Decree No. 2016-1538 of November 16, 2016 on the unique agreement for the implementation of commercial clinical trials involving human beings in health care institutions;
- Decree No. 2016-1537 of November 16, 2016 on research involving human beings;
- Order No. 2016-800 of June 16, 2016 on research involving human beings;
- Act No. 2016-41 of January 26, 2016 for the modernization of our health system;
- Decision of December 29, 2015 establishing the rules for good clinical practice;
- Act No. 2012-300 of March 5, 2012 (or *"Loi Jardé"*) related to biomedical research involving human beings;
- Act No. 2011-2012 of December 29, 2011 aiming to strengthen health safety of medicinal and health products;
- Decree No. 2007-454 of March 25, 2007 on agreements and relationships between companies and members of some healthcare professions, amending the PHC;
- Decision of December 11, 2006 establishing the rules of good manufacturing practice;
- Decision of November 24, 2006 establishing the rules for good clinical practice for research involving human subjects;
- Decree No. 2006-477 of April 26, 2006 amending Chapter I of Title II of Book I of the first part of the PHC on biomedical research;
- Act No. 2004-806 of August 9, 2004 on public health policy;
- Decision of January 5, 2006 concerning the approval of a methodology for the reference to the processing of personal data carried out within the context of biomedical research;
- Act No. 2002-3003 of March 4, 2002 on rights of patients and on the quality of the healthcare system and its implementing decrees;
- European Directive No. 2001/20/EC of the European Parliament and of the Council of April 4, 2001 relative to the implementation of good clinical practices in the conduct of clinical trials on medicinal products for human use;
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/CE (General Data Protection Regulation), and the Act No. 78-17 of January 6, 1978 on Information Technology, Data Files and Civil Liberties, as last amended in 2018, and its implementing decrees;
- Decision No. 2018-154 of May 3, 2018 concerning the approval of a standard methodology for processing personal data in the context of research in the field of health, which does not require the express consent of the person involved (methodology MR-003); and
- Decision No. 2018-153 of May 3, 2018 concerning the approval of a standard methodology for processing personal data in the context of research in the field of health, which requires the express consent of the person involved (standard methodology MR-001).

Ethics Committee assessment. Under French law, a favorable opinion of a competent research and ethics committee (*Comité de Protection des Personnes* or "CPP") of the jurisdiction in which the investigator exercises its activity is always required for the conduct of clinical trials. Under Article L.1123-7 of the PHC, the competent Ethics Committee – selected randomly by drawing lots under Article L.1123-6 of the PHC – shall notably assess whether the conditions in which the trial will be conducted are valid. This assessment should be based on whether: adequate protection is offered to individuals, in particular to participants; adequate information is provided to the participants and appropriate procedure is in place to obtain their informed consent; the project is relevant; the benefits/risks assessment is satisfactory; the objectives of the trial are adequate to the means implemented; the qualification of the investigator(s) is satisfactory; the conditions and amount of patients' remuneration is compliant; and the method for recruiting participants is adequate.

ANSM authorization. A prior authorization issued by the ANSM is required for some types of clinical trials (interventional clinical trials implying an intervention on a natural person that is not justified by his/her usual medical care).

In practice, the applicant must submit to the ANSM a request for authorization of a clinical trial along with a file, which shall, in particular, contain information on the clinical protocol and specific product data and its quality control, as well as results of preclinical studies. After submission of the complete file, the ANSM may inform the sponsor that it objects to the implementation of the research. The sponsor can then modify the contents of its research project and submit an amended or supplemented request to the ANSM; this procedure may not, however, be applied more than once. If the sponsor does not alter the content of its request, the request is considered rejected.

Under French law, the time limit for the examination of a request for authorization of a clinical trial cannot exceed 60 days from the date of receipt of the complete file by ANSM (Article R.1123-38 PHC) and 45 days for the CPP (Article R.1123-23 PHC). In the case of trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms the time limit for the examination by ANSM and CPP is a 90-day period may which can be extended by a further 90 days in the event of consultation of a group (Article R.1125-8, R.1125-10, R.1125-11 PHC).

In the event of a risk to public health or if the ANSM considers that the conditions in which the research is implemented no longer correspond to the conditions indicated in the request for authorization or does not comply with the provisions of the PHC, the ANSM may at any time request changes to procedures for the realization of research, and suspend or ban this research (Article L.1123-11 PHC).

Under Article L.1123-7 PHC, the CPP shall deliver its opinion on the conditions of validity of the research, particularly with respect to the protection of participants, their information and how they collect informed consent, as well as the project's general relevance, the satisfactory nature of the assessment of benefits and risks and the adequacy between the objectives pursued and the means implemented.

The decision of November 24, 2006 sets forth the rules for good clinical practice ("GCP"), for biomedical research on medicines for human use provided for in Article L.1121-3 PHC. The purpose of the rules for GCP is to ensure both the reliability of data arising from clinical trials and the protection of persons participating in these clinical trials. GCPs shall apply to all clinical trials, including pharmacokinetics, bioavailability and bioequivalence studies in healthy volunteers and Phase II to IV clinical trials.

Under French law, a specific authorization issued by the Director General of ANSM is required before commencing clinical trials involving some advanced therapy medicinal products, including in particular medicinal products for gene therapy and somatic cell therapy including xenogenic (see Article L.4211-9-1 PHC).

Protection of Clinical Trial Subjects. Under French law (Article L.1121-2 PHC), a clinical trial may be undertaken only if (i) it is based on the latest stage of scientific knowledge and on sufficient preclinical testing, (ii) the foreseeable risk incurred by the subjects is outweighed by the benefit expected for these persons or the interest of the research, (iii) it aims at expanding scientific knowledge and the means possible to improve the human condition and (iv) the research was designed to reduce the pain, inconveniences, fear and other predictable inconvenience connected to the disease or to the research, by taking into account in particular the degree of maturity of minors and the capacity of understanding of adults unable to express an informed consent. All these conditions must be fulfilled in order to start a clinical trial.

A clinical trial (Article L.1121-3 PHC) may be undertaken under the following technical conditions: (a) under the direction and the supervision of a qualified physician and (b) under adapted material and technical conditions, compatible with the rigorous imperatives of science and the safety of the clinical trial subjects.

Two documents must be provided to clinical trial subjects before the conduct of the trial. First, the patient must receive a patient information sheet which must contain in particular a description of the objective, the methodology and the time period of the research, as well as a description of the alternative treatments, the number of subjects expected to take part in the study, the anticipated benefits, the constraints and the foreseeable risks resulting from the administration of the products that are the object of the clinical trials but also the favorable opinion of the Ethics Committee and the authorization of the ANSM, and information on processing of personal data. The information communicated must be summarized in a written document delivered to the patient prior to any administration of products by the investigator or a physician (Article L.1122-1 PHC).

Second, the patient must confirm his or her agreement to participate in the clinical study by signing an informed consent form (Article L.1122-1-1 PHC). For each study, patient information must include a right to refuse to participate and to withdraw consent at any time and by any means without further consequences or prejudice. A clinical trial on a minor may be undertaken only if, in particular, the informed consent of the parents or legal representative has been obtained. Furthermore, a clinical trial on adults under guardianship requires the informed consent of the adult's legal representative.

Responsibility of the sponsor and insurance obligation of the sponsor. The sponsor shall indemnify the subject of the trial in case of damage arising as a consequence of the research, unless he proves that the damage does not result from his fault or the fault of any other person intervening in the trial (Article L.1121-10 PHC). The sponsor must have an insurance covering its civil liability and the liability of any person intervening in the research,

for any damage arising from the trial for a minimum of 10 years as of the end of the trial (Article L.1121-10 PHC).

Market protection in the European Union

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a Marketing Authorization Application (MAA). The application format used to file the MAA, *i.e.* the Common Technical Document (CTD), is harmonized between Europe, USA and Japan, with the exception of, among other things, country-specific document requirements. The European Union also provides data protection. In the European Union, upon receiving marketing authorization (or MA), new chemical entities receive eight years of data exclusivity and an additional two years of market protection.

Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the 10 years. This market protection period may be extended by one year in case of new indication.

Orphan Medicinal Products

The European Union provides opportunities for market exclusivity. Pursuant to abovementioned Regulation (EC) No. 141/2000, products receiving orphan designation in the EU can receive ten years of market exclusivity following the marketing approval, during which time no similar medicinal product may be placed on the market for the same therapeutic indication. Under Article 37 of the Regulation (EC) No 1901/2006, an orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies (in this case for orphan drugs no extension to any supplementary protection certificate can be granted, see further detail below).

Under Article 3 of the Regulation (EC) No 141/2000, a medicinal product may be designated as orphan if: (1) (a) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or (b) it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment; and (2) that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, that the drug will be of significant benefit to those affected by that condition, as defined in Regulation (EC) 847/2000.

Pursuant to Regulation (EC) No. 847/2000 of April 27, 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts "similar medicinal product" and "clinical superiority," a sponsor applying for designation of a medicinal product as an orphan medicinal product shall apply for designation at any stage of the development of the medicinal product.

Where a marketing authorization in respect of an orphan medicinal product is granted pursuant to Regulation (EC) No. 726/2004 or where all the Member States have granted marketing authorizations for this product, in accordance with the procedures for mutual recognition, the Community and the Member States shall not, for a period of 10 years, accept another application for a marketing authorization, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product.

The 10-year market exclusivity may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the above-mentioned criteria no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity (Article 8).

Pursuant to Regulation No. 1901/2006 on medicinal products for pediatric use, for orphan medicinal products, instead of an extension of the supplementary protection certificate, the 10-year period of orphan market exclusivity should be extended to 12 years if the requirement for data on use in the pediatric population is fully met (*i.e.* when the request contains the results of all studies carried out under the approved Pediatric Investigation Plan ("PIP") and when the declaration attesting the conformity of the request to this PIP is included in the marketing authorization).

However, by way of derogation, a marketing authorization may be granted, for the same therapeutic indication, to a similar medicinal product if:

- the holder of the marketing authorization for the original orphan medicinal product has given his consent to the second applicant; or
- the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product; or
- the second applicant can establish in the application that the second medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior.

The abovementioned Regulation (EC) No. 141/2000 provides for other incentives regarding orphan medicinal products. Orphan

medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and scientific assistance for study proposals (Articles 6 and 9). The application for orphan drug designation must be submitted before the application for marketing authorization (Article 5). The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Regulation (EC) No. 141/2000 also provides that medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Community and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings provided for in framework programs for research and technological development.

Protection of Personal Data

The Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, as well as EU Member State 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.

Also, in certain countries, in particular France, the conduct of clinical trials is subject to compliance with specific provisions of the Act No.78-17 of January 6, 1978 on Information Technology, Data Files and Civil Liberties, as amended, and in particular Chapter IX relating to the processing of personal data in the health sector. These provisions require, among others, the filing of compliance undertakings with "standard methodologies" adopted by the French Data Protection Authority (the CNIL), or, if not complying, obtaining a specific authorization from the CNIL.

The most common standard methodologies are the following:

- Decision No. 20186-263 154 of July 21, May 3, 2018 concerning the approval of a standard methodology for processing personal data in the context of research in the field of health, which does not require the express consent of the person involved (methodology MR-003);
- Decision No. 20186-153262 of July 21, May 3, 2018 concerning the approval of a standard methodology for the processing of personal data carried out within the context of research in the field of health clinical trials, which requires the express consent of the person involved (standard methodology MR-001).

In certain specific cases, entities processing health personal data may have to comply with article L1111-8 of the French Public Health Code which imposes certain certifications for the hosting service providers.

Expedited Programs at the EMA Expedited Development and Review Programs

EMA is authorized to expedite the review of MAAs in several ways.

Accelerated assessment, which shortens the CHMP review timeline to 150 days. In order to qualify, the sponsor must justify in their application that the drug is "of major public health interest". Typically, this requires evidence that the drug in question addresses an unmet medical need "to a significant extent".

Conditional marketing authorization pathway, which allows the CHMP to grant a conditional, annually renewable approval for drugs that meet certain criteria. In order to qualify, a drug must be aimed at treating, preventing, or diagnosing a serious or life-threatening disease; intended for emergency use; or designated as an orphan drug. Additionally, the CHMP must determine that the drug meets four key criteria: 1) based on the existing evidence, the drug's benefits outweigh the risks, 2) the sponsor will be able to collect comprehensive post-market data, 3) the drug fulfills an unmet medical need, and 4) the benefits of its immediate availability outweigh the risks associated with approving it with more limited data. The sponsor must continue to collect post-market data on the drug to confirm its benefit. The authorization may be converted to a standard approval once sufficient data is available, or revoked if it is determined that the drug's benefits do not outweigh its risks. In certain exceptional circumstances, EMA may also grant conditional authorization for a therapy that does not have comprehensive data on safety and efficacy (referred to as "authorization under exceptional circumstances"). This may occur when the condition or disease to be treated is very rare, or collection of full information is either not possible or would be considered unethical

PRIME scheme fosters frequent and early interaction between sponsors and regulators, and is aimed at improving trial design and streamlining the development process. Sponsors whose product has been approved under the PRIME pathway benefit from a designated CHMP liaison, early feedback on development and regulatory strategy, and scientific advice when certain development milestones have been met. While large pharmaceutical companies are eligible for PRIME following proof-of-concept trials, smaller companies and academic groups – which would particularly benefit from earlier scientific consultation and

advice – can apply at an earlier stage, on the basis of compelling non-clinical and tolerability data from initial clinical trials.

European Union Marketing Authorizations

In the EEA, medicinal products can only be commercialized after obtaining a marketing authorization or MA, from the competent regulatory authorities.

There are different types of marketing authorizations including:

Centralized Procedure

Regulation (EC) No. 726/2004 of the European Parliament and of the Council of March 31, 2014 provides for the Centralized authorization procedure. It results in a single marketing authorization, or MA, granted by the European Commission that is valid across the European Economic Area, or the EEA (*i.e.*, the EU as well as Iceland, Liechtenstein and Norway).

Under the annex to this Regulation, the centralized procedure is compulsory for the following medicinal products: (1) medicinal products developed by means of one of the following biotechnological processes: recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells, hybridoma and monoclonal antibody methods; (2) advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007; (3) medicinal products containing a new active substance which, on the date of entry into force of this Regulation, was not authorized in the Community, for which the therapeutic indication is the treatment of any of the following diseases: HIV/AIDS, cancer, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions and viral diseases; and (4) medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

Under Article 3 of this Regulation, the Centralized procedure is optional for any medicinal product not appearing in the Annex if: (1) the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorized in the Community; or (2) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in accordance with this Regulation is in the interests of patients or animal health at Community level.

The European Medicines Agency, or EMA, shall ensure in the scope of the Centralized procedure that the opinion of the Committee for Medicinal Products for Human Use, or CHMP, is given within 210 days after receipt of a valid application (Article 6.3). This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP (Article 7). At the end of the review period, the CHMP provides an opinion to the European Commission. If this is opinion favorable, the Commission may then adopt a decision to grant a MA.

When an application is submitted for a MA in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated. If the CHMP accepts the request, the time-limit laid down in Article 6(3), first subparagraph, shall be reduced to 150 days (Article 14(9)).

National authorization procedure

National MAs issued by the competent authorities of the Member States of the EEA, through the Mutual Recognition Procedure or Decentralized Procedure, only cover their respective territory. These procedures are not applicable to gene therapy product as they are available only for products not falling within the mandatory scope of the centralized procedure.

Regulatory Approval of Medical Devices in the European Union

CE Marking Requirements

Manufacturers of medical devices, in the EU are required under the EU Medical Devices Directive (Council Directive 93/42/EEC, the "MDD") to affix a CE marking of conformity (a "CE mark") to their products in order to sell these products in Member States of the EU. The CE mark is a symbol that demonstrates conformity to certain essential principles of safety and performance mandated in the MDD, which are referred to as the "Essential Requirements".

Subject to national restrictions, CE marked products may be sold within the European Economic Area (the "EEA"), which is composed of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein, as well as in other countries that recognize the validity of the CE mark.

Devices in the EU are classified in four different classes (I, IIa, IIb and III) depending on a number of factors that are defined in the MDD. Typically, the highest class (Class III) regroups those devices that are deemed to present the highest risk and are therefore subject to more stringent requirements.

Conformity Assessment Procedures

Premarket approval of medical devices does not exist in the European Union; however, the European Union has adopted numerous directives and standards regulating, among other things, the design, manufacture, clinical trials, labeling, approval and adverse event reporting for medical devices.

The conformity assessment of medical devices with the essential requirements varies depending on the classification of the device and the directive that is applicable. The lowest-risk devices require only a self- declaration of conformity by the manufacturer.

Higher-risk devices require the involvement of third-party bodies called "notified bodies," which are certification organizations designated by the competent authorities of Member States to carry out the conformity assessment procedures described in the Medical Devices Directives. The notified body's tasks will vary depending on the classification of the products concerned and the conformity assessment route a manufacturer has chosen.

Under the conformity assessment procedure, Notified Body will audit and examine the technical file and the quality system applied to the manufacture, design and final inspection of the products. Following successful completion of the applicable procedure, the Notified Body will issue an EC Certificate of Conformity. This certificate entitles a manufacturer to affix the CE mark to its medical devices after having prepared and signed a "EC Declaration of Conformity" indicating that the product meets the Essential Requirements. Such certificate is valid for a maximum of five years, and may be extended on application for a further period of five years.

Medical devices which comply with the essential requirements of the Medical Devices Directives must bear the conformity CE-marking when marketed in EU Member States. The CE-marking has to be placed visibly and legibly on the product or, if not possible due to the nature of the product, be affixed to the packaging and the accompanying documentation. If a notified body has been involved in the conformity assessment procedure, its identification number must also be displayed.

Compliance with these requirements is a prerequisite to be able to affix the CE Mark of Conformity to medical devices, without which they cannot be marketed or sold in the EEA. Actual implementation of these directives, however, may vary on a country-by-country basis.

If the devices are substantively modified, one may need to broaden, or re-perform, the certification underlying the CE marking of the modified product. The CE marking can be suspended or withdrawn. The same may be true for any new products that we may develop in the future.

The Medical Devices Regulation

New rules have recently been adopted in the EU on medical devices which will have a direct impact on our business in the near future. Specifically, on May 25, 2017, the new Medical Devices Regulation (Regulation (EU) 2017/745, the "MDR") entered into force, with a three-year transition period. The MDR will progressively replace the MDD and introduce substantial changes to the current regulatory regime applicable to medical devices.

Under the transitional provisions of the MDR, until May 26, 2020, the certification procedures underlying the CE marking of medical devices can be carried out, at the manufacturer's choice, either in accordance with the MDR or in accordance with the MDD. Should a manufacturer elect to perform certification under the MDD, the related certificates will remain valid until the earlier of: a) the end of the period indicated on the certificate (typically five years, but it could be less); and b) May 27, 2024. The medical devices to which these certificates apply may only be sold in the EEA if they continue to comply with the MDD and provided that no significant changes are brought to these devices' design or intended purpose. Moreover, the manufacturers of those devices that are certified under the MDD will have to comply with a number of requirements of the MDR, *e.g.*, those relating to post-market surveillance and vigilance, and they will be able to sell such devices only up until May 27, 2025 at the latest. After that date, all devices sold in the EEA will have to be fully compliant with the MDR.

Under the MDR, all devices incorporating or consisting of nanomaterials will be classified as Class III if they present a high or medium potential for internal exposure. The MDR introduces higher clinical data requirements for such Class III devices. In particular, manufacturers will be required to conduct new clinical investigations in case they do not have "sufficient" clinical data to support the safety, performance and clinical benefit claims of their devices.

The MDR also introduces increased scrutiny of conformity assessments by Notified Bodies for implantable Class III devices. For such devices, the MDR requires that relevant European Commission expert panels scrutinize, as part of the conformity assessment procedure, the clinical assessment of the concerned Notified Body. Such devices will be further subject to a mechanism allowing competent authorities of the EEA and the European Commission Medical Device Coordination Group to scrutinize the documentation submitted by the manufacturer as well as the documentation produced by the Notified Body and the relevant expert panels, in the context of the applicable conformity assessment procedure.

In addition, under the MDR, manufacturers of Class III devices will be subject to a new annual safety reporting requirement called the Periodic Safety Update Report, aimed at capturing the analyses of the post-market surveillance data gathered, including data from their Post-Market Clinical Follow-Up.

The amount of guidance available on these new requirements is currently very limited and the European Commission is set to adopt a number of delegated and implementing acts to further specify applicable requirements and obligations under the MDR.

EU France: Coverage and Reimbursement

In certain countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. In some countries, pricing and reimbursement coverage also depend

on assessments performed by national Health Technology Assessment (HTA) bodies. These assessments may be completed before or after a product is available in the market and may affect the net price of an approved drug.

The European Union provides options for its Member States of the EEA 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. For example, in France, effective access to the market assumes that our future products will be supported by the hospital (through an agreement for local communities) or reimbursed by social security. The price of medications in France is negotiated with the Economic Committee for Health Products, or CEPS.

The EU has legislation that provides for some harmonization of access to drugs that treat rare diseases. For example, Cross Border Healthcare Directive requires Member States to reimburse, possibly with restrictions, a treatment approved in the EU but currently unavailable locally. But the pricing and market access is dynamic, as the EU is evaluating multiple initiatives to provide access to rare disease therapies, particularly regenerative treatments like gene therapy, and national bodies are assessing their reimbursement pathways and valuation methodologies in light of the curative promise from these therapies.

France: Post-marketing requirements

Any pharmaceutical product or medical device distributed in France will be subject to pervasive and continuing regulation by the ANSM, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing updated safety and efficacy information, distribution requirements, complying with promotion and advertising requirements.

France: Advertising

French law strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities.

Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

French Pharmaceutical Company Status

To commercialize a product in France, it is mandatory to have the pharmaceutical establishment license directly, either as distributor *"exploitant"* or as manufacturer. This license can be obtained after the submission of a request file specific to each of the two qualifications with the ANSM, and only granted after review and evaluation by the ANSM, usually after verification that the company has adequate premises, the necessary personnel and an adapted structure with satisfactory procedures for carrying out the proposed pharmaceutical activities, in particular pharmaceutical supply and pharmacovigilance.

France: Declarations of Financial Interests

"Transparency" or "French Sunshine Act"

The French Public Health Code (PHC) contains certain provisions regarding transparency of fees and rewards received by some healthcare professionals from industries, *i.e.* companies manufacturing or marketing health products, resulting from Act No. 2011-2012 of December 29, 2011 aiming at strengthening health safety of medicinal and health products, amended by an Act No. 2016-41 of January 26, 2016, and corresponding implementing decrees. It results from these provisions (Article L.1453-1 and D.1453-1 *et seq.* PHC) that companies manufacturing or marketing healthcare products (medicinal products, medical devices, etc.) in France shall publicly disclose (on a specific public website available at: https://www.entreprises-transparence.sante.gouv.fr) the advantages and fees paid to healthcare professionals amounting to 10 euros or above, as well as the agreements concluded with the latter, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional, etc.).

"Anti-gift"requirements

The French Public Health Code also contains "anti-gift" provisions, which, subject to limited exceptions, prohibit payments and rewards from industries, *i.e.* companies manufacturing or marketing health products, to healthcare professionals and strictly defines the conditions under which such payments or rewards are lawful. The provisions enacted under Act No. 2011-2012 were amended by Order No. 2017-49 of January 19, 2017, which notably extended their application to a broader range of legal and physical persons, specified the scope of the operations excluded from the prohibition and those authorized under some conditions, and provided for a new authorization process. The amendments to the "anti-gift" rules in Articles L.1453-3 to L.1453-12 PHC entered into force on July 1, 2018, without new implementing provisions. Since the former implementing provisions in Article R. 4113-104 and seq. PHC have not been abrogated, they remain applicable to the extent that they are accurate and do not contradict the newly enacted amendments.

Some of the new legal provisions may already be applied without awaiting the new implementing provisions.

Failure to comply with the above applicable regulatory requirements may result in reputational risk, public reprimands, restrictions on the marketing of a product or withdrawal of the product from the market as well as possible administrative or criminal sanctions or fines.

Regulatory Framework in the United States

In the United States, biological products, including gene therapy products and medical devices are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and other national statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, export and import, reporting, approval, advertising and other promotional practices involving biological and medical device products.

Food and Drug Administration (FDA) approval must be obtained before marketing of biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and national statutes and regulations require the expenditure of substantial time and financial resources, and regulatory approval is not guaranteed.

The FDA works closely with the National Institute of Health (NIH) and its Recombinant DNA Advisory Committee (RAC), which makes recommendations to the NIH on gene therapy issues and engages in a public discussion of scientific, safety, ethical and societal issues related to proposed and ongoing gene therapy protocols. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols.

U.S. Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of non-clinical laboratory tests and animal studies according to GLP, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an Investigational New Drug (IND), which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of non-clinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with Good Manufacturing Practice (GMP), to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices, or GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the non-clinical and clinical trial sites that generated the data in support of the Biological License Application (BLA); and
- FDA review and approval, or licensure, of the BLA.

Where a gene therapy study is conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND application to the FDA, a protocol and related documentation is submitted to and the study is registered with the NIH Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA; however, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Institutions that receive NIH funding also are potentially subject to review by the NIH Office of Biotechnology Activities' RAC; the RAC will only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks.

The clinical trial sponsor must submit the results of the preclinical tests, 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. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a 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 impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. 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, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an 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 study 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 form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Clinical trials also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after the product's approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post-approval to gain more information about the product. Post-approval clinical trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional information from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of study subjects.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the NIH and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend 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 at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Sponsors of clinical trials of investigational products are required to register on clinicaltrials.gov, a National Institute of Health website registry database, and disclose certain clinical trial information. 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. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System which includes information on gene transfer studies and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these studies.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents (unwanted viruses or bacteria), with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Biological Product Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological 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 FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee on prescription biologics. 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. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that 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. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategies (REMS) is necessary to assure the safe use of the biological product. If the FDA concludes REMS is needed, the sponsor of the BLA must submit proposed REMS; the FDA will not approve the BLA without REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. For a gene therapy product, the FDA also will not approve the product if the manufacturer is not in compliance with the Good Tissue Practices (GTPs). The GTPs are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases 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. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase IV clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 12 months of receipt and 90% of priority BLAs in eight months of receipt, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not shorten the duration of the regulatory review and approval process.If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for 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 our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

Expedited Development and Review Programs

The FDA is authorized to expedite the review of BLAs in several ways. For example, the Fast Track program 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 and products designated as RMAT (regenerative medicines advanced therapy) are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to 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 at any time during the clinical development of the product. 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 breakthrough therapy designation, priority review and accelerated approval.

Priority review. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. 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.

Accelerated approval. 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 endpoint that is reasonably likely to predict a clinical

benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity that is likely to reasonably predict a clinical benefit. 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. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.

Fast Track designation, breakthrough designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological 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 GMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of the U.S. patents that we in-license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as 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. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or in-licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

A biological product can obtain pediatric 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 study in accordance with an FDA-issued "Written Request" for such a study. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve a biosimilar application.

The Biologics Price Competition and Innovation Act, or BPCIA, created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological 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 product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger and often more complex structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

Review and Approval of Medical Devices in the United States

Medical devices in the United States are strictly regulated by the FDA. Under the FD&C Act, a medical device is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a

component part, or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended purpose of the product is achieved through chemical action or by being metabolized by the body, the product is regulated as a drug or biological product.

Unless an exemption applies, a new or modified medical device may not be marketed in the United States unless and until it has been cleared through filing of a 510(k) premarket notification, or 510(k), or approved by the FDA pursuant to a Premarket Approval, or PMA, application. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new or modified medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness.

Class I devices are low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA's general controls for medical devices, which include applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions and truthful and non-misleading labeling. Many Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are moderate risk devices and are subject to the FDA's general controls, and any other special controls, such as performance standards, post-market surveillance and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for Class II devices are accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies.

Class III devices are deemed by the FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. A PMA application must provide valid scientific evidence, typically extensive preclinical and clinical trial data and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than are 510(k) premarket notifications.

510(k) Premarket Notification

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a predicate device, which is a previously cleared 510(k) device or a pre-amendment device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of a PMA application. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is submitted and filed with the FDA, but it can take significantly longer and clearance is never assured. The FDA has issued guidance documents meant to expedite review of a 510(k) and facilitate interactions between applicants and the agency. To demonstrate substantial equivalence, a manufacturer must show that the device has the same intended use as a predicate device and the same technological characteristics, or the same intended use and different technological characteristics and is as safe and as effective as the predicate device and does not raise new questions of safety and effectiveness than the predicate device.

Most 510(k)s do not require clinical data for clearance, but the FDA may request such data. The FDA seeks to review and act on a 510(k) within 90 days of submission, but it may take longer if the agency finds that it requires more information to review the 510(k). If the FDA determines that the device is substantially equivalent to a predicate device, the subject device may be marketed. However, if the FDA concludes that a new or modified device is not substantially equivalent to a predicate device, the new or modified device will be classified in Class III and the manufacturer will be required to submit a PMA application to market the product. Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III by operation of the FD&C Act, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, the FD&C Act allows the FDA to classify a low- to moderate-risk device not previously classified into Class I or II, a process known as the *de novo* process. A company may apply directly to the FDA for classification of its device as *de novo* or may submit a *de novo* petition within 30 days of receiving a not substantially equivalent determination.

Modifications to a 510(k)-cleared device may require the submission of a traditional 510(k), but modifications meeting certain conditions may be candidates for FDA review under a

Special 510(k). A new 510(k) is required when the modification constitutes a major change in the device's intended use or would significantly affect the safety or effectiveness of the device. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When the modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary.

A modification to a 510(k)-cleared product that would constitute a major change in its intended use or any change that would significantly affect the safety or effectiveness of the device may, in some circumstances, even cause the product to be a new, Class III device. In that case, the significant changes would require the submission of a PMA application, if the change raises complex or novel scientific issues or the product has a new intended use. A manufacturer may be required to submit extensive preclinical and clinical data depending on the nature of the changes.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA disagrees with the manufacturer's determination and requires a new 510(k) clearance, or even PMA application approval, for modifications to previously cleared products for which the manufacturer concluded that new a clearance or approval is unnecessary, the manufacturer may be required to cease marketing or distribution of the products or to recall the modified product until it obtains clearance or approval, and the manufacturer may be subject to significant regulatory fines or penalties. In addition, the FDA may make substantial changes to industry requirements regarding the 510(k) process.

Premarket Approval Application

The PMA application process for approval to market a medical device is more complex, costly and time-consuming than the 510(k) clearance procedure. A PMA application must be supported by extensive data, including technical information regarding device design and development, preclinical studies, clinical trials, manufacturing and controls information and labeling information that demonstrate the safety and effectiveness of the device for its intended use. After a PMA application is submitted, the FDA has 45 days to determine whether it is sufficiently complete to permit a substantive review. If the PMA application is complete, the FDA will file the PMA application. If the FDA accepts the application for filing, the agency will begin an in-depth substantive review of the application. By statute, the FDA has 180 days to review the application although, generally, review of the application often takes between one to three years, and may take significantly longer. If the FDA has questions, it will likely issue a first major deficiency letter within 150 days of filing. It may also refer the PMA application to an FDA advisory panel for additional review, and will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Medical Device Quality System Regulation, or QSR, either of which could extend the 180-day response target. In addition, the FDA may request additional information or request the performance of additional clinical trials in which case the PMA application approval may be delayed while the trials are conducted and the data acquired are submitted in an amendment to the PMA. Even with additional trials, the FDA may not approve the PMA application.

If the FDA's evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, the FDA will deny approval of the PMA application or issue a not approvable letter. The PMA application process, including the gathering of clinical and non-clinical data and the submission to and review by the FDA, can take several years, and the process can be expensive and uncertain. Moreover, even if the FDA approves a PMA application, the FDA may approve the device with an indication that is narrower or more limited than originally sought. The FDA can impose post-approval conditions that it believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. After approval of a PMA application, a new PMA application or PMA application supplement may be required for a modification to the device, its labeling, or its manufacturing process. PMA application supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel. The time for review of a PMA application supplement may vary depending on the type of change, but it can be lengthy. In addition, in some cases the FDA might require additional clinical data.

Investigational Device Exemption

A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical trial in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study trial involving the device is subject to the FDA's IDE regulation. The IDE regulation distinguishes between significant and nonsignificant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a

clinical trial. Nonsignificant risk devices are devices that do not pose a significant risk to the human subjects. A nonsignificant risk device study requires IRB approval prior to initiation of a clinical trial, and FDA approval of the study is deemed to be in effect if certain conditions are met.

An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. An IDE application is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor prior to 30 calendar days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. IDE approval permits a specified number of subjects to be enrolled at specified study centers. The clinical trial must be conducted in accordance, and FDA approval of the study is deemed to be in effect if certain conditions are met, with applicable regulations, including, but not limited to, the FDA's IDE regulations and GCP. The investigators must obtain subject informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. A clinical trial may be suspended or terminated by the FDA, the IRB or the sponsor at any time for various reasons, including a determination that the risks to the study participants outweigh the benefits of participation in the trial. Approval of an IDE does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Post-Approval Regulation of Biological Products and Medical Devices in the United States

After a biological product or device is placed on the market, numerous regulatory requirements apply including, but not limited to:

- submitting and updating establishment registration and device listings with the FDA;
- compliance with the manufacturing regulations and standards, including cGMP, for biological products, and the QSR, which require device manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process;
- unannounced routine or for-cause inspections by the FDA, which may include suppliers' facilities;
- advertising and promotion regulations, which prohibit the promotion of products for uncleared or unapproved or "off-label" uses and impose other restrictions on advertising and labeling;
- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish continued safety data or tracking products through the chain of distribution to the patient level; and
- compliance with the regulations requiring the reporting of adverse events and certain device malfunctions to the FDA.

The failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA application approvals of new products;
- withdrawals of 510(k) clearance or PMA application approvals; or
- criminal prosecution.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different Centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug or device where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, *e.g.*, to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug or device packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FD&C Act, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a device-drug combination product is attributable to the drug product, the FDA Center responsible for premarket review of the drug product would have primary jurisdiction for the combination product, but the other relevant FDA Centers would consult on the review. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

Other Healthcare Laws and Regulations

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal civil False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, 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, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including, without limitations, the federal civil False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including federal health care programs, such as, the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on "covered entities," including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, imposed annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical

industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and the healthcare fraud statute. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we or our directors, officers, employees, principal investigators or consultant partners may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, as well as reputational harm, which could significantly harm our business. Defending against any such actions may be costly, time-consuming and may require significant financial and personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

Coverage and Reimbursement

Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for our product candidates will be available from government payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payors. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medical products they will pay for and establish reimbursement levels. A number of gene therapy products have been approved over the past year by the FDA. Although the Center for Medicare and Medicaid Services, or CMS, subsequently approved its first method of coverage and reimbursement for one such product, the methodology has been subject to challenge by members of Congress. CMS's decision as to coverage and reimbursement for one product does not mean that all similar products will be eligible for analogous coverage and reimbursement. As there is no uniform policy for coverage and reimbursement amongst third-party payors in the United States, even if CMS approves coverage and reimbursement for any of our product candidates, it is unclear what affect, if any, such a decision will have on our ability to obtain and maintain coverage and adequate reimbursement from other private payors.

In addition, third-party payors are increasingly requiring that manufacturers provide them with predetermined discounts from list prices and are challenging the prices charged for products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be adequate, which may adversely affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement may be difficult. Third-party payors are also increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement compared to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidates for which marketing approval is obtained.

Further, the United States government, state legislatures and other governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. There has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed

to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of products under Medicare, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further 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 products under Medicare Part B, to allow some states to negotiate product prices under Medicaid, and to eliminate cost sharing for generics for low-income patients. While any proposed measures will require authorization through additional legislation 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 pharmaceutical costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological 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. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Healthcare Reform

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, then-President President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

The ACA established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government's comparative effectiveness research. In addition, the ACA implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

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, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Congress could consider additional legislation to repeal or repeal and replace certain elements of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, then-President President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2%

per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislation, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, then-President President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, 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.

There are several proposals being tabled in Congress, with industry participants providing input, to allow the use of value-based contracts and other innovative payment models for regenerative therapies while remaining consistent with rebate and price reporting requirements such as Medicaid Best Price.

Additional new laws may result in additional reductions in funding to Medicare and other federal health care programs. Further, new laws may, among other things, increase drug rebates or discounts owed under federal health care programs, impose additional reporting or compliance obligations, and/or otherwise put additional downward pressure on drug prices or increase the burden of compliance on pharmaceutical manufacturers.

Government Regulation Outside of the European Union and the United States

In addition to regulations in the European Union and the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, commercial sales and distribution of our products, and pricing and reimbursement. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. If we fail to comply with applicable national regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

10 TREND INFORMATION

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TREND INFORMATION

10.1

MOST SIGNIFICANT RECENT TRENDS SINCE THE END OF THE LAST FINANCIAL YEAR

Please refer to Section 18.7, "Significant Change in Financial position" of the Document.

10.2

INFORMATION ON ANY KNOWN TRENDS, UNCERTAINTIES, DEMANDS, COMMITMENTS OR EVENTS THAT ARE REASONABLY LIKELY TO HAVE A MATERIAL EFFECT ON THE COMPANY'S PROSPECTS

None.

PROFIT FORECASTS OR ESTIMATES

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PROFIT FORECASTS OR ESTIMATES

We have elected not to include a profit forecast or a profit estimate in this Universal Registration Document.

ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND SENIOR MANAGEMENT

12.1 COMPOSITION OF MANAGEMENT AND SUPERVISORY BODIES

We are a French corporation with limited liability *(société anonyme)* with a Board of Directors. A description of the main provisions of our bylaws relating to the functioning and powers of the Board of Directors as well as a summary of the main provisions of the internal regulations of the Board of Directors and of the special Board Committees that we have implemented, are included in Section 14, "Board Practices" and in Section 19, "Additional Information" of this Universal Registration Document.

12.1.1 DIRECTORS AND OFFICERS

We currently have eight directors and three non-voting members. Since the listing of our shares on Euronext Paris, Mr. Florent Gros, Mr. Earl Collier, Mr. Genghis Loyd-Harris and Mr. Guido Magni have resigned from their director positions and Bpifrance Participations, represented by Mr. Laurent Higueret, Ms. Simone Seiter and Ms. Natalie Mount respectively, have been coopted by the Board as directors.

The table below gives the identity of our directors and officers as of the date of this Universal Registration Document and the main positions and offices held by them outside of the Company during the last five years. Unless otherwise stated, the business address for our directors and officers is c/o GENSIGHT BIOLOGICS S.A., 74, rue du Faubourg Saint-Antoine, 75012 Paris, France.

Name	Expiration date of term of office(*)	Main position within the Company(**)	Main positions and offices held outside the Company during the last 5 years
Bernard Gilly	2021	Chief Executive Officer Director Co-Founder	Position and offices held as of the date of this Universal Registration Document: • Chairman of the Boards of Directors of Pixium Vision S.A., BrainEver SAS, Prophesee S.A., Eye TechCare S.A., Chronolife SAS, IBionext SAS, Tilak Healthcare SAS and Brainiac SAS Position and offices held during the last 5 years that are no longer held: • Chairman of the Board of Directors of the Company • Chief Executive Officer at Pixium Vision S.A. • Chairman of the Board of Directors of Enterome S.A. • Member of the Board of Directors of Kala Pharmaceuticals Inc. • Chairman of the Board of Directors and Chief Executive Officer of Général Mnemosyme • Chairman of the Board of Directors of Gecko Biomedicals S.A.
Michael Wyzga	2021	Chairman of the Board of Directors Independent Director	Position and offices held as of the date of this Universal Registration Document: • President of MSW Consulting Inc., a strategic consulting group focused in the life science area • Member of the Board of Directors, audit and compensation committees of Exact Sciences Corporation • Member of the Board of Directors and chair of the audit committee of OncoMed Pharmaceuticals, Inc. • Member of the Board of Directors of Mereo Pharmaceuticals and LogicBio • Chairman of the Board of Directors of X4 Pharmaceuticals, Inc. Position and offices held during the last 5 years that are no longer held: • Member of the Board of Directors, member of the compensation committee and chair of the audit committee of Akebia Therapeutics, Inc. • Member of the Board of Directors of Altus Pharmaceuticals, Inc. • Member of the Board of Directors of Idenix Pharmaceuticals, Inc. • Served as a member of the supervisory board of Prosensa Holding B.V.

Name	Expiration date of term of office(*)	Main position within the Company(**)	Main positions and offices held outside the Company during the last 5 years
Thomas Gidoin	–	Chief Financial Officer	Position and offices held as of the date of this Universal Registration Document: • None Position and offices held during the last 5 years that are no longer held: • Vice President Finance at DBV Technologies S.A.
Magali Taïël	–	Chief Medical Officer	Position and offices held as of the date of this Universal Registration Document: • None Position and offices held during the last 5 years that are no longer held: • VP clinical Development at ProQR Therapeutics
Peter Goodfellow	2020	Independent Director	Position and offices held as of the date of this Universal Registration Document: • Science advisor and consultant for Abingworth LLP, or Abingworth, Sanofi and the Bill and Melinda Gates Foundation • Chairman of the Board of Directors of GammaDelta Therapeutics Ltd. Non-Executive Board Member of Virion Health Position and offices held during the last 5 years that are no longer held: • Director of the Muscular Dystrophy Group • Director Institute of Cancer Research • Non-Executive Board Member of Prosensa
Simone Seiter	2022	Independent Director	Position and offices held as of the date of this Universal Registration Document: • None Position and offices held during the last 5 years that are no longer held: • Vice President at IQVIA
Natalie Mount	2020	Independent Director	Position and offices held as of the date of this Universal Registration Document: • Serves as Chief Scientific Officer at GammaDelta Therapeutics Position and offices held during the last 5 years that are no longer held: • Chief Clinical Officer at the Cell and Gene Therapy Catapult • Board member of Cell and Gene Therapy Catapult, CTTCR and Chimeric Therapeutics
Maritza McIntyre	2022	Independent Director	Position and offices held as of the date of this Universal Registration Document: • President/Owner Advanced Therapies Partners LLC • Board of Directors, American Society of Gene and Cell Therapies Position and offices held during the last 5 years that are no longer held: • Board Member, Standards Coordinating Body • Executive Director, Gene Therapy Product Lead-Pfizer Inc. • Executive Vice President Regulatory Affairs and Product Development-Bamboo Therapeutics • Vice President Regulatory Affairs-NanoCor Therapeutics • Vice President Regulatory Affairs-REGENXBIO
Sofinnova Partners SAS (as represented by Cédric Moreau)	2022	Director	Position and offices held as of the date of this Universal Registration Document: • Partner at Sofinnova Partners Position and offices held during the last 5 years that are no longer held: • Managing Director – Corporate Finance- Head of Healthcare at ODDO-BHF • Director – Corporate Finance – Healthcare at Bryan Garnier & Co

Name	Expiration date of term of office(*)	Main position within the Company(**)	Main positions and offices held outside the Company during the last 5 years
Bpifrance Participations (as represented by Laurent Higueret)	2022	Director	Position and offices held as of the date of this Universal Registration Document: • Serves as a non-voting observer on the board of DNA Script • Serves as a non-voting observer on the board of Enyo Pharma (as the representant of Bpifrance Participations) • Serves as a non-voting observer on the board of Poxel (as the representant of Bpifrance Participations) • Serves as a board member on the board of Voluntis (as the representant of Bpifrance Participations) Position and offices held during the last 5 years that are no longer held: • Member of the Board of Directors of Biom'up • Member of the Board of Directors of Poxel • Non-voting observer on the Board of Directors of H4D • Non-voting observer on the Board of Directors of GenSight Biologics • Non-voting observer on the Board of Directors of Txcell

(*) According to our bylaws, the duration of the term of office of the members of our Board of Directors is 3 years. The Expiration date is only provided for directors' current terms. The term expires at the end of the ordinary general meeting convened to approve the accounts for the previous financial year during the year in which their term office expires.

(**) Please note that, except for the Chief Executive Officer, none of the officers is a representative *(dirigeant mandataire social)* of the Company.

Mr. Collier has resigned from the Board of Directors and has been replaced by Ms. Seiter on April 19, 2017.

Ms. Mount joined the Board of Directors on May 31, 2017.

Mr. Lloyd-Harris has resigned from the Board of Directors on March 16, 2018.

Mr. Magni has resigned from the Board of Directors on April 24, 2019.

In consideration for the subscription by Sofinnova Crossover I SLP for the capital increase of €8 million implemented in February 2019, Sonfinnova Partners and one independant member proposed by Sofinnova, Maritza McIntyre have been appointed as Directors by the shareholders' meeting held on June 11, 2019.

The table below gives the identity of our non-voting observers are also attending board meetings as of the date of this Universal Registration Document:

Name	Expiration date of term of office
José-Alain Sahel	2021
Thibaut Roulon	2021
Audrey Cacaly	2020

In relation to the Kreos transaction, Kreos will be granted an observer seat (censeur) at the Company's Board of Directors.

Separation of the Offices of Chairman of the Board and Chief Executive Officers

On March 2, 2016, our Board of Directors decided to separate the offices of the Chairman of the Board of Directors and of the Chief Executive Officer. As of the date of this Universal Registration Document, Bernard Gilly is Co-Founder, Director and Chief Executive Officer and Michael Wyzga is the Chairman of our Board of Directors.

Director Independence

We consider that, under the recommendations of the MiddleNext Code, five current directors are "independent directors".

The MiddleNext Code sets out the five following criteria justifying the independence of directors, characterized by the absence of any significant financial, contractual or family relationship likely to affect their independence of judgment:

- they must not be a salaried employee or corporate officer of us or our Group and must not have held such a position within the last five years;
- they must not be in a significant business relationship with us or our Group (*e.g.*, client, supplier, competitor, provider, creditor, banker, etc.) within the last two years;
- they must not be a reference shareholder or hold a significant number of voting rights;
- they must not have close relationships or family ties with any of our corporate officer or reference shareholder; and
- they must not have been our auditor within the last six years.

Based on these criteria, our Board of Directors determined that Mr. Wyzga, Dr. Seiter, Ms. Mount, Dr. Goodfellow and Dr. McIntyre are "independent directors" under the independence

criteria of the MiddleNext Code. In making such determination, the Board of Directors considered the relationships that each non-employee director has with us and all other facts and circumstances the Board of Directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities, if any.

12.1.2 BIOGRAPHICAL INFORMATION ABOUT THE MEMBERS OF THE BOARD OF DIRECTORS AND OFFICERS OF THE COMPANY

Officers

Bernard Gilly, Ph.D., one of our founders, has served as our Chief Executive Officer since our creation. From our creation through 2016, Dr. Gilly served as Chairman of our Board of Directors. From 2011 through 2014, Dr. Gilly served as Chief Executive Officer at Pixium Vision and from which date he has served as non-executive Chairman of the Board of Directors. Additionally, Mr. Gilly currently serves on the boards of Prophesee S.A. (formerly Chronocam) and Gecko Biomedical. From 2005 to 2009, he founded and was Chairman and Chief Executive Officer of Fovea Pharmaceuticals S.A., or Fovea, a privately funded biotech company, which was acquired by Sanofi S.A., or Sanofi. He then became Senior Vice-President of the Ophthalmology Division of Sanofi and served in that role until March 2012. Prior to Fovea, Dr. Gilly was a partner at Sofinnova Partners S.A.S. from December 2000 to November 2005. From January 1992 to October 2000, he was Chief Executive Officer of Transgene S.A., a company listed on the NASDAQ stock exchange and the *Nouveau Marché* of Euronext Paris, France. Dr. Gilly received an engineering degree from *École Nationale d'Agronomie* and a Ph.D. from *Université de Rennes*.

Thomas Gidoin has been our Chief Financial Officer since June 2015. From 2012 to mid-2015, Mr. Gidoin was Vice President Finance at DBV Technologies S.A., where he led the Corporate Finance team and participated in public offerings and private placements, including the dual listing of DBV Technologies S.A. on the NASDAQ Global Select Market in 2014. From 2008 to 2011, Mr. Gidoin served in various positions at Ipsen S.A., including UK Operations Controller in London and Senior Financial Analyst in the Global Operations division in Paris. He started his career in audit at Ernst & Young. Mr. Gidoin received a Master's degree in International Finance from ESGF Paris and a Master's degree in International Management from Neoma Business School in France.

Magali Taiël, M.D. completed her doctorate in Medicine with a specialization in Ophthalmology from the University of Paris in 1993, and her Associate Professor Degree in 1998. Dr. Magali Taiël was an Associate Professor of Ophthalmology, standing in for the Ophthalmology Department Head for 3 years at Academic Hospital, France. After 13 years of ophthalmology public and private practice, she moved to the Pharma Industry: firstly worked as a R&D International Project Manager in Servier Company (2 years), then as Medical Advisor in Ophthalmology area (Glaucoma and AMD) in Pfizer (3 years), and then held international and management positions in various therapeutic areas, including both technical and supervision duties, at Eli Lilly Company (13 years). Since 2016, as VP Clinical Development, she leads Clinical Development and Operations, to develop drugs and gene therapy in Inherited Retinal and Neuro-Ophthalmology diseases, at ProQR Therapeutics and now at GenSight Biologics. She made several critical contributions to the clinical development plan and launch of products, and authored numerous protocols and publications.

Directors

Michael Wyzga has served as a director since October 2013 and as our Chairman since March 2016. Mr. Wyzga is currently the President of MSW Consulting Inc., a strategic consulting group focused in the lifesciences area. From December 2011 until November 2013, Mr. Wyzga served as President and Chief Executive Officer and a member of the Board of Directors of Radius Health, Inc., a publicly traded biopharmaceutical company. Prior to that, Mr. Wyzga served in various senior management positions at Genzyme Corporation, a publicly traded global biotechnology company. Mr. Wyzga joined Genzyme in February 1998 and most recently served as Executive Vice President, Finance from May 2003 until November 2011 and as chief financial officer from July 1999 until November 2011. From February 2014 to December 2018, Mr. Wyzga served as a member of the Board of Directors of Akebia Therapeutics, Inc., a publicly traded biopharmaceutical company, where he was also a member of the compensation committee and chair of the audit committee. Since February 2015, Mr. Wyzga has also served as a member of the Board of Directors of Exact Sciences Corporation, a publicly traded medical technology company, where he is also a member of the audit and compensation committees. Since October 2013, Mr. Wyzga has also served as a member of the Board of Directors of Oncomed Pharmaceuticals, Inc., where he is also a member of the audit committee. Since July 2018, Mr. Wyzga has also served as Chairman of the Board of Directors of X4 Pharmaceuticals. Mr. Wyzga also previously served as a member of the Board of Directors of Idenix Pharmaceuticals, Inc., a publicly traded biotechnology company that was acquired by Merck in August 2014, where he also served as the chair of the audit committee and a member of the compensation committee, and as a member of the Supervisory Board of Prosensa Holding B.V., a publicly traded biopharmaceutical company, from June 2014 until the Prosensa acquisition by BioMarin Falcon B.V. in December 2014. He received an MBA from Providence College and a B.S. from Suffolk University.

Peter Goodfellow, Ph.D. has served as a director since June 2014. Dr. Goodfellow is a scientific consultant for Abingworth, Sanofi and the Bill and Melinda Gates Foundation. Dr. Goodfellow was previously the Balfour Professor of Genetics at Cambridge University before working for SmithKline Beecham (later GlaxoSmithKline) as head of research. He has founded several biotechnology companies and has sat on the boards of Prosensa deCode and several medical charities. Dr. Goodfellow currently serves as the chairman of the Board of Directors of GammaDelta Therapeutics, a biotech developing novel immunotherapies for cancer and other diseases. Dr. Goodfellow holds doctorates from Oxford and Bristol Universities.

Simone Seiter, M.D., Ph.D. has served as a director since April 2017. Dr. Seiter has worked as a Vice President with IQVIA (formerly QuintilesIMS) based in Frankfurt, Germany from 2006 to 2019. Prior to joining IQVIA she worked at Capgemini as a consultant for six years and served as a postdoctoral Fellow at the National Institutes of Health (United States) for two years. Previously, Dr. Seiter worked at the Universities of Heidelberg and Homburg, Germany as board certified dermatologist. Dr. Seiter holds an M.D. Ph.D. degree from the University of Heidelberg and an MBA from the University of Applied Sciences in Neu-Ulm, Germany.

Natalie Mount, Ph.D. has served as a director since May 2017. Dr. Mount is currently Chief Scientific Officer, leading Research and Development activities at GammaDelta Therapeutics. Previously, she was Chief Clinical Officer at the Cell and Gene Therapy Catapult where she was responsible for the translational, regulatory and clinical development activities for a wide range of cell and gene therapies. Prior to that, Natalie spent 16 years at Pfizer leading development activities across various therapeutic areas, including cell based therapies in the Regenerative Medicine Unit. Dr. Mount has also sat on the boards of directors of the Cell and Gene Therapy Catapult, CTTCR and Chimeric Therapeutics. Dr. Mount has a first class degree in Natural Sciences from the University of Cambridge and a Ph.D. from University College, London.

Maritza C. McIntyre, Ph.D. is the President of Advanced Therapies Partners, LLC.

Dr. McIntyre has 20 years of experience in the development, evaluation and regulation of biological and small molecule products within startup biotech firms, the Food and Drug Administration (FDA), and as a consultant. Dr. McIntyre was a product reviewer and ultimately Branch Chief in the Division of Cellular and Gene Therapies at FDA/CBER, where she was actively involved policy development and liaison activities to stakeholder groups. She has since worked in regulatory affairs and product development at Bavarian Nordic, REGENXBIO, Inc. and NanoCor Therapeutics. She served as Executive Vice President of Regulatory Affairs and Product Development at Bamboo Therapeutics where, as part of the senior management team, she participated in portfolio selection, product development and fundraising that resulted in an initial $50 million finance round and ultimate the sale of the company to Pfizer.

As president of Advanced Therapies Partners LLC, Dr. McIntyre provides strategic regulatory and product development advice to biotech companies, academics, and venture capital firms. She has proven success in defining development strategies for products with complex regulatory challenges including special designations (orphan, RMAT, pediatric orphan drug designation), endpoint selection, accelerated approval, complete response letters and dispute resolution. She has also been involved in the preparation of some of the first BLA and MAA submissions for gene therapy products to FDA and EMA. She has multidisciplinary experience, including chemistry manufacturing and control (CMC), preclinical, and clinical with a wide range of product types, including novel gene and cell therapy products, vaccines, biological products and small molecules at varied stages of product development.

Through her participation in industry associations, including ASGCT and the Standards Coordinating Body she has continued to contribute to gene therapy regulatory policy development.

Dr. McIntyre received a Ph.D. in virology from the University of Chicago and graduated *magna cum laude* with an Honors B.S. in biology from Wayne State University.

Cédric Moreau has served as the representative of Sofinnova Partners since June 2019. Cédric joined Sofinnova Partners in June 2018 and brought 18 years of experience in life sciences investment banking. He brings to the Sofinnova Crossover team his transactional expertise in the biopharma industry, with an extensive network of Key Opinion Leaders (KOLs), bankers and lawyers.

Cedric joined from Oddo BHF where he was Managing Director and Head of Healthcare at the Corporate Finance department. In 2017, Oddo BHF was top ranked in the European biotech equity capital market deals league tables. Prior to this, he was Director at Bryan Garnier & Co where he completed several sizeable cross border transactions. In total, he has managed transactions (IPO/ FOn/ PIPEs) in European healthcare companies totaling around €2bn in value. He is well known to the Sofinnova team having executed several mandates for portfolio companies. Before his corporate finance career, he spent 10 years as a Healthcare Equity Analyst and was several times EXTEL top ranked (awarded for both individual and team performances) at Natixis and Fortis. He was in charge of both listed biotech and pharma companies coverage. He brings to the Crossover team his transactional expertise in the biopharma industry, with an extensive network of Key Opinion Leaders (KOLs), bankers and lawyers.

Cedric holds a Master's in Economics and post-graduate diploma in Finance and Taxation (Sorbonne) and Diploma from the *Société Française des Analystes Financiers* (SFAF).

Laurent Higueret has served as the representative of Bpifrance Participations since June 2019. Laurent is an investment director in the Large Venture Fund at Bpifrance, the VC arm of the Public Investment Bank of France, in charge of healthcare and life sciences investments. He currently serves as a board director at GenSight Biologics (gene therapy) and Voluntis (digital therapeutics). He is also a board observer at DNA Script (synthetic DNA), Enyo Pharma (NASH, HBV) and Poxel (T2D, NASH). Laurent also follows Bpifrance Participations' investments in DBV Technologies (food allergies) and MedDay Pharmaceuticals (progressive MS).

Before joining Bpifrance in 2014, he spent six years as an investment banker with BNP Paribas' Healthcare M&A Group.

Laurent qualified as a Doctor of Pharmacy at the University of Bordeaux and holds a Master Degree in Financial Engineering from the EM Lyon Business School.

12.1.3 BALANCE IN THE COMPOSITION OF THE BOARD OF DIRECTORS

Further to the nomination by the shareholders' meeting held on May 31, 2017 of Simone Seiter and Natalie Mount as members of the Board of Directors, the Board of Directors held on May 31, 2017 stated that since this date the Company complies with the balanced representation of men and women required by article L 225-18-1 of the French Commercial Code, which provides that the proportion of directors of each gender shall be no less than 40% or no more than a difference of two. To date, our Board of Directors is composed of 3 women and 5 men.

Therefore, the Board of Directors held on May 31, 2017 has decided to release the payment of attendance fees, which was suspended insofar as such requirement was not met on January 1, 2017, including any arrears.

12.1.4 LIMITATION OF AUTHORITY OF THE CHIEF EXECUTIVE OFFICER

Limitation of authority of the Chief Executive Officer

The rules of procedure of the Board of Directors provide that decisions deemed "important" as mentioned below are subject to prior approval of the Board ruling by simple majority:

"Any decision to make a transfer of any substantial asset or any substantial intellectual/industrial property belonging to the Company;

Any decision to make an acquisition of strategic assets, in particular an industrial property element for the benefit of the Company;

Any investment or divestment decision of any kind (whether in the form of CAPEX or OPEX), commitments or decommitments, acquisition or disposal of assets not provided for in the annual budget and for a unit amount in excess of €500,000 or a cumulative amount in excess of €1,000,000;

Any acquisition or sale, taking or disposal of stakes in other entities or joint ventures, exchanges concerning property, shares or securities within the scope of acquisition or sale transactions, for a unit amount in excess of €1,000,000 or a cumulative amount in excess of €2,000,000;

Any entry into financing (including credit facilities and leasing arrangements) not provided for in the annual budget, for a unit amount in excess of €1,000,000 or a cumulative amount in excess of €2,000,000;

Any decision to set up a structure outside French territory, in particular through offices, branches or establishments, including with regard to R&D activities, or withdrawal from any such structures, it being specified that the transfer of the Company's registered office or its management team outside France will require the express prior authorization of the director appointed upon the proposal of Bpifrance Participations, which may not be refused without reasonable cause duly substantiated to the Board;

Any decision to proceed with the creation of a subsidiary or any trading in the securities of any subsidiary of the Company;

Any significant transaction that could affect the Company's strategy or change its financial structure or its scope of business.

Furthermore, the Chief Executive Officer shall submit for the Board's approval the Company's annual budget and any revision of such budget and shall act within the limits set by the budget approved by the Board.

The Board carries out the controls and verifications it deems appropriate and may ask for the documents that it considers useful for the accomplishment of its tasks to be provided to it."

12.1.5 STATEMENT REGARDING THE MEMBERS OF THE ADMINISTRATIVE MANAGEMENT OR SUPERVISORY BODIES

As of the date of this Universal Registration Document, to our knowledge, there are no family relationships among any of our executive officers or directors.

To our knowledge, over the course of the past five years: (i) none of the above persons has been subject of any conviction in relation to fraudulent offences ; (ii) none of the above persons has been associated with any bankruptcy, receivership, liquidation or companies put into administration ; (iii) no official public incrimination and/or sanctions involving any of the above persons have been brought by statutory or regulatory authorities (including designated professional bodies); and (iv) none of the above persons has been disqualified by a court from acting as a member of the administrative, management or supervisory body of any company, or from acting in the management or conduct of the affairs of any issuer.

12.1.6 SUMMARY STATEMENT REGARDING TRANSACTIONS BY EXECUTIVE OFFICERS AND DIRECTORS INVOLVING SHARES OF THE COMPANY DURING THE FISCAL YEAR ENDED DECEMBER 31, 2019

During the fiscal year ended December 31, 2018, no transactions were carried out by the executive officers and directors on the Company's shares.

12.2 CONFLICTS OF INTEREST

To our knowledge, and subject to the relationships described in Section 17, "Related Party Transactions" and Section 3.4, "Risk Related to Our Business Operations," as of the date of this Universal Registration Document there are no potential conflicts of interest between the duties of the members of the administrative, management or supervisory bodies and their private interests (including Bernard Gilly's interests as non-executive Chairman of the Board of Directors of Pixium Vision, given the difference of technologies developed by Pixium Vision and the Company).

To our knowledge, as of the date of this Universal Registration Document, there are no conflicts of interest between Bernard Gilly's position in the Company and his positions as Chairman of the Boards of Directors of Brain Ever SAS, Pixium Vision S.A., Gecko Biomedical S.A., Prophesee S.A., Eye TechCare S.A., Chronolife SAS, IBionext SAS, Tilak Healthcare SAS and Brainiac SAS.

In addition, following his resignation as President of *Passage de l'Innovation*, Bernard Gilly retained approximately 27 per cent of the shares of this company.

To our knowledge, as of the date of this Universal Registration Document, there are no arrangement or undertakings of any kind with shareholders, customers, suppliers or others pursuant to which any member of our administrative, management or supervisory bodies was selected to such position.

As of the date of this Universal Registration Document, the members of the administrative, management or supervisory bodies have not agreed to any restriction on the disposal within a certain period of time of their holdings in the issuer's securities, with the exception of rules relating to the prevention of insider trading and the recommendations of the MiddleNext Code, as amended in September 2016, with respect to obligation to retain shares.

As of the filing date of this Universal Registration Document and subject to certain customary lockup agreements entered into with the underwriters in connection with our capital increase on June 27, 2017 (a description of which has to be included in the prospectus for that transaction), the members of our Board of Directors and officers have not agreed to any restrictions relating to the sale of their holdings in our share capital except for the rules relating to the prevention of insider trading.

Management of conflicts of interest within the Board of Directors

Concerning the prevention and management of conflicts of interest, the Board's rules of procedure provide:

"2.5 Conflict of interest – non-competition obligation – obligation of loyalty

Each director has the duty and obligation to inform the Board spontaneously of any conflict of interest situation, even a potential or future conflict, with the Company, or one of its subsidiaries, in which he/she is to be found or may find him/herself. He/she must refrain from participating in the discussions and the voting on the corresponding deliberation(s), and furthermore undertakes, in such event, to exit the Board meeting during the discussions and voting on such deliberation(s).

Any agreement of which the signature is planned, to be entered into between a director and the Company, directly or indirectly or via an intermediary, or between the Company and a company or an undertaking of which he/she is the owner, partner with unlimited liability, managing director, director, member of the Supervisory Board or, in general, a senior manager, except, in accordance with the provisions of Article L.225-39 of the French Commercial Code, (i) those concerning day-to-day transactions and entered into under arm's length conditions, and (ii) those entered into between two companies, one of which holds, directly or indirectly, the entire share capital of the other (where applicable, after deduction of the minimum number of shares required to satisfy the requirements of Article 1832 of the French Civil Code or Articles L.225-1 and L.226-1 of the French Commercial Code), must be communicated by the interested director to the Chairman of the Board. At the time of the Board's deliberation having the effect of authorizing the signature of that agreement, the director will refrain from taking part in the voting.

In general, the Board of Directors takes preventive action with regard to conflicts of interest by raising the awareness of directors and asking them to update their declarations regularly.

Finally, the Board of Directors reviews known conflicts of interest at least once a year.

For regulated related-party agreements, the Board may have an independent expert appraisal carried out when it considers this relevant.

A director or the permanent representative if the director is a legal entity cannot engage, on a personal basis, in companies or businesses that compete with the Company, without having previously informed the Board and without having received its authorization. The director is bound by a duty of loyalty.

A director who no longer believes he/she is in a position to fulfill his/her duties on the Board or the Committees of which he/she is a member, must resign."

COMPENSATION AND BENEFITS

13.1 COMPENSATION AND BENEFITS OF SENIOR EXECUTIVES

13.1.1 COMPENSATION POLICY

This part constitutes the report of the Board of Directors drawn up by application of articles L.225-37-2 and R.225-29-1 of the Commercial Code, that shall be submitted to the vote of the shareholders at the Annual Combined Shareholders' Meeting to be held on April 29, 2020 in its 7th, 8th and 9th resolutions.

On the recommendation of the Remuneration Committee and taking into account the recommendations of the Middlenext Code, the Board of Directors has established a remuneration policy for each of the corporate officers of the company in compliance to its social interest, contributing to its sustainability and forming part of its commercial strategy as described in Chapter 5 of the Universal Registration Document. To do this, the Board set the remuneration policy for the Chief Executive Officer, Chairman of the Board and the members of the Board of Directors in connection with these elements, in particular by setting criteria for our Chief Executive Officer variable remuneration and the allocation of free shares linked to the implementation of this commercial strategy while respecting the social interest.

No other remuneration, of any kind whatsoever, may be determined, awarded or paid by the company, nor any commitment made by the company if it does not comply with the approved remuneration policy or, in its absence , to the remuneration or practices existing within the Company. However, in exceptional circumstances, the board of Directors may derogate from the application of the remuneration policy if this derogation is temporary, in accordance with social interest and necessary to guarantee sustainability or viability of the society.

In the event of changes in governance, the remuneration policy will be applied to the new corporate officers of the company, if necessary with the necessary modifications.

General principles regarding the compensation of executive corporate officers

Within the context of the determination of the global remuneration of the directors who are Company representatives, the Board of Directors, at the proposal of the Remuneration Committee, has taken into consideration the following principles, pursuant to the recommendations of R13 of the Middlenext corporate governance code of September 2016:

- Exhaustiveness: the determination of the remuneration of directors who are Company representatives shall be exhaustive: fixed part, variable part (bonus), stock options, bonus shares, attendance fees, retirement conditions and specific benefits shall be considered in the global assessment of remuneration.
- Equilibrium between the elements of the remuneration: each element of the remuneration shall be grounded and shall correspond to the general interest of the Company.
- Benchmark: this remuneration shall be assessed, as far as possible, in the context of a business and of the reference market and proportional to the situation of the Company, while paying attention to its inflationary effect.
- Consistency: the remuneration of the director who is a Company representative shall be determined in accordance with that of the other directors and of the Company's employees.
- Comprehensibility of the rules: the rules shall be simple and transparent; the performance criteria used to establish the variable part of the remuneration or, as appropriate, for the attribution of options or bonus shares, shall be linked to the performance of the Company, correspond to its objectives, be demanding, explainable and, as far as possible, sustainable. These shall be detailed, albeit without calling into question the confidentiality which may be justified for certain elements.
- Measurement: the determination of the remuneration and attributions of options or of bonus shares must strike a fair balance and take account of the general interest of the Company, of market practices and of the performances of the directors.
- Transparency: the annual information annual of "shareholders" on all of the remuneration and benefits received by the directors shall be carried out pursuant to the applicable regulations.

Long term compensation policy

We believe that our ability to grant incentive awards is a valuable and necessary compensation tool that allows us to attract and retain the best available personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, historically, we have granted several different equity incentive instruments to our directors, executive officers, employees and other service providers. These are:

- share warrants for founders, otherwise known as bons de souscription de parts de créateurs d'entreprise, or BCE, granted to our officers and employees;
- share warrants, otherwise known as bons de souscription d'actions, or BSA, typically granted only to non-employee directors not eligible for share warrants for founders;
- stock options, otherwise known as options de souscription ou d'achat d'actions, or SO, granted to our officers and employees; and
- free shares, otherwise known as attributions gratuites d'actions, or AGA, granted to our officers and employees.

The Board of Directors' authority to grant these equity incentive instruments and the aggregate amount authorized to be granted must be approved by a two-thirds majority of the votes held by

our shareholders present, represented or voting by authorized means at the relevant extraordinary shareholders' meeting. Once approved by the shareholders, the Board of Directors can continue to grant equity awards for 18 months for share warrants for founders and share warrants and for 38 months for stock options and free shares authorized by the shareholders. As a result, we typically request that our shareholders authorize new pools of equity incentive instruments at every annual general shareholders' meeting.

In general, share warrants for founders and share warrants no longer continue to vest following termination of the employment, office or service of the holder and all vested shares must be exercised within post-termination exercise periods set forth in the grant documents. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the numbers of shares issuable and/or the exercise price of the outstanding warrants or share options.

13.1.1.1 Compensation policy of the Chairman of the Board of Directors

This compensation policy set by the Board, at the recommendation of the Remuneration Committee, is as follows:

Fixed remuneration

The Chairman of the Board of Directors shall receive fixed remuneration, payable in 12 monthly instalments. This amount shall be revised each year on the basis of market practices observed in comparable companies, through recommendations of the specialist external consulting firm.

It is determined upon the following criteria:

- responsibilities and assignments attached to this mandate, aiming in particular to ensure a proper governance and the correct functioning of the Company's corporate bodies (Board of Directors and its committees, General Meeting of shareholders);
- skills, experience, expertise and background required for assuming this function;
- market analyzes and studies on the remuneration of similar positions in comparable companies.

Since 2016, Our Chairman's fixed compensation was set at €145,154. It has been revised downwards since January 1, 2020 and set at €120,000.

Other Compensation

The Chairman of the Board of Directors does not benefit from any other compensation (including attendance fees) linked to his participation in meetings of the Board of Directors or specialized committees, nor from severance pay in the event of termination of his duty.

13.1.1.2 Compensation policy of the Chief Executive Officer

This compensation policy, set by the Board, at the recommendation of the Compensation Committee, is as follows:

Fixed remuneration

The Chief Executive Officer shall receive fixed remuneration, payable in 12 monthly instalments. This amount shall be revised each year on.

The fixed compensation is determined upon the following criteria:

- level and complexity of the missions and responsibilities attached to this function, the Chief Executive Officer having the broadest powers to act in all circumstances on behalf of the Company and to represent it in its dealings with third parties;
- skills, experience, expertise and background;
- market analyzes and studies on the remuneration of similar positions in comparable companies.

The fixed remuneration of our Chief Executive Officer has not changed since 2017 and is set at €365,000.

Annual variable remuneration

The annual variable remuneration is capped at a maximum of 50% of the fixed annual remuneration.

In view of the profile of the Company, the criteria for determining the annual variable remuneration are for all or for some qualitative. The qualitative criteria have been pre-established by the Board of Directors, at the proposal of the Remuneration Committee, but are not made public on grounds of confidentiality. They principally represent operational milestones linked to the development of research and development projects, funding options to ensure the viability of the Company and the conduct of operations and the development of the Company in general.

In respect of the 2019 Financial year, for the purpose of the determination of the annual variable remuneration, the performance criteria and respective weigh were the following:

20%	Corporate and Financial Objective
30%	Clinical Strategy Objective
20%	Manufacturing strategy Objective
30%	Regulatory Strategy Objective

Based on the work and review performed by the compensation committee, the Board of Directors met on December 17, 2019 and reviewed the level of achievement of the objectives. It was decided, upon recommendation of the compensation committee

and subject to the favorable vote of the General Meeting, that the achievement of the performance criteria would be set at 60%.

It was therefore decided that our Chief Executive Officer would receive, during the financial year 2020, for the financial year 2019, 60% of its annual variable portion, the latter thus amounting to €109,500 gross, or 30% of his annual fixed compensation.

In respect of the 2020 Financial year, for the purpose of the determination of the annual variable remuneration, the performance criteria and respective weigh were the following:

20%	Manufacturing stragtegy Objective
30%	Regulatory Strategy Ojective
30%	Corporate and Financial Objective
20%	Marketing Strategy Objective

Attribution of Free Shares (AGA)

The Board of Directors considers that the grant of performance shares, which also benefits to other key corporate functions, is particularly suited to the role of Chief Executive Officer given the expected level of its direct contribution to the long-term performance of the company. This mechanism, which is based on performance criteria in line with the objectives communicated to the market, as well as on the development of the value of the Company, strengthens the motivation and loyalty of the Chief Executive Officer while facilitating the alignment of his interests with those of the shareholders as well as with the social interest of the Company.

The amount of attributions of free shares is set on the basis of market practices observed in comparable companies, through recommendations of the specialist external consulting firm.

Performance conditions

The shares are subject to an acquisition period of one year, and achievement of performance criteria. The acquisition of shares varies according to the achievement of internal performance conditions, the measurement of which will be carried out over two years and the level of achievement of which will be communicated by criteria once the performance assessment has been established by board of directors.

The criteria used are intended to measure overall performance and are directly linked to the Company's main strategical development objectives.

For more details regarding the performance criteria attached to the free shares, see Section 19.1.4 of this Universal Registration Document.

Condition of presence

The acquisition of performance shares by the Chief Executive Officer is also subject to his presence in the Group on the date of acquisition of the shares.

Mandatory holding period

The Chief Executive Officer must respect a mandatory holding period of one year.

Benefits in kind

The Chief Executive Officer shall benefit from a Company flat.

Exceptional remuneration

The Board of Directors may decide, at the proposal of the Remuneration Committee, to grant exceptional remuneration to the Chief Executive Officer in view of very special circumstances. The payment of this type of remuneration must be justifiable by an event, such as the execution of a major transaction for the Company, or an operational outperformance measure.

The payment of the elements of variable remuneration and, as appropriate, exceptional remuneration attributed for a financial year, is conditional on approval by the Ordinary General Meeting of the elements of remuneration of the Chief Executive Officer, paid or attributed by way of the said financial year *(ex post vote)*.

In case the Board of Directors decides to combine the functions of Chairman and Chief Executive Officer, the compensation policy applicable to the Chief Executive Officer would be applicable to the Chairman and Chief Executive Officer, if necessary, with the necessary modifications (he could in particular collect attendance fees).

In case the Board of Directors decides the appointment of one or more Deputy Chief Executive Officers, the compensation policy applicable to the Chief Executive Officer would be applicable to the Deputy Chief Executive Officers, if necessary, with the necessary modifications.

13.1.1.3 Commitments with regard to the Chief Executive Officer

Departure indemnities

The amount of the sudden termination indemnity shall be equal to twelve (12) months' remuneration calculated on the basis of the last annual remuneration (fixed and variable) in the event of cessation by Mr. Bernard Gilly of his duties as Chief Executive Officer (or of Chairman and Chief Executive Officer, in the event that the Board of Directors subsequently decides to combine the functions of Chairman of the Board of Directors and those of Chief Executive Officer) for whatever reason.

As an exception to the above, this Termination Indemnity shall not be due:

(i) in the event of dismissal of Mr. Bernard Gilly from his duties as Chief Executive Officer (or of Chairman and Chief Executive Officer, in the event that the Board of Directors subsequently decides to combine the functions of Chairman of the Board of Directors and those of Chief Executive Officer) for serious misconduct or gross negligence, as these notions are defined by the case law applicable to Labour law; or

(ii) in the event of resignation by Mr. Bernard Gilly from his mandate as Chief Executive Officer (or of Chairman Chief Executive Officer, in the event that the Board of Directors subsequently decides to combine the functions of Chairman of the Board of Directors and those of Chief Executive Officer), unless this resignation is due to illness or for family reasons, it being specified that in these latter two cases, the Termination Indemnity shall then be due to Mr. Bernard Gilly.

The Termination Indemnity shall not be due if Mr. Bernard Gilly changes position within the Group or leaves the Company at his own initiative in order to take up new positions.

The payment of the Termination Indemnity shall be contingent on meeting the following conditions: Achievement of at least 50% of the annual objectives for the past year. These objectives both of quantitative and qualitative nature, are established annually by the Board of Directors, at the proposal of the Remuneration Committee, but are not made public for reasons of confidentiality. They principally represent operational milestones linked to the development of research and development projects, funding options to ensure the viability of the Company, the conduct of operations and the development of the Company in general.

The reference annual compensation will be his last annual gross compensation, including his last gross variable compensation paid to him for the last financial year.

The termination indemnity will not be definitively acquired until verification by the Board of Directors that the above criteria are met.

Non-competition commitment

The monthly non-competition commitment to the benefit of Mr. Bernard Gilly, Chief Executive Officer, authorized by the Board Meeting of March 9, 2017 for a period of one (1) year starting from his departure from the Company, equal to 40% of his last net monthly remuneration, excluding any bonus (after deduction of any other amount received in any capacity by way of a non-competition obligation) as consideration for the commitment made by this latter party for the same duration of one year starting from his departure:

- not to hold in Europe, Canada, the United States or any country in which the Company exercises its Activity, a position of manager, director, employee or consultant in a company conducting the Activity; or
- not to hold shares in the share capital of a company carrying out the Activity, with the exception of a holding in any listed company representing at most 1% of the share capital held exclusively for financial reasons.

13.1.1.4 Compensation policy of the board members

Our shareholders at the mixed general shareholders' meeting held on May 19, 2016 set the total annual attendance fees to be distributed among non-employee directors except those who are affiliated with one of our significant shareholders at €300,000 as a maximum for the 2016 fiscal year and for the following fiscal years.

The criteria for distributing the annual fixed sum allocated by the general meeting to the members of the board were set by the board, upon recommendation of the Compensation Committee and are as follows:

- only the independent directors receive a compensation;
- the annual attendance fee for an independent director at €45,000 for each director, irrespective of the number of Board meeting held during the year and their actual presence;
- an additional €15,000 as a chair of a committee, regardless of the number of meetings held.

Our Chairman of the Board of Directors and our Chief Executive Officer and Co-Founder, are directors but do not receive any additional compensation for their services as directors.

For information related to the composition of our Board of Directors, the term of their office, and their main positions and offices held outside the Company, see section 12.1.1 of this Universal Registration Document.

13.1.2 SUMMARY TABLE OF COMPENSATION, OPTIONS AND SHARES GRANTED TO SENIOR EXECUTIVES FOR THE FISCAL YEARS 2018 AND 2019

The tables below summarize the compensation and benefits of any kind paid to our Chief Executive Officer and to our directors, in accordance with the tables on executive compensation of the AMF recommendation No. 2014-14.

The aggregate compensation paid and benefits in kind granted by us to our current executive officers and directors, including share-based compensation, for the year ended December 31, 2019, was €1,319,330. For the year ended December 31, 2019, no amounts have been set aside or accrued to provide pension, retirement or similar benefits to our employees was attributable to our executive officers.

It is specified that the total remuneration of each corporate officer respects the remuneration policy approved by the general meeting of June 11, 2019 in its 15th and 16th resolutions.

The payment of the elements of variable remuneration and, as appropriate, exceptional remuneration attributed for a financial year to Chairman of the Board, the Chief Executive Officer and of the Deputy CEOs is conditional on approval by the next ordinary general meeting of their elements of remuneration, paid or attributed during the said financial year *(ex post vote)*. Our shareholders' meeting will be held on April 29, 2020, and will be asked in its 11th and 12th resolutions, to vote accordingly on the elements of remuneration granted and paid to Michael Wyzga and Bernard Gilly during the financial year 2019, that will be described in the report of the Board of Directors included in the notice of General Meeting.

Our shareholders' meeting will be held on April 29, 2020, and will be asked in its 10th resolution, to vote accordingly on the elements below that constitute the information given accordingly to the article L.225-37-3 of the French Commercial Code and comply with AMF recommendation 2014-14.

Table 1 (AMF definition)

(in euros)	Fiscal year ending December 31, 2018	Fiscal year ending December 31, 2019
Michael Wyzga Chairman		
Compensation granted for the fiscal year *(as detailed in Section 13.1.3 of this Universal Registration Document)*	145,154	145,154
Valuation of multi-year variable compensation granted in the course of the fiscal year	—	—
Valuation of share warrants granted during the fiscal year *(as detailed in Section 13.3.2 of this Universal Registration Document)*	20,200	36,529
Valuation of share warrants for founders granted during the fiscal year *(as detailed in Section 13.3.2 of this Universal Registration Document)*	—	—
Valuation of shares warrants granted during the fiscal year *(as detailed in Section 13.3.2 of this Universal Registration Document)*	—	—
TOTAL	**165,354**	**181,683**

(in euros)	Fiscal year ending December 31, 2018	Fiscal year ending December 31, 2019
Bernard Gilly Chief Executive Officer		
Compensation granted for the fiscal year *(as detailed in Section 13.1.3 of this Universal Registration Document)*	534,018	515,768
Valuation of multi-year variable compensation granted in the course of the fiscal year	—	—
Valuation of share warrants granted during the fiscal year *(as detailed in Section 13.3.2 of this Universal Registration Document)*	—	—
Valuation of share warrants for founders granted during the fiscal year *(as detailed in Section 13.3.2 of this Universal Registration Document)*	—	—
Valuation of free shares granted during the fiscal year *(as detailed in Section 13.3.2 of this Universal Registration Document)*	94,500	396,000
TOTAL	**628,518**	**911,768**

13.1.3 COMPENSATION OF SENIOR EXECUTIVES

Table 2 (AMF definition)

	Fiscal year ending December 31, 2018		Fiscal year ending December 31, 2019	
(in euros)	Granted	Paid	Granted	Paid
Michael Wyzga Chairman				
Fixed Compensation [1]	145,154	145,154	145,154	145,154
Variable Compensation	—	—	—	—
Valuation of multi-year variable compensation granted in the course of the fiscal year	—	—	—	—
Exceptional Compensation	—	—	—	—
Directors' Fees	—	—	—	—
Benefits in kind	—	—	—	—
TOTAL	**145,154**	**145,154**	**145,154**	**145,154**

	Fiscal year ending December 31, 2018		Fiscal year ending December 31, 2019	
(in euros)	Granted	Paid	Granted	Paid
Bernard Gilly Chief Executive Officer				
Fixed Compensation	365,000	365,000	365,000	365,000
Variable Compensation [2]	127,750	127,750	109,500	127,750
Valuation of multi-year variable compensation granted in the course of the fiscal year	—		—	
Exceptional Compensation	—		—	
Directors' Fees	—		—	
Benefits in kind [3]	41,268	41,268	41,268	41,268
TOTAL	**534,018**	**534,018**	**515,768**	**534,018**

(1) Mr. Wyzga was appointed Chairman of the Board of Directors on March 2, 2016. On March 9, 2017, the Board of Directors set Mr. Wyzga's fixed compensation at €145,154 gross for the fiscal year ended December 31, 2019.

(2) On December 19, 2018, the Board of Directors of the Company awarded Mr. Gilly a variable compensation of €127,750 as a bonus for achieving qualitative and quantitative objectives regarding the fiscal year ended December 31, 2018.
On December 17, 2019, the Board of Directors of the Company awarded Mr. Gilly a variable compensation of €109,500 as a bonus for achieving qualitative and quantitative objectives regarding the fiscal year ended December 31, 2019. It should be remembered that the payment of this variable is subject to a favorable vote of the 11th resolution the Ordinary General Meeting which will be held on April 29, 2020, pursuant to the "say-on-pay" regulation introduced by the Sapin 2 Law.

(3) Consisting of a housing allowance.

13.2 DIRECTORS' COMPENSATION

The table below summarize the compensation and benefits of any kind paid to our Directors during the period covered:

Table 3 (AMF definition)

(in euros)	Granted / Paid 2018	Granted / Paid 2019
Peter Goodfellow		
Directors' fee	60,000	60,000
Other Compensation	–	–
Genghis Lloyd-Harris[1]		
Directors' fee	–	–
Other Compensation	–	–
Guido Magni[2]		
Directors' fee	–	–
Other Compensation	–	–
Charlotte Corbaz[3]		
Directors' fee	–	–
Other Compensation	–	–
Natalie Mount		
Directors' fee	45,000	45,000
Other Compensation	–	–
Simone Seiter		
Directors' fee	45,000	55,333
Other Compensation	–	27,397
Cédric Moreau[4]		
Directors' fee	–	–
Other Compensation	–	–
Maritza McIntyre[5]		
Directors' fee	–	24,875
Other Compensation	–	–
TOTAL	150,000	185,208

(1) Mr. Lloyd-Harris resigned from the Board of Directors on March 16, 2018.
(2) Mr. Magni resigned from the Board of Directors on April 24, 2019.
(3) Ms. Corbaz was replaced by Mr. Laurent Higueret on June 11, 2019 as the representative of Bpifrance Participations.
(5) Mr. Moreau joined the Board of Directors on June 11, 2019 as the permanent representative of Sofinnova.
(6) Ms. McIntyre joined the Board of Directors on June 11, 2019.

Director's fees are paid quarterly.

Our other directors receive no compensation for their service as directors but are reimbursed for reasonable expenses incurred in connection with attending board and committee meetings.

Except as described in the Section 17.2 "Transactions with Key Management Persons" of this Universal Registration Document with respect to Mr. Gilly, there are no arrangements or understandings between us and any of our directors providing for benefits upon termination of their service as our directors.

13.3 SHARE WARRANTS, SHARE WARRANTS FOR FOUNDERS, STOCK OPTIONS AND FREE SHARES GRANTED TO SENIOR EXECUTIVES AND DIRECTORS

As of December, 31, 2019, BCE warrants and BSA warrants held by our directors could be exercised for the purchase of an aggregate of 449,000 ordinary shares at a weighted average exercise price of €3.466 per share. In addition, BCE warrants and BSA warrants could be exercised for the purchase of an aggregate of 1,528,342 ordinary shares at a weighted average exercise price of €3.20 per share. As of December 31, 2019, 265,000 AGA granted to our directors are outstanding and could be acquired subject to performance criteria.

13.3.1 SHARE WARRANTS OR SHARE WARRANTS FOR FOUNDERS GRANTED TO SENIOR EXECUTIVES AND DIRECTORS IN 2018, 2019 AND AS OF THE DATE OF THIS DOCUMENT

Table 4 (AMF definition)

Name	Grant Date	Type of Grant	Number of Ordinary Shares Underlying Awards (#)	Exercise Price (€)	Expiration Date
Michael Wyzga	09/18/2018	BSA (1)	10,000	2.22	09/18/2025
	07/23/2019	BSA (1)	20,000	1.45	07/23/2026
Simone Seiter	07/27/2017	BSA (1)	30,000	5.04	07/26/2024
	09/18/2018	BSA (1)	5,000	2.22	09/18/2025
	07/23/2019	BSA (1)	15,000	1.45	07/23/2026
Natalie Mount	07/27/2017	BSA (1)	30,000	5.04	07/26/2024
	09/18/2018	BSA (1)	5,000	2.22	09/18/2025
Maritza McIntyre	07/23/2019	BSA (1)	30,000	1.45	07/23/2026

(1) BCE refers to share warrants for founders. BSA refers to share warrants. AGA refers to free shares.

BSA are subscribed by directors at a price of 8% of the exercise price, therefore, representing an investment risk and aligning directors and shareholders interest. The exercise price of share warrants is determined as the weighted average of the share price of the last 20 trading sessions preceding the attribution date. Amounts reported as Other Compensation in the above table represent the net fair value of granted share warrants (BSA), including the payment of the subscription price, as determined by an independent expert using a Black-Scholes model. See section 7.2.5, "Critical accounting policies and estimates" of this Universal Registration Document for more information on the valuation method.

13.3.2 SHARE WARRANTS OR SHARE WARRANTS FOR FOUNDERS EXERCISED BY SENIOR EXECUTIVES AND DIRECTORS IN 2018, 2019 AND AS OF THE DATE OF THIS DOCUMENT

Table 5 (AMF definition)

Name	Grant Date	Number of Share Warrants and Share Warrants for Founders Exercised	Exercise Price (€)
Bernard Gilly	—	—	—
Peter Goodfellow	—	—	—
Michael Wyzga	—	—	—
Simone Seiter	—	—	—
Natalie Mount	—	—	—
Maritza McIntyre	—	—	—

13.3.3 FREE SHARES TO SENIOR EXECUTIVES AND DIRECTORS GRANTED IN 2018, 2019 AND AS OF THE DATE OF THIS DOCUMENT

Table 6 (AMF definition)

Name	Grant Date	Number of Shares Granted	Value of Shares according to IFRS 2	Beginning of Acquisition Period	End of Lock-up Period	Performance Criteria
Bernard Gilly	09/18/2018	45,000	94,500	09/18/2018 (1)	(2)	(3)
	07/23/2019	220,000	396,000	07/23/2019 (4)	(2)	(5)
	01/28/2020	490,000	1,666,000	01/28/2020 (6)	(2)	(7)

(1) If the performance criteria are not fulfilled by September 18, 2020 at the latest, the free shares granted will be canceled.
(2) The lock-up period will end one (1) year after the end of the actual acquisition date.
(3) The AGA 2018 granted to Key Managers, including Mr. Gilly, are subordinate to the achievement of the following performance criteria at the latest on September 18, 2020:
- 50% of AGA 2018 will be acquired at the completion of the recruitment of the patients of the Phase I/II clinical trials with GS030 in retinitis pigmentosa.
- 50% of the AGA 2018 will be acquired at the completion of the production of the first PPQ batch of GS010.

(4) If the performance criteria are not fulfilled by July 23, 2021 at the latest, the free shares granted will be canceled.
(5) The AGA 2018 granted to Key Managers, including Mr. Gilly, are subordinate to the achievement of the following performance criteria at the latest on July 23, 2021:
- 50% of AGA 2018 will be acquired upon the filing with the European Medicines Agency (EMA) the application for market authorization (MA) at the European level of the GS010.
- 50% of AGA 2018 will be acquired at the completion of the recruitment of the patients of the Phase I/II clinical trials with GS030 in retinitis pigmentosa.

(6) If the performance criteria are not fulfilled by January 28, 2022 at the latest, the free shares granted will be canceled.
(7) The AGA 2018 granted to Key Managers, including Mr. Gilly, are subordinate to the achievement of the following performance criteria at the latest on January 28, 2022:
- 50% of AGA 2018 will be acquired upon the filing with the European Medicines Agency (EMA) the application for market authorization (MA) at the European level of the GS010.
- 50% of AGA 2018 will be acquired filing with the Food and Drug Agency (FDA) of the application for Biologics License Application (BLA) for the GS010.

13.3.4 FREE SHARES AVAILABLE IN 2018, 2019 AND AS OF THE DATE OF THIS DOCUMENT

The following free shares became available during the fiscal year ended December 31, 2019.

Name	Grant Date	Number of Shares Granted	Number of Shares which became available during the exercise	Performance Criteria
Bernard Gilly	07/27/2017	200,000	100,000	(1)

(1) 50% of AGA 2017 were acquired at the completion of the enrollment of 50% of the patients of the Phase I/II clinical trials with GS030 in retinitis pigmentosa, on May 17, 2019.

13.4 HISTORY OF ALLOCATION OF SHARE WARRANTS, SHARE WARRANTS FOR FOUNDERS AND STOCK OPTIONS

13.4.1 HISTORY OF SHARE WARRANTS FOR FOUNDERS (BCE)

Table 8 (AMF definition)

	BCE Issued July 2013	BCE Issued April 2014	BCE Issued December 2014	BCE Issued July 2015
Date of shareholders' meeting	02/05/2013	02/05/2013	06/25/2014	06/29/2015
Date of allocation by the Board of Directors	07/08/2013	04/09/2014	12/03/2014	07/08/2015
Total number of BCE authorized	2,334,959	2,334,959	2,334,959	856,000
Total number of BCE granted	892,000	193,800	60,000	733,298
Including those granted to Mr. Gilly	300,000	–	–	161,000
Including those granted to Mr. Wyzga	–	–	–	–
Start date for the exercise of the BCE	07/08/2013	04/08/2014	12/03/2014	07/08/2015
BCE expiry date	07/07/2023	04/07/2024	12/02/2024	07/07/2025
BCE exercise price	€0.025	€0.025	€0.025	€3.275
Number of shares subscribed as of December 31, 2019	768,280	193,800	–	71,765
Total number of BSA canceled or obsolete as of December 31, 2019	–	–	–	178,952
Total number of BSA outstanding as of December 31, 2019	123,720	–	60,000	482,582
Total number of shares available for subscription as of December 31, 2019	123,720	–	60,000	482,582

13.4.2 HISTORY OF SHARE WARRANTS (BSA)

	BSA Issued July 2013	BSA Issued April 2014	BSA Issued July 2015	BSA Issued July 2016	BSA Issued July 2017	BSA Issued September 2018	BSA Issued July 2019
Date of shareholders' meeting	02/05/2013	02/05/2013	06/29/2015	05/19/2016	05/19/2016	04/12/2018	06/11/2019
Date of allocation by the Board of Directors	07/08/2013	04/09/2014	07/08/2015	07/26/2016	07/27/2017	09/18/2018	07/23/2019
Total number of BSA authorized	2,334,959	2,334,959	856,000	680,456		1,211,711	1,436,227
Total number of BSA subscribed	328,000	33,000	121,000	205,000	165,000	20,000	105,000
Including those granted to Mr. Gilly	–	–	–	–	–	–	–
Including those granted to Mr. Wyzga	–	–	40,000	31,000	15,000	10,000	20,000
Start date for the exercise of the BSA	07/08/2013	04/09/2014	07/08/2015	07/26/2016	07/27/2017	09/18/2018	07/23/2019
BSA expiry date	07/07/2023	04/08/2024	07/07/2025	07/25/2023	07/26/2024	09/18/2025	07/23/2026
BSA exercise price	€0.025	€0.025	€3.275	€8.08	€5.04	€2.22	€1.45
BSA subscription price	€0.002	€0.002	€0.25	€0.65	€0.40	€0.18	€0.13
Number of shares subscribed as o December 31, 2019	67,960	–	–	–	–	–	–
Total number of BSA canceled or obsolete as of December 31, 2019	–	–	–	47,000	–	–	–
Total number of BSA outstanding as of December 31, 2019	260,040	33,000	121,000	158,000	165,000	20,000	105,000
Total number of shares available for subscription as of December 31, 2019	260,040	33,000	121,000	158,000	165,000	20,000	105,000

13.4.3 HISTORY OF STOCK OPTIONS (SO)

	SO Issued July 2017	SO Issued December 2017	SO Issued March 2018	SO Issued September 2018
Date of shareholders' meeting	05/31/2017	05/31/2017	05/31/2017	04/12/2018
Date of allocation by the Board of Directors	07/27/2017	12/19/2017	03/14/2018	09/18/2018
Total number of SO authorized		977,022		1,211,711
Total number of SO granted	220,000	300,000	175,000	30,000
Including those granted to Mr. Gilly	—	—	—	—
Including those granted to Mr. Wyzga	—	—	—	—
Start date for the exercise of the SO	(1)	(2)	(2)	(2)
SO expiry date	07/26/2024	12/18/2024	03/14/2025	09/18/2025
SO exercise price	€5.040	€5.55	€6.98	€2.19
Number of shares subscribed as of December 31, 2019	—	—	—	—
Total number of SO canceled or obsolete as of December 31, 2019	220,000	300,000	175,000	30,000
Total number of SO outstanding as of December 31, 2019 (3)	—	—	—	—
Total number of shares available for subscription as of December 31, 2019	—	—	—	—

(1) 25% of the stock options are exercisable at the grant date; the remaining 75% will become exercisable at a rate of 1/36 per month during the 3 following years.
(2) 25% of the stock options are exercisable at the first anniversary of the grant date; the remaining 75% will become exercisable at a rate of 1/36 per month during the 3 following years.

13.5 SHARE WARRANTS, SHARE WARRANTS FOR FOUNDERS OR STOCK OPTIONS OF THE COMPANY GRANTED TO THE COMPANY'S TOP TEN EMPLOYEES

Table 9 (AMF definition)

	Total number of options awarded / shares subscribed or purchased	Weighted average price
Free shares granted during the fiscal year ended December 31, 2019 by the Company to the ten employees of the Company who received the highest number of such free shares (overall figure)	352,500	1.80
Free shares on the Company definitively acquired during the fiscal year ended December 31, 2019 by the ten employees of the Company who purchased or subscribed for the greatest number of options (overall figure)	—	—
Options granted during the fiscal year ended December 31, 2019 by the Company to the ten employees of the Company who received the highest number of such options (overall figure)	—	—
Options on the Company exercised during the fiscal year ended December 31, 2019 by the ten employees of the Company who purchased or subscribed for the greatest number of options (overall figure)	—	—

13.6 HISTORY OF ALLOCATION OF FREE SHARES AS OF DECEMBER 31, 2019

Table 10 (AMF definition)

	AGA Issued July 2016	AGA Issued July 2017	AGA Issued December 2017	AGA Issued September 2018	AGA Issued December 2018	AGA Issued July 2019
Date of shareholders' meeting	05/19/2016	05/19/2016	05/19/2016	04/12/2018	04/12/2018	04/12/2018
Date of allocation by the Board of Directors	07/26/2016	07/27/2017	12/19/2017	09/18/2018	12/19/2018	07/23/2019
Total number of AGA authorized	10% share capital at the grant date	10% share capital at the grant date	10% share capital at the grant date	10% share capital at the grant date	10% share capital at the grant date	10% share capital at the grant date
Total number of AGA granted	766,000	593,500	72,500	380,000	135,000	610,000
Including those granted to Mr. Gilly	250,000	200,000	–	45,000	–	220,000
Including those granted to Mr. Wyzga	–	–	–	–	–	–
Date of definitive acquisition of AGA	07/26/2017	07/27/2018	12/19/2018	09/18/2019(2)	12/19/2019(2)	07/23/2020(3)
End of lock-up period	(1)	(1)	(1)	(1)	(1)	(1)
Number of shares definitively acquired as of December 31, 2019	602,000	505,000	72,500	40,000	–	–
Total number of AGA canceled or obsolete as of December 31, 2019	164,000	88,500	–	65,000	–	5,000
Total number of AGA outstanding as of December 31, 2019	–	–	–	265,000	135,000	605,000

(1) The lock-up period will end one (1) year after the end of the actual acquisition date.
(2) If the performance terms are not fulfilled by September 18, 2020 at the latest, the free shares granted will be canceled.
(3) If the performance terms are not fulfilled by July 23, 2021 at the latest, the free shares granted will be canceled.

13.7 BENEFITS OF SENIOR EXECUTIVES

Table 11 (AMF definition)

	Employment Agreement		Supplemental Pension Plan		Benefits or advantages due or likely to be due as a result of termination or change of office		Benefits relating to a non-compete clause	
	Yes	No	Yes	No	Yes	No	Yes	No
Bernard Gilly Chief Executive Officer Beginning of term: 2018 End of term: General Meeting which will be held on 2021		X		X	X(1)		X(2)	
Michael Wyzga Chairman of the Board of Directors Beginning of term: 2018 End of term: 2021		X		X		X		X

(1) On February 14, 2013, our Board of Directors resolved that the Company may pay Mr. Gilly a termination payment equal to the last 12 months of his fixed and variable compensation and not capped except in the event of (1) dismissal by us for gross negligence or (2) resignation, other than resignation for health or family reasons.
- Subject to the satisfaction of certain performance criteria, the Company may pay Mr. Gilly a termination payment equal to the last 12 months of his fixed and variable compensation, except in the event of (1) dismissal by us for gross negligence or (2) resignation, other than resignation for health or family reasons. The Board resolved that such termination payment shall not be paid in the case of a change in the duties performed by Mr. Gilly or in the event that he decides on his own initiative to leave the Company to perform new duties.

(2) On March 9, 2017, our Board of Directors resolved that the Company may pay Mr. Bernard Gilly for a period of one year from the termination of his duties with the Company, a monthly payment of 40% of his total net monthly compensation excluding any bonuses in consideration of his undertaking not to engage in certain competitive activities for a period of one year from the termination of his duties.
- The principle of the benefits of the senior executives during 2019 and the compensation policy for our senior executives for 2020 will be subject to a report that will be submitted to the shareholders' meeting called to approve the consolidated financial statements for the fiscal year ended December 31, 2019.

13.8 EQUITY RATIO BETWEEN THE LEVEL OF COMPENSATION OF THE CHAIRMAN AND CHIEF EXECUTIVE OFFICER AND THE COMPENSATION AVERAGE AND MEDIAN OF THE COMPANY'S EMPLOYEES

This presentation was made in accordance with very recent terms of law n ° 2019-486 of May 22, 2019 relating to growth and transformation of companies, called "PACTE", for the sake of immediate compliance with new transparency requirements with regards to executive compensation.

It mentions the level of remuneration of the Chairman and CEO of the Company on the one hand, and on the other hand the average compensation and the median compensation of the employees (excluding the directors), as well that the evolution of these two ratios over the five most recent years.

	2015	2016	2017	2018	2019
Bernard Gilly CEO					
Ratio with average compensation	5,5	10,5	9,8	5	8,1
Ratio with median compensation	12	16,4	18,4	8,3	12,4
Michaël Wyzga (1) Chairman of the Board					
Ratio with average compensation	N/A	1,2	1,1	1,3	1,5
Ratio with median compensation	N/A	1,9	2,0	2,2	2,4

(1) Mike Wyzga has been appointed Chairman of the Board on March 2016.

	Annual evolution of the remuneration of Chairman of the Board of Directors (N/N-1)	Annual evolution of the remuneration of Chief Executive Officer (N/N-1)	Annual evolution of the average compensation of the Company's employees	Annual evolution of the Company's performance	Annual evolution of equity ratios with CEO's compensation		Annual evolution of equity ratios with Chairman's compensation	
					/ average compensation of the Company's employees	/ median compensation of the Company's employees	/ average compensation of the Company's employees	/ median compensation of the Company's employees
2015	N/a	N/c	N/c	N/a	N/c	N/c	N/a	N/a
2016	N/a	85,90%	-1,50%	N/a	88,80%	36,10%	N/a	N/a
2017	-40,70%	-35,50%	-31,30%	N/a	-6,10%	12,30%	-13,60%	3,30%
2018	-2,20%	-59,70%	-20,20%	N/a	-49,50%	-54,90%	22,50%	9,40%
2019	9,90%	50,80%	-7,50%	N/a	63,00%	48,90%	18,80%	8,50%

The ratios have been calculated on the basis of fixed and variable compensation paid during the years mentioned, as well as free shares granted during the same periods and valued at their fair value at the date of grant. The figures include the information regarding the employees of GenSight Biologics S.A only.

The significant variations of both Chief Executive Officer's compensation and average compensation of the Company's employees year-on-year is explained by the allocation of free shares and performance shares during the fiscal year, and especially the share price on the date of attribution which is used to calculation the global valuation of the free shares, whose fluctuations since our IPO have therefore had a significant impact on the total remuneration level.

As mentioned in section 13.1.1.2, the performance shares are subject to an acquisition period, conditional on the presence and achievement of performance criteria linked to the strategy and development objectives of the Company.

Main explanation regarding the evolution of the ratio:

- 2016: The Company completed our Initial Public Offering (IPO) on Euronext Paris. GenSight granted its first AGA plan in July when the stock price was €8. Mr Gilly has been granted with 250,000 AGA.
- 2017: Mr Gilly was granted with 200,000 AGA at a grant price of €5.12. In addition, his annual compensation increased from €250 K in 2016 to €365 K in 2017.
- 2018: Mr Gilly was granted with 45,000 AGA at a grant price of €2.10.
- 2019: Mr Gilly was granted with 220,000 AGA at a grant price of €1.80.

13.9 COMPLIANCE OF TOTAL EXECUTIVE DIRECTOR COMPENSATION WITH THE RECOMMENDATIONS OF MIDDLENEXT CODE

Since the listing of our shares on Euronext Paris, we comply with the MiddleNext Code, as amended on September 2016, (See Section 14.4, "Statement relating to Corporate governance" of this Universal Registration Document for more information).

The MiddleNext Code may be consulted on the Internet. We keep copies of such code available to the members of our governing bodies at all times.

13.10 AMOUNT OF PROVISIONS MADE OR RECORDED BY THE COMPANY FOR THE PAYMENT OF PENSIONS, RETIREMENT PLANS OR OTHER BENEFITS

We have not provisioned any amounts for payments of pensions, retirements or other similar benefits to our directors.

BOARD PRACTICES

14.1 TERMS OF OFFICE OF MEMBERS OF THE CORPORATE BODIES AND MANAGEMENT BODIES

The terms of office of the members of our Board of Directors and senior management can be found in Section 12.1, "Composition of Management and Supervisory Bodies" of this Universal Registration Document.

14.2 INFORMATION ON SERVICE CONTRACTS BETWEEN MEMBERS OF THE ADMINISTRATIVE AND MANAGEMENT BODIES AND THE COMPANY

As of the date of this Universal Registration Document and to our knowledge, apart from the contract mentioned in the paragraph below, there are no service contracts between the members of the administrative, management or supervisory bodies and the issuer or any of its subsidiaries providing for benefits upon termination of employment.

A consulting contract was signed between the Company and Dr. Sahel in the course of 2018. Pursuant to this agreement, Dr. Sahel is entitled to a remuneration based on an hourly rate of $350, which shall not exceed an annual amount of €45,000. This agreement was signed for a 12 months period and is tacitly renewable with a limit of two renewals.

Dr. Sahel was appointed as non-voting observer *(censeur)* of our Board of Directors in 2013. His term was renewed at the ordinary general meeting held on April 12, 2018 and will expire at the end of the ordinary general meeting to be held in 2021 for rulling on the financial statements for the financial year ending December 31, 2020.

14.3 COMMITTEES OF THE BOARD OF DIRECTORS

Pursuant to the internal rules *(règlement intérieur)* of our Board of Directors, our Board of Directors may create committees charged with examining questions submitted to it by the Board or its Chairman.

Since the listing of our shares on Euronext Paris, three such Board Committees have been created: an Audit Committee, a Compensation Committee and a Nominations Committee. The composition and duties of these committees are described below. The composition and functioning of all of our committees comply with all applicable requirements of the French Commercial Code.

In accordance with French law, Committees of our Board of Directors only have an advisory role and can only make recommendations to our Board of Directors. As a result, decisions will be made by our Board of Directors taking into account the non-binding recommendations of the relevant Board Committee.

In accordance with the MiddleNext Code, below is a table of the composition of our Board of Directors and our Committees.

Name and title of Board members	Independent Board member	Year of first nomination	Audit Committee	Compensation Committee	Nominations Committee
Michael Wyzaga, Chairman of the Board of Directors	Yes	2013	Chairman	—	Member
Peter Goodfellow	Yes	2014	—	Member	Chairman
Simone Seiter	Yes	2017	Member	Chairman	—
Natalie Mount	Yes	2017	—	—	Member
Bpifrance Participations (as represented by Laurent Higueret)	No	2017	Member	—	Member
Maritza McIntyre	Yes	2019	—	—	—
Sofinnova Partners (as represented by Cédric Moreau)	No	2019	—	Member	—

14.3.1 AUDIT COMMITTEE

Our Audit Committee reviews our internal accounting procedures, consults with and reviews the services provided by our statutory auditors and assists the Board of Directors in its oversight of our corporate accounting and financial reporting.

14.3.1.1 Composition

The Audit Committee is composed of at least three members including at least one who is particularly knowledgeable in finance and accounting and one who is independent, nominated by our Board of Directors further to an opinion from the Compensation Committee.

The term of office of the Audit Committee members is renewable.

The length of the term of members of the Audit Committee coincides with the length of their term as a member of the Board of Directors.

The chairman of the Audit Committee is appointed by the members of the Audit Committee for the length of his term of office as a committee member, from among the independent directors.

Our Audit Committee is composed of Mr. Wyzga, Ms. Seiter and Bpifrance Participations represented by Mr. Higueret. Mr. Wyzga is the Chairman of the Audit Committee. Mr. Wyzga and Ms. Seiter are independent members of the Board of Directors.

14.3.1.2 Duties

Under French law, the Audit Committee oversees matters related to the preparation and control of accounting and financial information. Our Board of Directors has specifically assigned the following duties to the Audit Committee:

- monitoring the process for preparing financial information and making recommendations to guarantee its integrity;
- ensuring the effectiveness of the internal control and risk management systems as well as of internal audit, with regard to the procedures relating to the preparation and processing of accounting and financial information, without infringing on its independence;
- making recommendations to the Board of Directors on the statutory auditors proposed for nomination to general meetings for appointment as well as renewal;
- monitoring the performance by the statutory auditors of their engagement;
- ensuring the independence of the statutory auditors and take appropriate enforcement action, if necessary;
- regularly reviewing the status of major disputes;
- approving the provision of non-audit services;
- reporting on a regular basis to the Board of Directors on the performance of its duties; and
- in general, providing advice and making appropriate recommendations in connection with the above matters.

The Audit Committee regularly reports to the Board of Directors on the performance of its tasks and the results of the statutory audit engagement, its contribution to the integrity of the financial information and the role that it played in this process. The Audit Committee must inform the Board of Directors without delay of any difficulty it encounters.

The Board of Directors or the Chairman of the Board of Directors may also submit any other issue to the Audit Committee for its opinion. In addition, the Audit Committee may decide to consider any issue and give its opinion thereon.

14.3.1.3 Activities of the Committee during the last fiscal year

The Audit Committee met three times in 2019. The main topics discussed by the Committee, and on which it made recommendations to the Board of Directors, were the review and approval of 2018 full year financial statements, 2019 half year consolidated financial statements, and 2020 budget.

14.3.2 COMPENSATION COMMITTEE

Our Compensation Committee assists the Board of Directors in reviewing and making recommendations to the Board of Directors with respect to the compensation of our executive officers and directors.

14.3.2.1 Composition

The Compensation Committee is composed of at least three members, nominated by our Board of Directors, among which at least one will be chosen from the independent members of the Board of Directors.

The Compensation Committee may not include any senior executive or officer of the Company.

The term of office of the Compensation Committee members is renewable.

The length of the term of members of the Compensation Committee coincides with the length of their term as a member of the Board of Directors.

Our Compensation Committee is composed of Dr. Seiter, Dr. Goodfellow.and Sofinnova Partners SAS represented by Mr. Moreau. Dr. Seiter is the chairman of the Compensation Committee.

None of the members of the Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the Board of Directors or Compensation Committee of any entity that has one or more executive officers serving on our Board or Compensation Committee. For a description of any transactions between us and members of the Compensation Committee and affiliates of such members, please see Section 17, "Related Party Transactions" of this Universal Registration Document.

14.3.2.2 Duties

The principal duties and responsibilities of our Compensation Committee include:

- reviewing the main objectives proposed by executive management with respect to compensation of our managers who are not corporate officers, including free share plans and share subscription or purchase options;

- reviewing the compensation of our managers who are not corporate officers, including free share plans and share subscription or purchase options, retirement and insurance plans and benefits in kind;
- submitting recommendations and proposals to the Board of Directors concerning:
  - compensation, retirement, insurance and benefit plans, non-cash benefits, and other financial rights, including severance pay, of executive officers *(mandataires sociaux)*. The Committee proposes compensation amounts and structures, in particular the rules for calculating the variable component of compensation, taking into account our strategies, objectives and performance, as well as market practices; and
  - free share plans, share subscription or stock options, and any other similar incentive plan, in particular benefits granted to specific corporate officers who are eligible for such plans;
- reviewing the total amount of directors' fees and the method for distributing them among the directors, as well as the requirements for obtaining reimbursement of expenses that directors of the Board may incur;
- preparing and submitting to the Board of Directors any reports that may be required by the internal rules;
- making any other recommendation concerning compensation that may be requested of it by the Board of Directors; and
- in general, the Compensation Committee provides advice and makes appropriate recommendations in connection with the above matters.

The Board of Directors or the Chairman of the Board of Directors may also submit any other issue to the Compensation Committee for its opinion. In addition, the Compensation Committee may decide to consider any issue and give its opinion thereon.

14.3.2.3 Activities of the Committee during the last fiscal year

The Compensation Committee met twice in 2019. The main topics discussed by the Committee, and on which it made recommendations to the Board of Directors, were the grant of share options (BSA) to independent directors and consultants, and free shares (AGA) to employees and senior executives, as well as the review of corporate objectives achievement for 2019 and the related variable compensation for officers.

14.3.3 NOMINATIONS COMMITTEE

Our Nominations Committee makes proposals to the Board of Directors relating to the appointment or renewal of the offices of directors submitted to the general meeting or relating to the cooptation of directors.

14.3.3.1 Composition

The Nominations Committee is composed of at least three members, nominated by our Board of Directors, among which at least one is chosen from the independent members of the Board of Directors.

The length of the term of members of the Nominations Committee coincides with the length of their term as member of the Board of Directors.

The term of office of the Nominations Committee members is renewable.

As of date of this Universal Registration Document, we have a Nominations Committee composed of Dr. Goodfellow, Mr. Wyzga, Ms. Mount and Bpifrance Participations represented by Ms. Higueret. Dr. Goodfellow is the chairman of the Nominations Committee.

14.3.3.2 Duties

The principal duties and responsibilities of our Nominations Committee include:

- making all proposals to the Board of Directors related to the identification of candidates for the post of director, in particular both within the scope of the Company's obligation to comply with the provisions of Article L.225-18-1 of the French Commercial Code and in connection with the identification of independent directors and more generally in connection with the changes in the composition of the Board;
- assisting the Board of Directors in connection with the assessment of the independence criteria making it possible to classify a director as an independent director in the light of the code of corporate governance chosen by the Company;
- assisting the Board of Directors in setting up a succession plan for the executive officers, in particular, in the event of an unanticipated vacancy;
- assisting the Board of Directors in a review of the insurance coverage of the corporate officers' civil liabilities; and
- in general, making any proposal to the Board of Directors concerning the appointment or renewal of the offices of directors submitted to the general meeting of shareholders or concerning the cooptation of directors.

The Board of Directors or the Chairman of the Board of Directors may also decide to submit to it for its opinion any issue in relation with the appointment of directors and, more generally, the composition of the Board of Directors. Likewise, the Nominations Committee may decide to look at any issue and express any opinions.

14.3.3.3 Activities of the Committee during the last fiscal year

The Nominations Committee did not meet in 2019.

14.4 STATEMENT RELATING TO CORPORATE GOVERNANCE

14.4.1 CORPORATE GOVERNANCE

Regarding the Code of Corporate Governance, our Company refers to the MiddleNext Code of Corporate Governance for Small and Medium-Sized Companies as amended in September 2016, available on the MiddleNext website (www.middlenext.com), hereinafter the Code of Practice.

The Board of Directors acknowledges that it is familiar with the information presented under the "due diligence points" *(Points de vigilance)* section of this Code of Practice. The Board of Directors considers that its organization and the procedures it has implemented allow it to satisfactorily address these due diligence points and all the Code of Practice's recommendations.

Pursuant to the MiddleNext Code, three powers are involved in the governance of a company:

- "sovereign power", expressed in particular at the general meeting of shareholders;
- "supervisory, advisory and control power": the directors; and
- "executive power": the managers.

For the fiscal year ended December 31, 2019, in addition to the information provided in this section, the status of application of the guidelines in the MiddleNext Code is as follows:

Recommendations of the MiddleNext Code	Adopted	Will be adopted
I. The sovereign body		
This Code does not provide any recommendation intended for the shareholders.		
II. The supervisory body		
R 1: Ethics for the members of the Board of Directors	X	
R 2: Conflicts of interest	X	
R 3: Composition of the Board – Presence of independent members of the Board	X	
R 4: Information to the members of the Board	X	
R 5: Organization of the meetings of the Board and committees	X	
R 6: Creation of committees	X	
R 7: Implementation of an internal regulation of the Board	X	
R 8: Election of each director	X	
R 9: Term of office of the members of the Board	X	
R 10: Compensation of directors	X	
R 11: Implementation of an assessment of the work of the Board	X	
R 12: Relationship with the "shareholders"	X	
III. The executive body		
R 13: Definition and transparency of the compensation of senior executives	X	
R 14: Succession plan of senior executives	X	
R 15: Combined employment / corporate office contracts	X	
R 16: Severance compensation	X	
R 17: Supplementary pension schemes	X	
R 18: Stock options and allocation of bonus shares	X	
R 19: Review of points of vigilance	X	

14.4.2 CODE OF ETHICS *(CODE DE DÉONTOLOGIE)*

Each director shall refrain from engaging in any transaction involving our shares when such director, by virtue of his or her position within the Company, is in possession of material non-public information.

Sale and purchase transactions involving our securities or derivatives carried out by our corporate executives and directors whether on the open market or in off-market block trading, be it directly or indirectly, are forbidden during the period of:

- thirty (30) calendar days preceding the day of publication of our half-yearly and annual financial statements; and
- fifteen (15) calendar days preceding the day of publication of our quarterly information if applicable.

Persons subject to these black-out periods are not permitted to trade in our securities until the day after the information has been released.

In any case, the Board of Directors can decide, in the event of a material fact that could significantly affects the market price of our securities, to set a period during which sale and purchase transactions involving our securities or derivatives carried out by our corporate executives and directors whether on or off-market, be it directly or indirectly, will be forbidden.

14.5 OPERATING PRINCIPALS OF THE BOARD OF DIRECTORS

14.5.1 CONDITIONS OF PREPARATION FOR BOARD'S ACTIVITIES

To allow the board members to usefully prepare meetings, the chairman seeks to provide all necessary information or documents in advance.

Thus, the draft of the annual consolidated financial statements was sent to the directors several days before the board meeting to approve them was held.

Whenever a board member so requests, the chairman shall send all possible additional information and documents requested.

14.5.2 CONTENT OF BOARD MEETINGS

Meetings are convened in writing at least five business days in advance.

Meetings are held at the corporate headquarters.

The Board of Directors met 8 times in 2019.

During this period, members' attendance at Board meetings was as follows:

- 100% of directors at the meeting on February 21, 2019;
- 57% of directors at the meeting on February 25, 2019;
- 71% of directors at the meeting on April 23, 2019;
- 100% of directors at the meeting on June 11, 2019;
- 100% of directors at the meeting on July 23, 2019;
- 100% of directors at the meeting on September 25, 2019;
- 100% of directors at the meeting on December 17, 2019;
- 50% of directors at the meeting on December 19, 2019.

Average attendance was thus 85% during the period.

The statutory auditors were convened to Audit Committee meetings in preparation for meetings of the Board of Directors convened to approve the half year and annual consolidated financial statements.

They effectively attended them.

14.5.3 RULES OF PROCEDURE OF THE BOARD OF DIRECTORS

Internal rules of the Board of Directors may be consulted on our website (www.gensight-biologics.com).

In accordance with the MiddleNext Code, our internal rules of the Board of Directors with at least the following 8 headings:

- role of the Board of Directors and, where applicable, transactions subject to prior authorization of the Board of Directors;
- composition of the Board of Directors/criteria of independence of its members;
- definition of the role of specialized committees, if any;
- duties of the members of the Board of Directors (professional responsibility: loyalty, non-competition, disclosure of conflicts of interest and duty of abstention, ethics, confidentiality, etc.);
- operation of the Board of Directors (frequency, convening, information to members, self-assessment, use of videoconferencing and telecommunications facilities, etc.) and, when there are committees, specify their missions;
- terms and conditions of protection for corporate officers: civil liability insurance for corporate officers;
- rules for determining directors' compensation;
- the question of the succession plan for the "manager" and key persons.

14.5.4 TOPICS DISCUSSED DURING BOARD MEETINGS AND ACTIVITY REPORT

During fiscal year 2019, the Board of Directors specifically discussed the following subjects:

- **Financial:** Preparation of the annual financial statements and half-year consolidated financial statements, examination of

draft management documents, and review and approval of the 2020 budget and long-term strategic plan; review and analysis of the financing strategy, completion of two capital increases and issue of a convertible bond financing;

- **Compensation:** Examination and modification of the compensation of the chairman and chief executive officer, grant of free shares to all employees, grant of share purchase warrants to independent directors, and certain consultants, review of corporate objectives and grant of 2019 performance bonuses, implementation and review of 2019 corporate objectives, review of compensation for independent directors and officers;
- **Strategy:** Review of the medium- and long-term strategic plan; update on Business Development initiatives;
- **Governance:** Renewal of the term of Chairman of the Board of Directors, nomination of a new member of the Compensation Committee, review of the status of independent Board Members.

14.5.5 PROCEDURE IMPLEMENTED TO REVIEW THE ORDINARY AGREEMENTS SIGNED WITH RELATED PARTIES

Background and scope

Following the enactment of French Law 2019-486 of May 22, 2019, known as Loi Pacte, the Company's Supervisory Board created a procedure to regularly assess whether the agreements with related parties which relate to ordinary transactions and have been entered into upon customary terms & conditions (Ordinary Agreements) meet the legal requirements to qualify as such. This procedure applies to all members of the Legal and Finance Departments within the Group, as well as to the members of the Management Board and Supervisory Board.

Description and implementation of the procedure

Any member of the Legal or Finance Departments who is aware of an agreement, or a draft agreement, that may fall within the scope of Articles L.225-86 *et seq.* of the French Commercial Code shall report thereon to the General Counsel without delay. The General Counsel, or any qualified person designated by the General Counsel, determines, in accordance with the applicable legal criteria, whether the agreement in question falls within the regime of regulated agreements or constitutes an Ordinary Agreement. If the General Counsel or his designee determines that the agreement falls within the scope of the Ordinary Agreements, he/she shall record the reasons accurately and in writing. The explanatory memorandum will be kept in the archives of the Legal Department. It may be provided to the Statutory Auditors upon request.

At least once per calendar year, the Management Board will provide the Audit and Corporate Governance Committee and the Supervisory Board with a summary of the Ordinary Agreements entered into or performed during the previous fiscal year, together with the reasons justifying their categorization as Ordinary Agreements. This will be followed by a discussion of the Supervisory Board, during which the Board will check that the agreements so reported do indeed meet the criteria required by law to qualify as Ordinary Agreements.

The Company's Supervisory Board reviewed the qualification of the Ordinary Agreements entered into or performed during the fiscal year 2019, during its meeting held on March 12, 2020. Qualification of these agreements as Ordinary Agreements was confirmed.

14.5.6 SELF-EVALUATION OF THE BOARD OF DIRECTORS

In accordance with the recommendation of the Code of Practice, at its meeting of March 11, 2020, the Board of Directors undertook a review, followed by an evaluation, of its work and activities, and that of its special committees, as described in Section 14.3 of this Universal Registration Document. This review, articulated around an open discussion, highlighted positive findings for the Board of Directors as to its operations, information and the quality of its discussions.

EMPLOYEES

15.1 HUMAN RESOURCES MANAGEMENT

15.1.1 NUMBER AND BREAKDOWN OF EMPLOYEES

As of December 31, 2019, we had 25 employees, 24 of whom are full-time, 8 of whom hold Ph.D., Pharm.D. or M.D. degrees, 19 of whom are engaged in preclinical development and regulatory affairs, clinical development, research, engineering and production, 5 of whom are engaged in management and administration and 1 of whom is engaged in sales and marketing.

As of December 31, 2019, all of our employees were located in France.

The table below shows the changes in the number of our employees over the last two years.

	2018	2019
As of January 1	34	33
New hires	12	5
Departures[1]	13	9
Dismissals[2]	—	4
As of December 31	33	25

(1) This category includes both voluntary and involuntary departures.
(2) Individual dismissals (for cause).

15.1.2 HUMAN RESOURCES POLICY

Our human resources management is organized around the following principles:

We apply the *"Convention collective nationale des ingénieurs et cadres de la métallurgie"*.

There are no company-wide agreements, other than our internal rules and regulations.

Standard employment contracts contain clauses that deal with inventions and copyright. As from the end of their employment contracts, our management employees are bound by a one-year covenant not to compete and a two-year obligation not to solicit our customers.

With respect to remuneration policy, all employees hired pursuant to permanent employment contracts receive a variable remuneration in addition to their fixed remuneration, which is a percentage ranging between 10% and 40% of their fixed salary.

15.1.3 CORPORATE SOCIAL RESPONSIBILITY

Employment

As at December 31, 2019, GenSight Biologics personnel totaled 25, distributed by contract type, sex and age range as follows:

	2018	2019
Headcount as at December 31	33	25
of which permanent	33	24
of which fixed-term	—	1
of which women	18	13
of which men	15	12
< 35 years old	9	7
> 35 years old	24	18

Employee movements during the fiscal year ended December 31, 2019 (hirings and departures) may be broken down as follows:

	2018	2019
Number of hirings[1]	12	5
of which permanent	12	4
of which fixed-term	—	1
Number of departures[2]	13	13

(1) These hirings are related to the activity growth of the Society as well as replacements.
(2) These departures correspond to both voluntary departures and dismissals.

There were four layoffs during the period.

Compensation

The payroll expense for the fiscal year ended December 31, 2019 was the following:

in thousands of euros	2018	2019
Payroll expense	5,889	5,385

Employees under a permanent employment contract are entitled to fixed salary and a variable compensation in the form of a bonus scheme based on both corporate and individual objectives and ranging from 10% to 40% of the fixed amount. They are eligible to receive employee share warrants (*bons de souscription de parts de créateur d'entreprise* or "BCEs") or free shares (*attributions gratuites d'actions*, or AGA).

Organization of work

As at December 31, 2019, out of 25 employees, 7 were senior managers (*"cadre dirigeant"*), 18 were managers (*"cadre"*). Managers worked 37 hours weekly and were compensated by 12 days of additional holiday (*"Réduction du Temps de Travail"*).

As at December 31, 2019, 96% of employees were full-time and 4% were part-time.

The table below presents the absenteeism rate for the years 2018 and 2019:

	2018	2019
Absenteeism rate	3.23%	1.81%

Corporate dialogue

Given the size of the Company and the number of employees, corporate dialogue is a natural component of the working environment at GenSight Biologics. Personnel representatives elections took place on May 13, 2019. The Company acknowledged the absence of a candidate.

Health & Safety

In compliance with regulations, GenSight Biologics has carried out in its *"Document Unique d'Entreprise"* a risk analysis of its activities and proposed an action plan to mitigate these risks.

One case of work-related disease was declared in 2019. No accident at work was declared in 2019.

GenSight Biologics considers that it does not expose its employees to any specific risk.

Training

The Company aims to provide its employees with training opportunities, to develop general skills (management and languages, etc.) as well as technical skills specific to each position.

	2018	2019
Number of training hours taken	173	91

Diversity

GenSight Biologics gives special attention to the diversity of its teams. The distribution by sex, as presented in the table below, is a meaningful measure of this commitment:

	2018	2019
Percentage of female employees	55%	52%

The proportion of women within the Management Committee was 57% in 2019, versus in 44% 2018.

GenSight Biologics does not employ any disabled persons, and will pay an annual financial contribution of €15,045 to the Agefiph, the French public agency that promotes integration into the workplace of disabled people.

100% of employees GenSight Biologics are based in France. The Company complies with all applicable regulations.

Furthermore, France has ratified the eight fundamental conventions of the ILO. The ILO has qualified as "fundamental agreements" the conventions concerning the following principles and fundamental labor rights: freedom to unionize and effective recognition of the right of collective bargaining, elimination of forced or compulsory work, effective abolition of child labor and elimination of discrimination in the area of employment and profession.

GenSight Biologics shares these principles, which are implemented in the Company's social relations, its policy regarding recruitment and equality of opportunity.

15.2 SHAREHOLDINGS AND STOCK OPTIONS

See Section 13, "Compensation and Benefits" of this Universal Registration Document.

15.3 EMPLOYEE ARRANGEMENTS

See Section 13, "Compensation and Benefits" of this Universal Registration Document.

MAJOR SHAREHOLDERS

16.1 ALLOCATION OF SHARE CAPITAL

16.1.1 SHAREHOLDERS

As of the date of this Universal Registration Document, we are not controlled by any majority shareholder and our share capital is equal to €820,684.05 divided into 32,827,362 fully authorized, subscribed and paid-up ordinary shares with a nominal value of €0.025.

The table below sets forth the non-diluted share capital structure, based on available information as of the date of this Universal Registration Document.

Shareholders	Number of shares/ voting rights	% of share capital/ voting rights (non-diluted)
5% Shareholders:		
Sofinnova	5,610,044	17.09%
3SBio	2,110,595	6.43%
Kreos Capital (Expert Fund) LP	—	—
Versant	2,322,048	7.07%
Bpifrance Participations	2,000,000	6.09%
Bpifrance Investissement	975,666	2.97%
Directors and Executive Officers:		
Bernard Gilly	947,600	2.89%
Thomas Gidoin	157,610	0.48%
Magali Taïël	—	—
Michael Wyzga	—	—
Peter Goodfellow	—	—
Simone Seiter	—	—
Natalie Mount	—	—
Maritza McIntyre	—	—
Employee Shareholding	295,500	0.90%
Former employees	1,226,244	3.74%
Other Shareholders (total)	17,182,055	52.34%
TOTAL	32,827,362	100.00%

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MAJOR SHAREHOLDERS

The table below sets forth our fully-diluted share capital structure, based on available information as of the date of this Universal Registration Document.

Shareholders	Number of shares/ voting rights	% of share capital/ voting rights (fully diluted)
5% Shareholders:		
Sofinnova	5,610,044	14.90%
3SBio	2,110,595	5.61%
Kreos Capital (Expert Fund) LP	1,336,302	3.55%
Versant	2,322,048	6.17%
Bpifrance Participations	2,000,000	5.31%
Bpifrance Investissement	975,666	2.59%
Directors and Executive Officers:		
Bernard Gilly	1,863,600	4.95%
Thomas Gidoin	762,610	2.03%
Magali Taïël	340,000	0.90%
Michael Wyzga	116,000	0.31%
Peter Goodfellow	57,000	0.15%
Simone Seiter	50,000	0.13%
Natalie Mount	35,000	0.09%
Maritza McIntyre	30,000	0.08%
Employee Shareholding	**783,500**	**2.08%**
Former employees	**1,503,546**	**3.99%**
Other Shareholders (total)	**17,756,095**	**47.16%**
TOTAL	**37,652,006**	**100.00%**

16.1.2 HISTORY OF ALLOCATION OF SHARE CAPITAL

Shareholders	As of December 31, 2016		As of December 31, 2017		As of December 31, 2018		As of December 31, 2019	
	Number of shares/ voting rights post-reverse stock split	% of share capital/ voting rights	Number of shares/ voting rights post-reverse stock split	% of share capital/ voting rights	Number of shares/ voting rights post-reverse stock split	% of share capital/ voting rights	Number of shares/ voting rights post-reverse stock split	% of share capital/ voting rights
Founders	**1,710,684**	**8.65%**	**2,095,086**	**8.81%**	**2,320,086**	**9.35%**	**2,420,086**	**7.37%**
Sofinnova Partners	–	–	–	–	–	–	5,610,044	17.09%
Novartis Pharma AG	3,521,774	14.53%	3,521,774	18.14%	3,521,774	14.20%	1,390,487	< 5%
Abingworth Bioventures VI LP	2,873,306	12.96%	3,139,973	14.80%	3,139,973	12.66%	1,402,588	< 5%
Versant	2,947,048	13.54%	3,280,381	15.18%	3,280,381	13.23%	3,280,381	9.99%
Vitavest S.à.r.l	1,206,373	5.53%	1,339,706	6.22%	1,339,706	5.40%	1,339,706	< 5%
Bpifrance Investissement	975,666	4.03%	975,666	5.03%	975,666	3.93%	975,666	< 5%
Fidelity	1,860,895	6.72%	1,628,865	9.59%	1,060,344[1]	4.28%	1,060,344	< 5%
Bpifrance Participations	1,500,000	8.25%	2,000,000	7.73%	2,000,000	8.06%	2,000,000	6.09%
Other investors	2,813,955	25.80%	6,252,772	14.50%	7,165,043	28.89%	13,348,060	40.66%
Total	**19,409,701**	**100%**	**24,234,223**	**100%**	**24,802,973**	**100%**	**32,827,362**	**100%**

(1) As per public filing dated October 19, 2018.

During the last four years, the following events have changed the number and classes of the issued and our outstanding shares:

- In 2016:
  - On July 13, 2016, we completed our Initial Public Offering (IPO) on Euronext Paris, raising €40.0 million, and issued 5,000,000 ordinary shares.
  - On August 10, 2016, we partly exercised the overallotment option as part of our IPO on Euronext Paris, raising an additional €5.2 million, and issued 655,859 ordinary shares.
  - These figures give effect to the 5-for-2 reverse split of our outstanding shares approved by the general shareholders' meeting on August 17, 2015, which became effective on September 3, 2015, 15 days after publication of the notice of the split in the French *Bulletin des Annonces Légales Obligatoires*, or BALO, pursuant to French law.
- In 2017:
  - On June 27, 2017, we issued 3,750,000 ordinary shares in a private placement on Euronext Paris for which we received net proceeds of €20,724 K.
- In 2019:
  - On February 25, 2019, we issued 3,921,568 ordinary shares in a private placement subscribed entirely by Sofinnova Crossover I SLP for which we received net proceeds of €7,906 K.
  - On December 19, 2019, we issued 3,799,071 new shares with a nominal value of €0.025 each in a private placement subscribed entirely by Sofinnova Crossover I SLP and 3SBio for which we received net proceeds of €8,276 K.

16.2 SHAREHOLDERS' VOTING RIGHTS

Each of our share, either ordinary or preferred, entitles the holder to one vote.

Our bylaws, by express derogation to article L.225-123 paragraph 3 of the French Commercial Code, do not grant double voting rights to our shares.

16.3 CONTROL STRUCTURE

As of the date of this Universal Registration Document, no shareholder has exclusive control over the Company.

16.4 AGREEMENT LIKELY TO A CHANGE OF CONTROL

To our knowledge, there are no provisions either in the Company's bylaws or in any internal charter or internal rules that could have the effect of delaying, postponing or preventing a change of control of the Company.

7 RELATED PARTY TRANSACTIONS

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RELATED PARTY TRANSACTIONS

We comply with French law regarding approval of transactions with related parties. Since January 1, 2015, we have engaged in the following transactions with our directors, executive officers and holders of more than 5% of our outstanding voting securities and our affiliates, which we refer to as our related parties.

17.1 AGREEMENTS WITH THE COMPANY'S MAJOR SHAREHOLDERS

17.1.1 SHAREHOLDERS' AGREEMENT

In connection with our initial public offering on Euronext Paris, Bpifrance Participations, Mr. José Sahel, Mr. Bernard Gilly, Novartis Pharma AG, Abingworth Bioventures VI L.P., Versant Venture Capital IV, L.P., Versant Side Fund IV, L.P., Vitavest S.à.r.l. and *Fonds Biothérapies Innovantes et Maladies Rares*, several of our major shareholders, have entered into a shareholders' agreement to organize their relationship as shareholders of our Company. Under this shareholders' agreement, the parties have also agreed to vote in a certain way with respect to (i) the election of a director and an observer proposed by Bpifrance Large Venture and (ii) the modification of the internal rules in order to grant the Board of Directors the power to approve strategic investments and to increase its information rights.

17.1.2 LICENSE AGREEMENT WITH NOVARTIS PHARMA AG

On February 5, 2013, we entered into a license agreement with Novartis Pharma AG, or Novartis, pursuant to which we have an exclusive in-license to research, develop, make, use, sell, offer for sale or otherwise distribute, import and export any products within the scope of the patents and patent applications under two patent families for all ophthalmologic uses. This license agreement relates to our GS020 product candidate, which is not currently part of our product and development pipeline. As the licensee, we may grant and authorize sublicenses within the scope of the license granted by Novartis, as the licensor, provided that we notify Novartis for prior approval, which shall only be withheld by Novartis for duly justified ethical reasons. In consideration for the rights granted by Novartis to us, we paid Novartis an upfront license fee through the issuance of 670,588 (corresponding to 268,235 after taking into account the reverse share split on September 3, 2015) new ordinary shares, corresponding to 15% of our share capital. The subscription of such shares was made by offsetting the upfront license fee claim against Novartis. In compliance with IAS38, the rights acquired have been recorded as intangible assets at the fair value of the ordinary shares issued in payment. The fair value of the 670,588 ordinary shares is €0.41 per ordinary share. For more information, please see Note 21 to our consolidated financial statements as of December 31, 2019 and Section 5.2.3, "Our Second Product Candidate: GS030 for the Treatment of Photoreceptor Degeneration" of this Universal Registration Document.

17.2 TRANSACTIONS WITH KEY MANAGEMENT PERSONS

17.2.1 FOUNDER NON-COMPETE UNDERTAKING

In March 2017, the Board of Directors authorized our entry into an agreement with Mr. Gilly pursuant to which Mr. Gilly would agree not to engage in certain competitive activities for a period of one year from his departure from the Company in the event that he terminates his duties with us. For a period of one year from the termination of this undertaking, and unless we elect to waive these restrictions, we will be required to make a monthly payment of 40% of Mr. Gilly's last total net monthly compensation excluding any bonuses for a period of one year following his termination.

17.2.2 LEASE AGREEMENT WITH *PASSAGE DE L'INNOVATION*

On January 1, 2015, we entered into a sublease agreement for our new premises with *Passage de l'Innovation*, amended on October 1, 2015, January 1, 2016, April 25, 2017, July 1, 2018, October 1, 2018 and November 1, 2019. Pursuant to this last amendment, we will have to pay €494 K excluding taxes, on an annual basis, comprised of €285 K for rent, €17 K for rental charges and up to €190 K for other services provided by the lessor through the end of 2024. In 2019, we paid an amount of €526 K, comprised of €289 K for rent, €17 K for rental charges and €219 K for other services (including reception desk, maintenance, cleaning services, IT management and services, access to shared areas such as equipped meeting rooms and a lunch area). The decrease of rental costs from 2018 to 2019 derives from a slight decrease of the total rented space. The President of the *Passage de l'Innovation* and one of its shareholders was Bernard Gilly, our Chief Executive Officer, until he resigned from this position in *Passage de l'Innovation* on June 30, 2016. Mr. Gilly has retained a shareholding interest in this company. The amounts the *Passage de l'Innovation* has charged, and currently charges us are at fair market value.

17.2.3 EMPLOYMENT ARRANGEMENTS

Bernard Gilly

Mr. Gilly, our Chief Executive Officer, does not have an employment agreement with us. Mr. Gilly's compensation is determined by our Board of Directors upon recommendation of the Compensation Committee. On February 14, 2013, our Board of Directors resolved that we may pay Dr. Gilly a termination payment equal to the last 12 months of his fixed and variable compensation not capped except in the event of (1) dismissal by us for gross negligence or (2) resignation, other than resignation for health or family reasons. On March 9, 2017, our Board of Directors resolved to replace this termination payment by a termination payment satisfying the requirements under Article L.225-42-1 of the French Commercial Code. Consequently, subject to the satisfaction of certain performance criteria, the Company may pay Mr. Gilly a

termination payment equal to the last 12 months of his fixed and variable compensation, except in the event of (1) dismissal by us for gross negligence or (2) resignation, other than resignation for health or family reasons. The Board of Directors resolved that such termination payment shall not be paid in the case of a change in the duties performed by Mr. Gilly or in the event that he decides on his own initiative to leave the Company to perform new duties.

On March 9, 2017, our Board of Directors resolved that we may pay to Mr. Gilly for a period of one year from the termination of his duties, a monthly payment of 40% of his total net monthly compensation excluding any bonuses in consideration of his undertaking not to engage in certain competitive activities for a period of one year from the termination of his duties.

Pursuant to the Sapin 2 Law, the terms of Bernard Gilly's employment arrangement must be approved by the shareholders' meeting which will be held on June 11, 2019.

Employment Agreements with Key Management Persons

We have entered into employment agreements with Thomas Gidoin and Magali Taïël. These agreements have standard terms relating to base salary, bonuses, equity grants, termination and restrictions on competitive activities.

17.3 REGULATED AGREEMENTS

Agreements entered into between a corporate officer or a shareholder holding more than 10% of the Company's voting rights, and another corporation controlled by the Company within the meaning of Article L.233-3 of the French Commercial Code (excluding agreements which relate to ordinary transactions and have been entered into upon customary terms & conditions).

No such agreements exisit.

17.4 STATUTORY AUDITORS' SPECIAL REPORT ON REGULATED AGREEMENTS

Shareholders' Meeting held to approve the financial statements for the year ended December 31, 2019

This is a free translation into English of the Statutory Auditors' report on regulated agreements with third parties that is issued in the French language and is provided solely for the convenience of English speaking readers. This report on regulated agreements should be read in conjunction, and construed in accordance with, French law and professional auditing standards applicable in France. It should be understood that the agreements reported on are only those provided by the French Commercial Code and that the report does not apply to those related party transactions described in IAS 24 or other equivalent accounting standards.

To the GENSIGHT BIOLOGICS S.A. Shareholders' Meeting,

In our capacity as Statutory Auditors of your Company, we hereby report on regulated agreements.

We are required to inform you, based on information provided to us, of the characteristics and principal terms and conditions as well as the reasons justifying the interest for your Company of those agreements of which we have been informed or which we discovered at the time of our engagement, without expressing an opinion on their usefulness and appropriateness or identifying such other agreements, if any. It is your responsibility, pursuant to article R.225-31 of the French Commercial Code *(Code de Commerce)*, to assess the interest involved in respect of the conclusion of these agreements prior to their approval.

Furthermore, we are required, where applicable, to inform you in accordance with article R.225-31 of the French Commercial Code *(Code de Commerce)* relating to the performance, during the past fiscal year, of the agreements already approved by the Annual Shareholders' Meeting.

We performed the procedures that we considered necessary with regard to the professional guidelines of the French National Institute of Statutory Auditors *(Compagnie Nationale des Commissaires aux Comptes)* applicable to this engagement.

AGREEMENTS SUBMITTED TO THE APPROVAL OF THE ANNUAL SHAREHOLDERS' MEETING

We hereby inform you that we have not been advised of any agreement authorized and concluded during the year to be submitted to the approval of the Shareholders' Meeting pursuant to Article L.225-38 of the French Commercial Code *(Code de Commerce)*.

AGREEMENTS PREVIOUSLY APPROVED BY THE SHAREHOLDERS' MEETING

We hereby inform you that we have not been advised of any agreements previously approved by the Shareholders' Meeting which continued in effect during the year.

Paris and Bordeaux, April 8, 2020

The Statutory Auditors
French original signed by

Becouze
Fabien BROVEDANI

Deloitte & Associés
Stéphane LEMANISSIER

FINANCIAL INFORMATION CONCERNING THE GROUP'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES

18.1 HISTORICAL FINANCIAL INFORMATION

The tables below present selected financial information and the income statement and other data of the Company, as of and for the periods ended on the dates indicated below.

This Universal Registration Document includes our annual consolidated financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2019 presented in this Universal Registration Document in Section 18.1.1, "Company's Annual Consolidated Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2019."

This Universal Registration Document also includes the financial statements of the parent company, prepared in accordance with French accounting standards for the fiscal year ended December 31, 2019. These financial statements are presented in Section 18.1.3, "Company's Annual Financial Statements (French GAAP) for the Fiscal Year Ending December 31, 2019" of this Universal Registration Document.

Unless otherwise indicated, the selected financial information as of and for the fiscal year ended December 31, 2019 has been derived from our consolidated financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2019. These consolidated financial statements for the fiscal year ended December 31, 2019 have been audited by Deloitte & Associés and Becouze, statutory auditors. The statutory auditors' report on the consolidated financial statements as of and for the fiscal year ended December 31, 2019 is included in Section 18.1.2, "Statutory Auditors' Report on the Company's Annual Consolidated Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2019" of this Universal Registration Document.

The information in this section should be read together with (i) our consolidated financial statements contained in Section 18.1.1, "Company's Annual Consolidated Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2019" of this Universal Registration Document, (ii) our analysis of our results presented in Section 7, "Operating and Financial Review," and (iii) our analysis of our liquidity and capital resources presented in Section 8, "Capital Resources."

18.1.1 COMPANY'S ANNUAL CONSOLIDATED FINANCIAL STATEMENTS (IFRS) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2019

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		As of December 31,	
In thousands of euros	Notes	2018	2019
ASSETS			
Non-current assets			
Intangible assets	4	168	154
Property, plant and equipment	5	1,396	4,228
Other non-current financial assets	7	331	336
Total non-current assets		**1,895**	**4,718**
Current assets			
Trade accounts receivable	8	2	846
Other current assets	8	8,840	7,669
Cash and cash equivalents	9	26,241	19,250
Total current assets		**35,084**	**27,765**
TOTAL ASSETS		**36,979**	**32,483**

In thousands of euros	Notes	As of December 31, 2018	2019
LIABILITIES			
Shareholders' equity	10		
Share capital		620	821
Premiums related to the share capital		112,135	128,130
Reserves		(55,432)	(86,495)
of wich cumulative translation adjustment		*(32)*	*(22)*
Net income (loss)		(33,453)	(30,710)
Total shareholders' equity		**23,870**	**11,746**
Non-current liabilities			
Corporate bonds– non-current portion	11	—	3,732
Conditional advances – non-current portion	11	3,441	3,633
Lease liability – non-current portion	11	—	2,763
Non-current provisions	12	65	103
Total non-current liabilities		**3,506**	**10,231**
Current liabilities			
Corporate bonds– current portion	11	—	889
Lease liability – current portion	11	—	563
Trade accounts payable	13	7,593	7,139
Current provisions		—	22
Other current liabilities	13	2,009	1,893
Total current liabilities		**9,602**	**10,506**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		**36,979**	**32,483**

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

		As of December 31,	
In thousands of euros	Notes	2018	2019
Operating income			
Revenues	15	—	700
Other income	16	4,346	4,210
Total operating income		**4,346**	**4,910**
Operating expenses			
Research and development	17	29,031	28,710
General and administrative	17	7,010	5,736
Sales and marketing	17	1,350	762
Total operating expenses		**37,391**	**35,208**
Operating profit (loss)		**(33,045)**	**(30,298)**
Financial income	19	44	95
Financial expenses	19	(452)	(504)
Financial income (loss)		**(408)**	**(409)**
Income tax	20	—	(4)
Net income (loss)		**(33,453)**	**(30,710)**
Basic and diluted earnings (loss) per share (in euro)	23	**(1.37)**	**(1.08)**

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	As of December 31,	
In thousands of euros	2018	2019
Net income (loss)	(33,453)	(30,710)
Actuarial gains and losses on employee benefits, net of income tax	16	(1)
Foreign currency translation differences, net of income tax	(32)	(15)
Total comprehensive income (loss)	**(33,469)**	**(30,726)**

CONSOLIDATED STATEMENTS OF CASH FLOWS

		As of December 31,	
In thousands of euros	Notes	2018	2019
Cash flows from operating activities			
Net income (loss)		(33,453)	(30,710)
Operating activities			
Amortization and depreciation	4 & 5	315	985
Retirement pension obligations	12	28	35
Expenses related to share-based payments	18.5	2,422	1,307
Other financial items	19	410	371
Other non-monetary items		—	45
Operating cash flows before change in working capital		**(30,278)**	**(27,967)**
Accounts receivable		9	(844)
Accounts payable, net of prepayments		5,233	(223)
Other receivables		(3,478)	964
Other current liabilities		132	(42)
Change in working capital		**1,896**	**(145)**
Net cash flows from operating activities		**(28,383)**	**(28,112)**
Cash flows from investment activities			
Acquisitions of property, plant and equipment	5	(789)	(69)
Acquisitions of intangible assets	4	(2)	(7)
Acquisitions/reimbursement of non-current financial assets		8	(26)
Acquisitions/reimbursement of current financial assets		120	—
Net cash flows from investment activities		**(663)**	**(102)**
Cash flows from financing activities			
New borrowings obtained	11	—	5,672
Repayment of obligation under finance leases	10	—	(649)
Treasury shares		(123)	26
Warrants issuance	17	8	6
Capital increases, net of transaction costs	9	—	16,190
Net cash flows from financing activities		**(115)**	**21,245**
Increase/(decrease) in cash and cash equivalents		**(29,160)**	**(6,969)**
Cash and cash equivalents at the beginning of the period		55,448	26,241
Effect of changes in exchange rates on cash and cash equivalents		(47)	(22)
Cash and cash equivalents at the close of the period		**26,241**	**19,250**

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

In thousands of euros, except for number of shares	Share Capital		Premiums related to the share capital	Reserves	Net income (loss)	Total Shareholders' Equity
	Number of shares	Amount				
At January 1, 2018	**24,234,223**	**606**	**112,140**	**(33,638)**	**(24,112)**	**54,996**
Net income (loss)	—	—	—	—	(33,453)	(33,453)
Cumulative translation adjustment	—	—	—	(32)	—	(32)
Other comprehensive income	—	—	—	16	—	16
Total comprehensive income (loss)	**—**	**—**	**—**	**(16)**	**(33,453)**	**(33,469)**
Allocation of prior period net income (loss)	—	—	—	(24,112)	24,112	—
Allocation to reserves	—	—	—	—	—	—
Capital increase by issuance of ordinary shares	568,750	14	(5)	—	—	9
Capital increase transaction costs	—	—	—	—	—	—
Capital increases related to exercises of warrants	—	—	—	—	—	—
Treasury shares	—	—	—	(88)	—	(88)
Share-based payments	—	—	—	2,422	—	2,422
At December 31, 2018	24,802,973	620	112,135	(55,432)	(33,453)	23,870
At January 1, 2019	**24,802,973**	**620**	**112,135**	**(55,432)**	**(33,453)**	**23,870**
Net income (loss)	—	—	—	—	(30,710)	(30,710)
Cumulative translation adjustment	—	—	—	(15)	—	(15)
Other comprehensive income	—	—	—	(1)	—	(1)
Total comprehensive income (loss)	**—**	**—**	**—**	**(16)**	**(30,710)**	**(30,726)**
Allocation of prior period net income (loss)	—	—	—	(33,453)	33,453	—
Allocation to reserves	—	—	—	—	—	—
Capital increase by issuance of ordinary shares	8,024,389	193	16,807	—	—	17,000
Capital increase transaction costs	—	—	(818)	—	—	(818)
Convertible bonds reclassification	—	—	—	1,070	—	1,070
Exercise and subscription of equity instruments	—	8	6	—	—	14
Treasury shares	—	—	—	29	—	29
Share-based payments	—	—	—	1,307	—	1,307
At December 31, 2019	32,827,362	821	128,130	(86,495)	(30,710)	11,746

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1: General information about the Company

Founded in 2012, GenSight Biologics S.A. (hereinafter referred to as **"GenSight Biologics"** or the **"Company"** and together with its subsidiary as the **"Group"**) is a clinical-stage biotechnology group discovering and developing novel therapies for neurodegenerative retinal diseases and diseases of the central nervous system. GenSight Biologics' pipeline leverages two core technology platforms, the Mitochondrial Targeting Sequence (MTS) and optogenetics, to help preserve or restore vision in patients suffering from severe degenerative retinal diseases. The Group focus is in ophthalmology where it develops product candidates to restore eyesight to patients suffering from retinal diseases that would otherwise lead to blindness.

The Company has incurred losses and negative cash flows from operations since its inception and shareholders' equity amounts to €11,746 K as of December 31, 2019 as a result of several financing rounds (see Note 9). The Group anticipates incurring additional losses until such time, if ever, that it can generate significant revenue from its product candidates in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

The Group's future operations are highly dependent on a combination of factors, including: (i) the success of its research and development; (ii) regulatory approval and market acceptance of the Group's proposed future products; (iii) the timely and successful completion of additional financing; and (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies.

The presented consolidated Financial Statements are expressed in thousands of euros, unless stated otherwise. The reporting date for the consolidated financial statements is December 31, and covers a twelve-month period. The individual statements of the consolidated subsidiary GenSight Biologics Inc. are prepared at the same reporting date, *i.e.*, December 31, and cover a one-year period for both the parent company and its subsidiary.

The consolidated financial statements as of December 31, 2019 have been prepared under the responsibility of management of the Group and were approved on March 11, 2020 by the Board of Directors.

MAIN EVENTS OF THE FISCAL YEAR

On February 4, 2019, GenSight Biologics reports topline results at Week 48 of the RESCUE Phase III clinical trial of GS010, which evaluates the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) occurred up to 6 months prior to study treatment.

On February 25, 2019, GenSight Biologics announced the completion of a capital increase of €8 million subscribed entirely by Sofinnova Crossover I SLP ("Sofinnova"). The purpose of this capital increase is to pursue the final stages of clinical development of GS010, and file for marketing authorization in Europe. .

On April 17, 2019, the Company announced results from the second scheduled readout, at Week 72, of the RESCUE Phase III clinical trial evaluating the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) occurred up to 6 months prior to study treatment.

On May 7, 2019, GenSight Biologics announced that the independent Data Safety Monitoring Board (DSMB) completed its first safety review of the ongoing PIONEER Phase I/II clinical trial of GS030 combining gene therapy and optogenetics for the treatment of Retinitis Pigmentosa. The DSMB confirmed the absence of any safety issues for the first cohort of three subjects who received a single intravitreal injection of 5e10 vg combined with a wearable optronic visual stimulation device. The DSMB recommended moving forward as planned without any modification in the protocol and recruiting the second cohort of three subjects receiving an escalating dose of 1.5e11 vg.

On May 15, 2019, GenSight Biologics reported a first set of results from Week 96 of the REVERSE Phase III clinical trial. The trial evaluated the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 37 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) commenced between 6 and 12 months prior to study treatment.

On July 11, 2019, the Company announced that enrollment in REFLECT, a Phase III clinical trial of GS010 for the treatment of Leber Hereditary Optic Neuropathy (LHON), was successfully completed ahead of schedule.

On September 23, 2019, GenSight Biologics reported the first set of results from Week 96 of the RESCUE Phase III clinical trial. The trial evaluated the efficacy and safety of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) commenced up to 6 months prior to study treatment.

On October 9, 2019, the Company reported positive proof of GS010 DNA transfer from one eye to the other eye following unilateral intravitreal injection of primates. In a non-clinical study to investigate the local biodistribution of GS010, tissue samples from the non-injected eye of monkeys that had been unilaterally injected with GS010 were found to contain GS010 DNA three months after injection, indicating the expression of the therapeutic gene in the contralateral eye.

On December 9, 2019, GenSight announced that the French Competent Authority, the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM), granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*.

On December 11, 2019, the Group reported results from the REALITY registry study and an analysis of REVERSE and RESCUE Phase III data, which further highlight the poor prognosis for patients with loss of vision due to Leber Hereditary Optic Neuropathy (LHON) associated with the ND4 mutation. The results confirm LHON experts' observations from their clinical practice and contrast sharply against the bilateral improvement observed in LUMEVOQ™ (GS010)'s Phase III studies.

On December 20, 2019, GenSight Biologics announced that it had obtained committed financing in the form of a bond financing of up to €12 million from Kreos Capital VI (UK) Limited ("Kreos") and issued a drawdown notice thereunder for the first tranche of €6 million (the "Kreos Transaction") concurrently with the completion of a capital increase of €9 million subscribed for by one of its main shareholders Sofinnova Crossover I SLP ("Sofinnova") and by a new strategic Chinese investor Strategic International Group Limited, a wholly owned subsidiary of 3SBio Inc. ("3SBio") (the "3SBio-Sofinnova Transaction").

Note 2: Statement of compliance and transition to IFRS

2.1 Statement of compliance

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). As the shares of the Company are listed on Euronext Paris, in compliance with European regulation n°1606 / 2002 adopted on July 19, 2002 by the European Parliament and the European Council, the Group's consolidated financial statements for the year ended December 31, 2019 were prepared in accordance with IFRS, as endorsed by the European Union on the date of preparation.

The IFRS as adopted by the European Union differ in certain aspects with the IFRS published by the IASB. Nevertheless, the Group ensured that the financial information for the periods presented is not substantially different between IFRS published by the IASB and IFRS as adopted by the European Union. International accounting standards include IFRS, International Accounting Standards (IAS), as well as the interpretations issued by the Standing Interpretations Committee (SIC), and the International Financial Reporting Interpretations Committee (IFRIC).

New standards, amendments and interpretations that became applicable to the Group from January 1, 2019

- Impact of initial application of IFRS 16 Leases

In the current year, the Group has applied IFRS 16 (as issued by the IASB in January 2016) that is effective for annual periods that begin on or after January 1, 2019.

IFRS 16 introduces new or amended requirements with respect to lease accounting. It introduces significant changes to lessee accounting by removing the distinction between operating and finance lease and requiring the recognition of a right-of-use asset and a lease liability at commencement for all leases, except for short-term leases and leases of low value assets. In contrast to lessee accounting, the requirements for lessor accounting have remained largely unchanged. Details of these new requirements are described in Note 6: IFRS 16 - Leases. The impact of the adoption of IFRS 16 on the Group's consolidated financial statements is described below.

The Group has opted for the simplified retrospective method, which consists of recognizing the impact of the first-time adoption of IFRS 16 on January 1, 2019.

(a) Impact of the new definition of a lease

The Group has made use of the practical expedient available on transition to IFRS 16 not to reassess whether a contract is or contains a lease. Accordingly, the definition of a lease in accordance with IAS 17 and IFRIC 4 will continue to be applied to those contracts entered or modified before 1 January 2019.

The change in definition of a lease mainly relates to the concept of control. IFRS 16 determines whether a contract contains a lease on the basis of whether the customer has the right to control the use of an identified asset for a period of time in exchange for consideration. This is in contrast to the focus on 'risks and rewards' in IAS 17 and IFRIC 4.

The Group applies the definition of a lease and related guidance set out in IFRS 16 to all contracts entered into or changed on or after January 1, 2019. In preparation for the first-time application of IFRS 16, the Group has carried out an implementation project. The project has shown that the new definition in IFRS 16 will not significantly change the scope of contracts that meet the definition of a lease for the Group.

(b) Impact on Lessee Accounting

(i) Former operating leases

IFRS 16 changes how the Group accounts for leases previously classified as operating leases under IAS 17, which were off balance sheet.

Applying IFRS 16, for all leases (except as noted below), the Group:

(a) Recognizes right-of-use assets and lease liabilities in the consolidated statement of financial position, initially measured at the present value of the future lease payments;

(b) Recognizes depreciation of right-of-use assets and interest on lease liabilities in profit or loss;

(c) Separates the total amount of cash paid into a principal portion (presented within financing activities) and interest (presented within financing activities) in the consolidated statement of cash flows.

Lease incentives (*e.g.* rent-free period) are recognized as part of the measurement of the right-of-use assets and lease liabilities whereas under IAS 17 they resulted in the recognition of a

lease incentive, amortized as a reduction of rental expenses generally on a straight-line basis.

Under IFRS 16, right-of-use assets are tested for impairment in accordance with IAS 36.

For short-term leases (lease term of 12 months or less) and leases of low-value assets (such as tablet and personal computers, small items of office furniture and telephones), the Group has opted to recognize a lease expense on a straight-line basis as permitted by IFRS 16. This expense is presented within 'other expenses' in profit or loss.

(ii) Former finance leases

The main differences between IFRS 16 and IAS 17 with respect to contracts formerly classified as finance leases is the measurement of the residual value guarantees provided by the lessee to the lessor. IFRS 16 requires that the Group recognizes as part of its lease liability only the amount expected to be payable under a residual value guarantee, rather than the maximum amount guaranteed as required by IAS 17. This change did not have a material effect on the Group's consolidated financial statements.

- Other standards
  - In the current year, the Group has applied a number of amendments to IFRS Standards and Interpretations issued by the IASB that are effective for an annual period that begins on or after January 1, 2019. Their adoption has not had any material impact on the disclosures or on the amounts reported in these financial statements.
  - Amendments to IFRS 9 Prepayment Features with Negative Compensation
  - Amendments to IAS 28 Long-term Interests in Associates and Joint Ventures
  - Annual Improvements to IFRS Standards 2015–2017 Cycle Amendments to IFRS 3 Business Combinations, IFRS 11 Joint Arrangements, IAS 12 Income Taxes and IAS 23 Borrowing Costs
  - Amendments to IAS 19 Employee Benefits Plan Amendment, Curtailment or Settlement
  - IFRIC 23 Uncertainty over Income Tax Treatments

  The Group has adopted IFRIC 23 for the first time in the current year. IFRIC 23 sets out how to determine the accounting tax position when there is uncertainty over income tax treatments. The Interpretation requires the Group to:
  - determine whether uncertain tax positions are assessed separately or as a group; and
  - assess whether it is probable that a tax authority will accept an uncertain tax treatment used, or proposed to be used, by an entity in its income tax filings: If yes, the Group should determine its accounting tax position consistently with the tax treatment used or planned to be used in its income tax filings.

  If no, the Group should reflect the effect of uncertainty in determining its accounting tax position using either the most likely amount or the expected value method.

New and revised IFRS Standards in issue but not yet effective

At the date of authorization of these financial statements, the Group has not applied the following new and revised IFRS Standards that have been issued but are not yet effective:

- IFRS 17 *Insurance Contracts*
- IFRS 10 and IAS 28 (amendments) *Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*
- Amendments to IFRS 3 *Definition of a business*
- Amendments to IAS 1 and IAS 8 *Definition of material*
- Conceptual Framework *Amendments to References to the Conceptual Framework in IFRS Standards*

The directors do not expect that the adoption of the Standards listed above will have a material impact on the financial statements of the Group in future periods.

2.2 Going concern

Since its incorporation, the Company has funded its activities through several equity financings, grants, conditional advances and Research Tax Credit. In 2019, the Company started to generate revenue from the sale of LUMEVOQ™ (GS010) to the *CHNO des Quinze-Vingts* in Paris, since the National Drug Safety Agency (ANSM) granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™. To date, the Company continues to actively prepare for the launch of LUMEVOQ™ in Europe in 2021 and in the United States in 2022.

Current cash and cash equivalents on hand are not projected to be sufficient to support the Company's current operating plan for a period of 12 months following the date of issuance of the 2019 annual consolidated financial statements. Considering the cash position as of December 31, 2019 (amounting to €19.2 million), the reimbursement of the 2019 Research Tax Credit contemplated in 2020 for a consideration of €4.2 million and additional expected income related to the ATU in France cautiously forecasted at €7.0 million, the Company expects to cover its cash requirements until the end of November 2020.

We believe that the €7.0 million income from the ATU in France, representing 10 patients treated, is a cautious estimate. Any additional request approved would reduce the need for financing and extend the runway accordingly.

In order to meet these obligations and subject to the realization of a Qualifying Financing[(1)] of €10 million, the Company will be able to receive a second tranche of €4.0 million from the bond issuance with Kreos Capital. The Company will also explore other financing options through debt or equity in order to complete its working capital needs and to finance its operating expenses. In

this respect, a third optional tranche of €2 million could be made available to the Company by Kreos Capital at a later date.

The annual consolidated financial statements have been prepared on a going concern basis assuming that the Company will either be successful in its additional financing objections or that the Company will modify its operating plans, in particular by delaying or limiting the scope of its research and development programs. However, no assurance can be given at this time as to whether the Company will be able to achieve these financing objectives. As such, there are material uncertainties regarding the Company's ability to continue as a going concern. No adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should the Company not be able to continue as a going concern.

Note 3: Accounting principles

3.1 Consolidation scope and methods

On April 28, 2017 the Group incorporated GenSight Biologics Inc. in the United States. As 100% of the voting rights and ownership interests are held by the Group, GenSight Biologics Inc. is fully consolidated.

3.2 Functional currency and translation of financial statements in foreign currency

The Financial Statements are presented in thousands of euros ("KEuros"), which is also the functional currency of the parent Company GenSight Biologics S.A. The statements of financial position of GenSight Biologics Inc. having a functional currency different from the euro are translated into euros at the closing exchange rate (spot exchange rate at the statement of financial position date), and the statements of income, statements of comprehensive income and statement of cash flow of GenSight Biologics Inc. are translated at the average period to date exchange rate. The resulting translation adjustments are included in equity under the caption "Cumulative translation adjustment" in the Consolidated Statement of Changes in Shareholders' Equity.

3.3 Intangible assets

Pursuant to IAS 38 *Intangible Assets* **("IAS 38")**, intangible assets acquired are recognized as assets on the Consolidated Statement of Financial Position at their acquisition cost.

Research and development

Research costs are recorded in the Financial Statements as expenses.

In accordance with IAS 38, development costs are recognized in the Financial Statements as intangible assets only if all of the following criteria are met:

(a) it is technically feasible to complete the development of the project;

(b) intention on the part of the Company to complete the project and to utilize it;

(c) capacity to utilize the intangible asset;

(d) proof of the probability of future economic benefits associated with the asset;

(e) availability of the technical, financial and other resources for completing the project; and

(f) reliable evaluation of the development expenses.

Because of the risks and uncertainties related to regulatory authorizations and to the research and development process, the Company believes that the six criteria stipulated by IAS 38 have not been fulfilled to date and the application of this principle has resulted in all development costs to be expensed as incurred in all periods presented.

Software

The costs related to the acquisition of licenses for software are recognized as assets on the basis of the costs incurred to acquire and to implement the software. They are amortized using the straight-line method over a period of one to three years depending on the anticipated period of use.

License

In February 2013, the Company entered into a partnership agreement with Novartis Pharma AG ("Novartis") which provides for exclusive in-licenses for two patent families. The Company issued 670,588 ordinary shares as consideration paid for the exclusive licenses. Given that the fair value of the licenses cannot be reliably estimated, in accordance with IFRS 2, the amount of the intangible asset being recognized has been determined by reference to the fair value of the ordinary shares that were granted by the Company, based on an independent valuation. The licenses are amortized over 15 years from the date the agreement was signed, which corresponds to the expected useful life of the licenses.

3.4 Property, plant and equipment

Property, plant and equipment are recorded at their acquisition cost or, if applicable, at their production cost.

Property, plant and equipment are depreciated using the straight-line method over the estimated useful period of the property.

(1) Qualifying Financing means a financing of the Company in the form of equity (or Non-Dilutive Payment or subordinated convertible bonds, or a combination of the above) from existing shareholders and/or new top tier investors reasonably satisfactory to Kreos, with a minimal amount of gross proceeds of €10 million, being specified that such amount may be reduced, up to a maximal amount of €2 million, by the proceeds susceptible to be received by the Company under *Autorisations Temporaires d'Utilisation payantes*.

Rented fixtures are depreciated over the term of their lifetime or over the term of the rental agreement, whichever is shorter.

The depreciation periods used are the following:

Property, plant and equipment item	Depreciation period
Fixtures and improvements in structures	9 years
Research and development / production tools	5 to 10 years
Computer equipment	3 years
Office equipment and furniture	5 years

3.5 Financial assets

Financial assets are initially measured at fair value plus directly attributable transaction costs in the case of instruments not measured at fair value through profit or loss. Directly attributable transaction costs of financial assets measured at fair value through profit or loss are recorded in the consolidated statement of income (loss).

Under IFRS 9, financial assets are classified in the following three categories:

- Financial assets at amortized cost;
- Financial assets at fair value through other comprehensive income ("FVOCI"); and
- Financial assets at fair value through profit or loss.

The classification of financial assets depends on:

- The characteristics of the contractual cash flows of the financial assets; and
- The business model that the entity follows for the management of the financial asset.

Financial assets at amortized cost

Financial assets are measured at amortized cost when (i) they are not designated as financial assets at fair value through profit or loss, (ii) they are held within a business model whose objective is to hold assets in order to collect contractual cash flows and (iii) they give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding ("SPPI" criterion). They are subsequently measured at amortized cost, determined using the effective interest method ("EIR"), less any expected impairment losses in relation to the credit risk. Interest income, exchange gains and losses, impairment losses and gains and losses arising on derecognition are all recorded in the consolidated statement of income (loss).

This category primarily includes trade receivables, as well as other loans and receivables. Long-term loans and receivables that are not interest-bearing or that bear interest at a below-market rate are discounted when the amounts involved are material.

Financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income is mainly comprised is composed of debt instruments whose contractual cash flows represent payments of interest or repayments of principal, and which are managed with a view to collecting cash flows and selling the asset. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such assets are derecognized, the cumulative gains and losses previously recognized in equity are reclassified to profit or loss for the period within the line items Financial income or Financial expenses. The Company did not hold this type of instrument as of January 1, 2019 nor as of December 31, 2019.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss is comprised of:

- instruments whose contractual cash flows represent payments of interest or repayments of principal, but which are managed other than with a view to collecting cash flows and/or selling the asset; and
- instruments that management has designated as "fair value through profit or loss" on initial recognition.

Gains and losses arising from changes in fair value are recognized in profit or loss within the line items financial income or financial expenses.

Impairment of financial assets measured at amortized cost

The main assets involved are trade receivables and others. Trade receivables are recognized when the Company has an unconditional right to payment by the customer. Impairment losses on trade receivables and others are estimated using the expected loss method, in order to take account of the risk of payment default throughout the lifetime of the receivables. The expected credit loss is estimated collectively for all accounts receivable at each reporting date using an average expected loss rate, determined primarily on the basis of historical credit loss rates. However, that average expected loss rate may be adjusted if there are indications of a likely significant increase in credit risk. If a receivable is subject to a known credit risk, a specific impairment loss is recognized for that receivable. The amount of expected losses is recognized in the balance sheet as a reduction in the gross amount of accounts receivable. Impairment losses on accounts receivable are recognized within Operating expenses in the consolidated statement of income (loss).

3.6 Recoverable amount of the intangible assets and property, plant and equipment

The property, plant and equipment and intangible assets that have an established lifetime are subject to an impairment test when the recoverability of their book value is called into question by the existence of indications of impairment. An impairment is

recognized in the Financial Statements up to the amount of the excess of the book value over the recoverable value of the asset. The recoverable value of an asset corresponds to its fair value minus the costs of sale or its use value, whichever is higher.

3.7 Cash and cash equivalents

Cash equivalents are short-term, highly liquid investments, that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value. Cash and cash equivalents comprise the cash that is held at the bank and petty cash as well as the short-term fixed deposits for which the maturity is less than three months.

For the purpose of establishing the consolidated statement of cash flows, cash and cash equivalents include cash in hand, demand deposits and short fixed-term deposits with banks and short-term highly liquid investments with original maturities of three months or less, net of bank overdrafts.

Cash and cash equivalents are initially recognized at their purchase costs on the transaction date, and are subsequently measured at fair value. Changes in fair value are recognized in profit or loss.

3.8 Share capital

Ordinary shares are classified under shareholders' equity. The costs of share capital transactions that are directly attributable to the issue of new shares or options are recognized in shareholders' equity as a deduction from the revenue from the issue, net of tax.

The Company's own shares bought in the context of a brokering/liquidity agreement are presented as a reduction in shareholders' equity until their cancellation, their reissuance or their disposal.

3.9 Compound instruments

The component parts of convertible loan notes issued by the Group are classified separately as financial liabilities and equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument. A conversion option that will be settled by the exchange of a fixed amount of cash or another financial asset for a fixed number of the Company's own equity instruments is an equity instrument.

At the date of issue, the fair value of the liability component is estimated using the prevailing market interest rate for a similar non-convertible instrument. This amount is recorded as a liability on an amortized cost basis using the effective interest method until extinguished upon conversion or at the instrument's maturity date.

The conversion option classified as equity is determined by deducting the amount of the liability component from the fair value of the compound instrument as a whole. This is recognized and included in equity, net of income tax effects, and is not subsequently remeasured. In addition, the conversion option classified as equity will remain in equity until the conversion option is exercised, in which case, the balance recognized in equity will be transferred to share premium. Where the conversion option remains unexercised at the maturity date of the convertible loan note, the balance recognized in equity will be transferred to retained profits. No gain or loss is recognized in profit or loss upon conversion or expiration of the conversion option.

Transaction costs that relate to the issue of the convertible loan notes are allocated to the liability and equity components in proportion to the allocation of the gross proceeds. Transaction costs relating to the equity component are recognized directly in equity. Transaction costs relating to the liability component are included in the carrying amount of the liability component and are amortized over the lives of the convertible loan notes using the effective interest method.

3.10 Share-based payment

Free shares (*Attributions gratuites d'Actions*, or "AGA"), stock-options (*Options de souscription et/ou d'achat d'actions*, or "SO") and employee warrants (*Bons de souscription de parts de créateur d'entreprise*, or "BCE") are awarded to employees or executives. Non-employee warrants (*Bons de souscription d'actions*, or "BSA") are primarily awarded to directors and scientific consultants. Pursuant to IFRS 2, these awards are measured at their fair value on the date of grant. The fair value is calculated with the most relevant formula regarding the settlement and the conditions of each plan. The fair value is recorded in personnel expenses (allocated by function in the Consolidated Statement of Income) on a straight-line basis over each milestone composing the vesting period with a corresponding increase in shareholders' equity.

At each closing date, we re-examine the number of options likely to become exercisable. If applicable, the impact of the review of the estimate is recognized in the Consolidated Statement of Income with a corresponding adjustment in equity.

3.11 Financial liabilities

Borrowings and other financial liabilities are measured initially at their fair value and then at amortized cost, calculated on the basis of the EIR method.

The transaction expenses that are directly attributable to the acquisition or to the issue of a financial liability reduce that financial liability. These expenses are then amortized actuarially over the lifetime of the liability, on the basis of the EIR.

The EIR is the rate that equalizes the anticipated flow of future cash outflows with the current net book value of the financial liability in order to deduct its amortized cost therefrom.

Other financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

3.12 Research tax credit, subsidies and conditional advances

Research tax credit

The research tax credit (*Crédit d'Impôt Recherche*, or "CIR") (the "Research Tax Credit") is granted to companies by the French tax authorities in order to encourage them to conduct technical

and scientific research. Companies that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that can be used for the payment of the corporate tax due for the fiscal year in which the expenditures were made and the next three fiscal years, or, as applicable, can be reimbursed in cash. The expenditures taken into account for the calculation of the Research Tax Credit involve only research expenses.

The Company has received the Research Tax Credit since its inception.

The Company received the reimbursement of the Research Tax Credit for the year 2018 in December 2019 for an amount of €4,290 K. It will request the reimbursement of the 2019 Research Tax Credit in 2020 under the Community tax rules for small and medium firms in compliance with the regulatory texts in effect for the amount of €4,242 K.

The CIR is presented under other income in the Consolidated Statement of Income (Loss) as it meets the definition of government grant as defined in IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance*.

Subsidies and conditional advances

Due to the innovative nature of its product candidate development programs, the Company has benefited from certain sources of financial assistance from Bpifrance Financement. Bpifrance Financement's mission is to provide financial assistance and support to emerging French enterprises to facilitate the development and commercialization of innovative technologies.

The funds received by the Company are intended to finance its research and development efforts and the recruitment of specific personnel. The Company has received such funding in the form of non-refundable subsidies and conditional advances.

Subsidies

Subsidies received are grants that are not repayable by the Company and are recognized in the Financial Statements where there exists reasonable assurance that the Company will comply with the conditions attached to the subsidies and the subsidies will be received.

Subsidies that are upfront payments are presented as deferred revenue and recognized ratably through income over the duration of the research program to which the subsidy relates.

A public subsidy that is to be received either as compensation for expenses or for losses already incurred, or for immediate financial support of the Company without associated future costs, is recognized in the Financial Statements as other income for the period in which the grant is classified as a receivable.

Conditional advances

Funds received from Bpifrance Financement in the form of conditional advances are recognized as financial liabilities, as the Company has a contractual obligation to reimburse Bpifrance Financement based on a repayment schedule. Each advance is made to fund a specific development milestone. Details concerning conditional advances are provided in Note 10. Receipts and reimbursements of conditional advances are reflected as cash flows from financing activities in the Consolidated Statement of Cash Flows.

The rate used to determine the amount recognized annually as a finance cost, the EIR takes into account the estimated future cash flows.

In the event of a change in payment schedule of the stipulated repayments of the conditional advances, the Company recalculates the net book value of the debt resulting from the discounting of the anticipated new future cash flows at the initial EIR. The adjustment that results therefrom is recognized in the Consolidated Statement of Income (Loss) for the period during which the modification is recognized.

The conditional advance that can be subject to this type of modification is the advance received from Bpifrance Financement, presented in Note 10.2.

3.13 Retirement pension obligations

The employees of the Company receive the retirement benefits stipulated by law in France:

- compensation paid by the Company to employees upon their retirement (defined-benefit plan) and;
- a payment of retirement pensions by the Social Security agencies, which are financed by the contributions made by companies and employees (defined-contribution plans).

For the defined-benefit plans, the costs of the retirement benefits are estimated by using the projected credit unit method. According to this method, the cost of the retirement benefit is recognized in the Consolidated Statement of Income (Loss) so that it is distributed uniformly over the term of the services of the employees. The retirement benefit commitments are valued at the current value of the future payments estimated using, for discounting, the market rate for high quality corporate bonds with a term that corresponds to that estimated for the payment of the benefits.

The difference between the amount of the provision at the beginning of a period and at the close of that period is recognized through profit or loss for the portion representing the costs of services rendered and the net interest costs, and through other comprehensive income for the portion representing the actuarial gains and losses.

The Company's payments for the defined-contribution plans are recognized as expenses on the Consolidated Statement of Income (Loss) of the period during which they become payable.

3.14 Provisions for risks and expenses

The provisions for risks and lawsuits correspond to the commitments resulting from lawsuits and various risks whose due dates and amounts are uncertain.

A provision is recognized in the Financial Statements when the Group has a legal or implicit obligation to a third party resulting from a past event, which is likely or certain to cause an outflow of resources to that third party, and provided that the future outflows of liquid assets can be estimated reliably.

The amount recognized in the Financial Statements as a provision is the best estimate of the expenses necessary to extinguish the obligation.

3.15 Leases

The Group applies the definition of a lease and related guidance set out in IFRS 16 to all contracts entered into or changed on or after January 1, 2019.

Applying IFRS 16, for all leases (except as noted below), the Group:

(a) Recognizes right-of-use assets and lease liabilities in the consolidated statement of financial position, initially measured at the present value of the future lease payments;

(b) Recognizes depreciation of right-of-use assets and interest on lease liabilities in profit or loss;

(c) Separates the total amount of cash paid into a principal portion (presented within financing activities) and interest (presented within financing activities) in the consolidated statement of cash flows.

Lease incentives (*e.g.* rent-free period) are recognized as part of the measurement of the right-of-use assets and lease liabilities whereas under IAS 17 they resulted in the recognition of a lease incentive, amortized as a reduction of rental expenses generally on a straight-line basis.

Under IFRS 16, right-of-use assets are tested for impairment in accordance with IAS 36.

For short-term leases (lease term of 12 months or less) and leases of low-value assets (such as tablet and personal computers, small items of office furniture and telephones), the Group has opted to recognize a lease expense on a straight-line basis as permitted by IFRS 16. This expense is presented within 'other expenses' in profit or loss.

3.16 Revenue

In accordance with IFRS 15, variable considerations cannot be included in the estimated transaction price as long as it is not highly probable that the related revenue will not be reversed in the future. According to the level of uncertainty relating to the results of preclinical and clinical trials and the decisions relating to the regulatory approvals, variable considerations depending on these events are excluded from the transaction price as long as the trigger event is not highly probable. When the trigger event occurs, the corresponding milestone is added to the transaction price. Such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the period of adjustment.

On December 9, 2019, GenSight Biologics announced that the French Competent Authority, the National Drug Safety Agency, granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*.

In France, use of pharmaceutical products not yet approved with a Marketing Authorization (AMM) and not recruiting for a clinical trial requires first obtaining an ATU from the ANSM.

GenSight Biologics will be paid a preliminary price by the hospitals. Upon obtaining full marketing authorization and completing pricing negotiations, GenSight may be required to rebate to the foreign government the difference between the preliminary price and the final price.

As of December 2019, payment terms have been established and GenSight reasonably estimated the amount of consideration to which it will ultimately be entitled on the basis of the future negotiations with the National Drug Safety Agency and prices for comparable treatments.

3.17 Income tax

Deferred taxes are recognized for all the temporary differences arising from the difference between the tax basis and the accounting basis of the assets and liabilities that appear in the Financial Statements. The primary temporary differences are related to the tax losses that can be carried forward or backward. The legal tax rates as of the closing date are utilized to determine the deferred taxes.

The deferred tax assets are recognized in the Financial Statements only to the extent that it is likely that the future profits will be sufficient to absorb the losses that can be carried forward or backward. Considering its stage of development, which precludes the income projections from being sufficiently reliable to be made, the Group has not recognized deferred tax assets in relation to tax loss carryforward in the Consolidated Statement of Financial Position.

3.18 Segment information

The Company operates in a single operating segment: the conducting of research and development of novel therapies for mitochondrial and neurodegenerative diseases of the eye and central nervous system in order to market them in the future. The assets, liabilities and operating loss realized are located mainly in France.

In 2019 revenue was entirely generated by one customer.

3.19 Presentation of financial assets and financial liabilities measured at fair value

In accordance with IFRS 7 Financial Statements: Disclosures, financial instruments are presented in three categories based on a hierarchical method used to determine their fair value:

- level 1: fair value calculated using quoted prices in an active market for identical assets and liabilities;
- level 2: fair value calculated using valuation techniques based on observable market data such as prices of similar assets and liabilities or parameters quoted in an active market; and
- level 3: fair value calculated using valuation techniques based wholly or partly on unobservable inputs such as prices in an inactive market or a valuation based on multiples for unlisted securities.

3.20 Use of estimates

The Financial Statements are prepared in accordance with IFRS. The preparation of the Financial Statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, income and expenses during the reporting period. The Group bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Group's actual results may differ from these estimates under different assumptions or conditions. There have been no significant changes from original estimates in any periods presented.

These estimates and judgments involve mainly:

- the estimate of the amount of the intangible asset recognized in the context of a license agreement. The acquisition of this license in 2013 resulted in the issuance of ordinary shares as consideration paid for the license. The amount of the intangible asset recognized was determined based on the fair value of the ordinary shares, €0.41 per share, issued as consideration for the license (see Note 4);
- the estimate of the repayments of the conditional advances obtained by the Company from public institutions, such as Bpifrance Financement. The anticipated repayments of the conditional advances are analyzed at each reporting period (see Note 10), and the measurement of the conditional advances classified as financial liabilities based on the effective rate method;
- the measurement of the fair value of the various equity instruments granted to employees, executives or non-employee members of the Board of Directors as well as scientific consultants and service providers, such as AGA, SO, BCE or BSA, which is performed on the basis of actuarial models; these models require the use by the Company of certain calculation assumptions such as the expected volatility of the underlying security (see Note 17);
- research and development expenses include estimates of the amount recognized over the year for subcontracts. At year-end closing, an analysis of the services already perfomed but not yet invoicedand/or already invoiced but not yet performed is carried out by the project managers and validated by the company's management;
- the measurement of the fair value of the liability component of the convertible bond, calculated on the basis of the contractually agreed interest and amortisation payments discounted at market interest rates;
- the estimate of the selling price for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*. The National Drug Safety Agency, granted to GenSight Biologics a Temporary Authorization for Use ("ATU nominative"). Variable consideration under IFRS 15 are required to be estimated at contract inception. The Group assessed individual contracts to determine the estimated variable consideration and related constraints;
- the estimate of the amount due to one of key suppliers with which contractual relationship ended during 2019 as mentioned in Note 13.1. The amount booked as a liability corresponds to Management best estimate of its future cash outflow.

Note 4: Intangible assets

The intangible assets are broken down as follows:

	As of December 31,	
In thousands of euros	2018	2019
Patents, licenses, trademarks	275	275
Software	12	18
Total historical cost	**287**	**293**
Accumulated amort. of patents, licenses and trademarks	108	127
Accumulated depreciation of software packages	11	12
Accumulated amortization and depreciation	**119**	**139**
Net total	**168**	**154**

An intangible asset was recognized at December 31, 2013 as a result of the license agreement signed with Novartis. The initial recognition cost amounted to €275 K and was determined by reference to the fair value of the 670,588 ordinary shares, €0.41 per ordinary share, issued as consideration for the license.

There has been no recognition of impairment losses in application of IAS 36 *Impairment of Assets* over the periods presented.

Note 5: Property, plant and equipment

Changes in property, plant and equipment gross book values and accumulated depreciation are presented in the following table:

In thousands of euros	As previously reported at December 31, 2018	IFRS 16 impact	Increase	Decrease	Currency translation adjustment	As of December 31, 2019
Technical equipment and installations	586	—	27	—	2	615
IFRS 16 – Right-of-use – Building	—	3,653	—	—	44	3,696
Leasehold improvement	976	—	2	—	6	984
Office and computer equipment	172	—	31	—	—	203
IFRS 16 – Right-of-use – Others	—	19	—	—		19
Furniture	495	—	8	—	3	507
Total gross property, plant and equipment	**2,229**	**3,672**	**69**	**—**	**55**	**6,025**
Accumulated depreciation of technical equipment and installations	227	—	102	—	—	329
IFRS 16 – Right-of-usee – Building	—	612	—	—	(1)	611
Accumulated depreciation of leasehold improvement	248	—	110	—	—	358
Accumulated depreciation of office and computer equipment	124	—	36	—	—	161
IFRS 16 – Right-of-use – Others	—	9	—	—	—	9
Accumulated depreciation of furniture	234	—	96	—	—	330
Total accumulated depreciation	**833**	**621**	**344**	**—**	**(1)**	**1,797**
Total net property, plant and equipment	**1,396**	**3,051**	**(274)**	**—**	**54**	**4,228**

Note 6: IFRS 16 - Leases

The main impacts on the balance sheet and the income statement resulting from the first application of the new standard as of December 31, 2019 are the following:

Balance sheet

Right-of-use

	As previously reported at December 31, 2018	IFRS 16 impact [1]	**As restated at January 1, 2019**	New contracts	Amortization	Currency translation adjustment	As of December 31, 2019
Right-of-use - Buildings	—	3,653	3,653	—	(612)	44	3,085
Right-of-use - Others	—	19	19	—	(9)	—	11
Net value of the righ-of-use	**—**	**3,672**	**3,672**	**—**	**(621)**	**44**	**3,096**

(1) The weighted average marginal debt ratio used to value the lease debts at the date of transition is 5.0%.

Lease liability

	As previously reported at December 31, 2018	IFRS 16 impact	**As restated at January 1, 2019**	New contracts	Repayments	Currency translation adjustment	As of December 31, 2019
Lease liability - Buildings	—	2,716	2,716	—	—	47	2,763
Lease liability - Others	—	—	—	—	—	—	—
Total non-current	**—**	**2,716**	**2,716**	**—**	**—**	**47**	**2,763**
Lease liability - Buildings	—	1,015	1,015	—	(462)	(1)	552
Lease liability - Others	—	19	19	—	(8)	—	11
Total current	**—**	**1,034**	**1,034**	**—**	**(470)**	**(1)**	**563**
Total	**—**	**3,751**	**3,751**	**—**	**(470)**	**(46)**	**3,326**

Profit and Loss

	As of December 31, 2019 *excluding IFRS 16*	IFRS 16 impact	As of December 31, 2019 *published*
Revenues	700	—	700
Other income	4,210	—	4,210
Total operating income	**4,910**	**—**	**4,910**
Research and Development	(28,761)	51	(28,710)
General and Administration	(5,755)	19	(5,736)
Sales and Marketing	(764)	2	(762)
Operating Profit	**(30,370)**	**72**	**(30,298)**
Financial income (loss)	(230)	(179)	(409)
Income tax	(4)	—	(4)
Net income (loss)	**(30,604)**	**(107)**	**(30,710)**

Commitments under the scope of IFRS 16

Agreement with *Passage de l'Innovation*

On January 1, 2015, we entered into a lease agreement for our headquarters premises in Paris, France with *Passage de l'Innovation*, which was amended on October 1, 2015, January 1, 2016, May 1, 2017, January 8, 2018, July 1, 2018, October 1, 2018 and November 1, 2019. As the company pursued its development, additional spaces were included in the contract. The main space's lease ends in December 2024, however, our engagement with smaller surfaces ends in 2027. The agreement includes expenses for rent, rental charges and other services provided by the lessor.

The amendment signed on November 1, 2019 consisted especially in a decreased rent as the Group is using less office space. The associated services (*e.g.*, reception, printers and information technology and access to meeting rooms) have increased.

U.S.- based subsidiary

The Group entered into a binding office lease agreement in New York for its U.S.-based subsidiary on September 6, 2017. The lease commencement was based upon substantial completion of the landlord's work and delivery of possession of the premises and occurred on April 18, 2018. The lease term is 7 years and 5 months.

Note 7: Other non-current financial assets

The non-current financial assets correspond to the deposits paid to the lessor for the registered offices of the Group in Paris and New York.

	As of December 31,	
In thousands of euros	2018	2019
Guarantee deposits	331	336
Total non-current financial assets	**331**	**336**

Note 8: Accounts receivable and other current assets

8.1 Accounts receivable and related receivables

All accounts receivable have payment terms of less than one year.

No valuation allowance was recognized on accounts receivable as there is no past due receivable.

As of December 31, 2019, the Company has receivables mainly resulting from the Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted to the CHNO of the *Quinze-Vingts* for €700 K excluding VAT.

8.2 Other current assets

The other current assets are broken down as follows:

	As of December 31,	
In thousands of euros	2018	2019
Prepayments	370	135
Research tax credit	4,322	4,242
Other taxes receivable	822	1,019
Liquidity contract	247	273
Prepaid expenses	3,079	2,000
Total	**8,840**	**7,669**

Prepayments are made of advances to suppliers.

Other taxes receivable essentially refers to VAT receivables.

As of December 31, 2019, prepaid expenses were primarily manufacturing costs, rental, scientific collaborations and travel expenses.

Research Tax Credit

The Company benefits from the provisions in Articles 244 quater B and 49 *septies* F of the French Tax Code related to the Research Tax Credit. In compliance with the principles described in Note 3.11, the Research Tax Credit is recognized in the Consolidated Statement of Income (Loss) in "other income" during the year in which the eligible research expenditures are incurred.

Changes in the Research Tax Credit over the last two periods are presented as follows:

	Amounts in K€
Opening balance sheet receivable as of January 1, 2018	**3,692**
Other operating income	4,322
Payment received	(3,692)
Closing balance sheet receivable as of December 31, 2018	**4,322**

	Amounts in K€
Opening balance sheet receivable as of January 1, 2019	**4,322**
Other operating income	4,210
Payment received	(4,290) (1)
Closing balance sheet receivable as of December 31, 2019	**4,242**

(1) The amount of Research Tax Credit for FY18 received at the end of 2019 differed form the amount booked in the 2018 Financial Statement for €32 K.

Note 9: Cash and cash equivalents

Cash and cash equivalents items are broken down as follows:

	As of December 31,	
In thousands of euros	2018	2019
Cash	26,241	19,250
Cash equivalents	—	—
Total cash and cash equivalent as reported in the statements of financial position	**26,241**	**19,250**
Bank overdrafts	—	—
Total net cash and cash equivalents as reported in the statements of cash flows	**26,241**	**19,250**

The Group does not hold any short-term investment and all of its cash balances are cash at hand deposits with high-credit quality financial institutions.

Note 10: Capital

The share capital as of December 31, 2019 amounts to €820,684.05. It is divided into 32,827,362 fully authorized, subscribed and paid-up ordinary shares with a nominal value of €0.025.

On July 13, 2016, the Company completed its Initial Public Offering (IPO) on Euronext Paris, raising €40 million in gross proceeds, and the Company issued 5,000,000 ordinary shares with a nominal value of €0.025 and a share premium of €7.975 per share.

On August 10, 2016, the Company partly exercised its overallotment option as part of its IPO on Euronext Paris, raising an additional €5.2 million in gross proceeds, and the Company issued 655,859 ordinary shares with a nominal value of €0.025 and a share premium of €7.975 per share.

On June 27, 2017, the Company operated a capital increase whose gross proceeds amounted to €22.5 million, by means of a private placement reserved to a category of persons, U.S. and European institutional investors specialized in healthcare and biotechnology. The majority of the new shares were allocated to U.S. investors. This increase corresponds to 3,750,000 new shares, par value €0.025 each.

On February 25, 2019, GenSight Biologics announced the completion of a capital increase of €8 million subscribed entirely by Sofinnova Crossover I SLP ("Sofinnova"). The purpose of this capital increase is to pursue the final stages of clinical development of GS010, and file for marketing authorization in Europe. This increase corresponds to 3,921,568 new shares, par value €0.025 each.

On December 20, 2019 GenSight Biologics announced that it had completed a capital increase of €9 million subscribed for by one of its main shareholders Sofinnova Crossover I SLP ("Sofinnova") and by a new strategic Chinese investor Strategic International Group Limited, a wholly owned subsidiary of 3SBio Inc. ("3SBio"). This increase corresponds to 3,799,071 new shares, par value €0.025 each.

The 32,827,362 outstanding shares does not include BSA, BCE and AGA. BSA are granted to investors and other individual non-employees, BCE are granted to employees only, AGA are granted to employees and / or executives.

The table below shows the changes occurred in the share capital during the last two periods:

In thousands of euros, except for number of shares	Share Capital	Share premium	Number of shares
Balance as of January 1, 2018	**606**	**112,140**	**24,234,223**
Capital increase by issuance of ordinary shares	—	—	—
Less cost of issuance of shares	—	—	—
Issue of shares upon exercise of subscription warrants (1)	14	(5)	568,750
Total as of December 31, 2018	620	112,135	24,802,973
Balance as of January 1, 2019	**620**	**112,135**	**24,802,973**
Capital increase by issuance of ordinary shares	193	16,807	7,720,639
Less cost of issuance of shares	—	(818)	—
Issue of shares upon exercise of subscription warrants (1)	8	6	303,750
Total as of December 31, 2019	821	128,130	32,827,362

(1) The share premium includes the subscription price of non-employee warrants and the exercise price in excess of the share nominal value for employee and non-employee warrants.

All the changes relating to employee warrants, non-employee warrants and free shares, as well as their impact on the profit and loss for the period are detailed in Note 18.

Note 11: Financial liabilities

11.1Bond financing

In December 2019, GenSight Biologics obtained committed financing in the form of a bond financing of up to €12 million from Kreos Capital VI (UK) Limited and issued a drawdown notice thereunder for the first tranche of €6 million, including a €4.2 million straight bond issuance and a €1.8 million convertible bonds issuance.

The financial transaction is structured as follows:

- a capital increase for a total amount of €9 million representing 3,799,071 new shares subscribed for €4 million by Sofinnova Crossover I and for €5 million by Strategic International Group Limited, a wholly owned subsidiary of 3SBio Inc. (the "3SBio-Sofinnova Transaction"); and
- subject to the realization of the 3SBio-Sofinnova Transaction described above, a bond issuance for a maximum amount of €10 million divided in 2 tranches as follows:
  - a first tranche (the "Tranche A") in the form of:
    - a bond issuance subscribed by Kreos Capital VI (UK) Limited for an amount of €6 million including €1.8 million subscribed by Kreos Capital VI (Expert Fund) LP in the form of convertible bonds, and
    - a concurrent issuance of share warrants for an amount the potential exercise of which would represent €1.2 million subscribed by Kreos LP; and
  - a second tranche, exercisable, subject to the realization of a Qualifying Financing(1), at the Company's option until September 1, 2020, in the form of:
    - a bond issuance subscribed by Kreos UK for an amount of €4 million including a maximum amount of €1.2 million susceptible to be subscribed at its election by Kreos LP in the form of convertible bonds, and
    - a concurrent issuance of share warrants for an amount the potential exercise of which would represent €300 K.

The Company has the option to issue additional bonds similar to the bonds described above (assimilables) to Kreos UK for an amount of €2 million.

The convertible loan notes were issued on December 19, 2019 at an issue price of €2.245 per note. The notes are convertible into ordinary shares of the Company at any time between the date of issue of the notes and their settlement date. On issue, the loan notes were convertible at a ratio of 1/2.245 shares per 1 convertible note. The conversion price is at a 10% discount to the volume weighted average share price of the ordinary

(1) Qualifying Financing means a financing of the Company in the form of equity (or Non-Dilutive Payment or subordinated convertible bonds, or a combination of the above) from existing shareholders and/or new top tier investors reasonably satisfactory to Kreos, with a minimal amount of gross proceeds of €10 million, being specified that such amount may be reduced, up to a maximal amount of €2 million, by the proceeds susceptible to be received by the Company under *Autorisations Temporaires d'Utilisation payantes*.

shares for the 3 days period prior to the Board Meeting date, *i.e.* December 16, 17 and 18, 2019.

If the notes have not been converted, they will be redeemed on May 1, 2023 at par. Interest of 9.25% per cent will be paid annually up until that settlement date.

The net proceeds received from the issue of the convertible loan notes have been split between the financial liability element and an equity component, representing the fair value of the embedded option to convert the financial liability into equity of the Company and the warrants, as follows:

• Proceeds of issue of not convertible loan notes in euros	4,200,000
• Advance Payment	(133,023)
• Transaction costs in euros	(87,500)
• **Net proceeds from issue of not convertible loan notes in euros**	**3,979,477**
• Proceeds of issue of convertible loan notes in euros	1,800,000
• Transaction costs in euros	(87,500)
• **Net proceeds from issue of convertible loan notes in euros**	**1,712,500**
• **Amount classified as equity in euros**	**1,069,568**
• Liability component at date of issue (net of transaction costs)	4,602,642
• Interest charged (using effective interest rate)	18,002
• **Carrying amount of liability component at December 31, 2019**	**4,620,645**

The equity component of €1 million has been credited to the option premium on convertible notes reserve (see note 10).

The interest expensed for the year is calculated by applying an effective interest rate to the liability component. The liability component is measured at amortized cost. The difference between the carrying amount of the liability component at the date of issue and the amount reported in the reporting at December 31, 2019 represents the effective interest rate less interest paid to that date.

11.2 Conditional advances

In 2014, the Company received a grant from Bpifrance Financement in the form of both subsidies and conditional advances in relation to the development of its technology platform. The program will be funded according to a specified schedule set forth in the contract, subject to completion of milestones. As the program advances, the Company will provide Bpifrance Financement with interim progress reports and a final report when the funded project ends. Based on these reports, the Company is entitled to conditional advances from Bpifrance Financement. Each award of an advance is made to help fund a specific development milestone. The total amount initially planned of the conditional advances is €5,686 K. The Company has committed to reimburse a total amount of €6,490 K (included accrued interests; determined at an annual rate of 1.44%). If the total advances actually paid by Bpifrance Financement are less than €5,686 K, the reimbursements will be reduced in proportion to the advances actually paid.

The advances were initially planned to be paid according to the following schedule, subject to completion of milestones:

- €678 K received in December 2014;
- €2,279 K received in July 2016 (1);
- €494 K initially expected to be received in the first half of 2018 (2);
- €853 K initially expected to be received in November 2018; and
- €986 K initially expected to be received in November 2019.

After review and analysis of the stage of completion of the remaining milestones, level of expenses that have been incurred as of December 31, 2018 and 2019, and given that the initial agreement was on November 30, 2019, the Group considers that it would not be able to complete the remaining key milestones on time and therefore should not receive any more conditional advance from Bpifrance Financement.

The advances already paid in 2017 and 2016 and the corresponding accrued interests are both recognized as non-current liabilities in the statement of financial position.

The updated repayment schedule for a total amount of €3,303 K of all of the conditional advances received as of December 2019 is as follows:

- €550 K on or before June 30, 2022;
- €1,000 K on or before June 30, 2023;
- €1,500 K on or before June 30, 2024; and
- €253 K on or before June 30, 2025.

Following the repayment of all of the conditional advances, the Company may be required to make additional payments over a period of two years of up to €1.4 million (€603 K the first year and €823 K the second year), depending on whether the Company reaches cumulative revenues, excluding taxes, of €80 million. These additional repayments should be done within 15 years following the first year of reimbursement, *i.e.* 2037.

(1) The estimated amount from the initial payment schedule was €2,675 K. The costs occurred by Company amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.
(2) The corresponding milestone occurred in November 2017.

The obligation to repay these amounts is based on the technical and commercial success of the funded program, as determined by the revenues forecast or revenues deriving from direct or indirect exploitation of those products and results of its optogenetics technology platform. In the event Bpifrance Financement determines that the program is not successful, Bpifrance Financement will meet with the Company to assess the impact on the repayments and the repayment schedule.

The Company has decided to include the future cash flows resulting from the additional payments in the calculation of the EIR, based on the first sales projections of its second product.

The table below presents the details of the financial liabilities recorded on the statements of financial position:

In thousands of euros	
Balance as of January 1, 2019	**3,441**
Receipts	—
Repayments	—
Accrued interest	191
Other	—
Balance as of December 31, 2019	**3,633**
Non-current portion	3,633
Current portion	—

11.3 Maturity dates

Maturity dates of financial liabilities as of December 31, 2018 are as follows:

In thousands of euros	Gross amount	Less than one year	One to five years	More than five years
Conditional advances	3,441	—	1,550	1,891

Maturity dates of financial liabilities as of December 31, 2019 are as follows:

In thousands of euros	Gross amount	Less than one year	One to five years	More than five years
Conditional advances	3,633	—	3,050	583
Corporate bonds	4,621	889	3,732	—
Lease Liability	3,326	563	2,340	423
Total financial liabilities	11,580	1,452	9,122	1,006

Note 12: Non-current provisions

Non-current provisions are exclusively composed of employee benefits relating to a compensation payable to French employees upon their retirement - *Indemnités de Fin de Carrière* ("IFC").

The following tables show the changes in the provision during the last two periods:

	In thousands of euros
As of January 1, 2018	**88**
Costs of services rendered (operating expense)	28
Interest expense	1
Benefits paid	—
Actuarial gain (loss)	(52)
As of December 31, 2018	**65**
As of January 1, 2019	**65**
Costs of services rendered (operating expense)	36
Interest expense	1
Benefits paid	—
Actuarial gain (loss)	1
As of December 31, 2019	**103**

The main assumptions used for the purposes of actuarial valuations are listed below:

- Social security contribution: 45% in 2018 and 2019;
- Salary increase: 3% in 2018 and 2019;
- Discount rate: iBoxx Corporates AA 10+ index, 1.30% and 0.77% in 2018 and 2019, respectively;
- Retirement age: 67;
- Terms of retirement: voluntary retirement;
- Life table: TGHF 2005;
- Collective agreement: *Convention Collective Nationale des Ingénieurs et des Cadres de la Métallurgie* (National Collective Agreement for Engineers and Executives in the Metalworking Industry); and
- Personnel turn-over: 10% (20-49), 0% above 50.

Note 13: Accounts payable and other current liabilities

13.1 Accounts payable and related payables

With respect to accounts payable and related payables, no discounting effect has been recognized to the extent that amounts did not represent payables on terms longer than one year at the end of each period presented.

Maturity dates of accounts payables as of December 31, 2019 are as follows:

In thousands of euros	Gross amount	Less than one year	One to five years	More than five years
Trade accounts payable	7,139	7,139	—	—

The Group terminated its contractual relationship with one of its key suppliers during the year. No financial compensation was required. In November 2019 GenSight received two invoices from this supplier for a total amount of USD2.6 million. The Company considers that the main part of services billed by this supplier have not been performed. As of December 31, 2019, discussions between this supplier and GenSight are still ongoing. The Group's legal counsels have advised that they do not consider that the claim has merit, and they have recommended that it be contested. The Company booked a liability for €2.4 million offset by a credit note to be received for €2.2 million, considering that only €0.2 million could be due to this supplier.

13.2 Other current liabilities

The following table provides the detail of other current liabilities for the presented periods:

	As of December 31,	
In thousands of euros	2018	2019
Employee-related payable	1,720	1,265
Other taxes liabilities	201	625
Deferred revenue	82	—
Financial liabilitites	—	1,452
Other current liabilities	6	3
Total	**2,009**	**3,345**

Note 14: Financial instruments recognized in the consolidated statements of financial position and related effect on the consolidated statement of income (loss)

In thousands of euros	Book value on the statement of financial position	Fair value through profit and loss[1]	Loans and receivables[2]	At amortized cost[3]	Fair Value
As of December 31, 2018					
Financial assets					
Non-current financial assets	331	—	—	331	331
Current financial assets	247	247	—	—	247
Accounts receivable and related receivables	2	—	2	—	2
Cash and cash equivalents	26,241	—	—	26,241	26,241
Total financial assets	**26,821**	**247**	**2**	**26,572**	**26,821**
Financial liabilities					
Conditional advances (non-current portion)	3,441	—	—	3,441	3,441
Accounts payable and related payables	7,593	—	—	7,593	7,593
Total financial liabilities	**11,034**	**—**	**—**	**11,034**	**11,034**

In thousands of euros	Book value on the statement of financial position	Fair value through profit and loss[1]	Loans and receivables[2]	At amortized cost[3]	Fair Value
As of December 31, 2019					
Financial assets					
Non-current financial assets	336	—	—	336	336
Current financial assets	273	273	—	—	273
Accounts receivable and related receivables	846	—	846	—	846
Cash and cash equivalents	19,250	—	—	19,250	19,250
Total financial assets	**20,705**	**273**	846	**19,586**	**20,705**
Financial liabilities					
Bond financing	4,621	—	—	4,621	4,621
Conditional advances (non-current portion)	3,633	—	—	3,633	3,633
Lease liability – Buildings	3,315	—	—	3,315	3,315
Lease liability – Others	11	—	—	11	11
Accounts payable and related payables	7,139	—	—	7,139	7,139
Total financial liabilities	**18,719**	**—**	**—**	**18,719**	**18,719**

(1) The fair value of financial assets classified as fair value through profit and loss corresponds to the market value of the assets.
(2) The fair value of loans and receivables corresponds to the value reported in the statement of financial position meaning the value at the transaction date and then tested for impairment on each reporting date.
(3) The book amount of financial liabilities measured at amortized cost was deemed to be a reasonable estimation of fair value.

Note 15: Income

Total income as of December 31,2019 solely comes from the named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted by the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) to the CHNO of the *Quinze-Vingts* on December 9, 2019. The price per patient was set at €700 K by the Group (€350 K per eye).

Should our commercial price set at a lower price than the one used for the ATU, the Company will have to reimburses the Health Insurance for the overpayment received during the ATU phase.

Note 16: Other income

Other income is detailed in the table below:

	As of December 31,	
In thousands of euros	2018	2019
Research tax credit (see Note 8)	4,322	4,210
Subsidies	24	—
Total	**4,346**	**4,210**

Note 17: Operating expenses

17.1 Research and development expenses

The table below shows the breakdown of general and administrative expenses by cost nature for the periods presented:

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	4,691	3,458
Sub-contracting, collaboration and consultants	21,288	23,027
Licensing and intellectual property	752	383
Offices cost	727	32
Travel and entertainment expenses	760	774
Depreciation and amortization expense	270	554
Other	543	482
Total R&D expenses	**29,031**	**28,710**

(1) Includes €950 K and €385 K related to share-based compensation expense as of December 31, 2018 and 2019 respectively.

17.2 General and administrative expenses

The table below shows the breakdown of general and administrative expenses by cost nature for the periods presented:

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	2,993	2,877
Professional Fees	2,062	881
Communication and travel expenses	1,051	959
Offices cost	255	52
Equipment rental	3	2
Office furniture and small equipment	146	142
Postal and telecommunication expenses	25	26
Depreciation and amortization expense	45	401
Attendance fees	150	185
Insurance	48	47
Others	232	164
Total G&A expenses	**7,010**	**5,736**

(1) Includes €1,132 K and 801 K related to share-based compensation expense as of December 31, 2018 and 2019 respectively.

17.3 Sales and Marketing expenses

The table below shows the breakdown of sales and marketing expenses by cost nature for the periods presented:

	As of December 31,	
In thousands of euros	2018	2019
Personnel expenses[1]	658	393
Professional Fees	493	229
Communication and travel expenses	39	66
Offices cost	108	2
Depreciation and amortization expense	—	30
Others	52	42
Total S&M expenses	**1,350**	**762**

(1) Includes €340 K and €121 K related to share-based compensation expense as of December 31, 2018 and 2019, respectively.

17.4 Personnel expenses

The Group was employing 25 people on permanent contract as of December 31, 2019 compared with 33 as of December 31, 2018.

The following table shows the nature of costs included in personnel expenses:

	As of December 31, 2018				As of December 31, 2019			
In thousands of euros	R&D	G&A	S&M	TOTAL	R&D	G&A	S&M	TOTAL
Wages and salaries	2,847	1,463	187	4,497	2,139	1,379	191	3,709
Social contributions	870	391	131	1,392	908	691	77	1,676
Service cost (employee benefit)	23	5	—	28	25	6	4	35
Share-based payments	950	1,132	340	2,422	385	801	121	1,307
Total	**4,690**	**2,991**	**658**	**8,339**	**3,458**	**2,877**	**393**	**6,728**

Note 18: Share-based payments

The Board of Directors has been authorized by the general meeting of the shareholders to grant to employees BCE, BSA, AGA and SO and to implement share options plans as follows:

- with the authorization of the General Meeting of Shareholders on February 5, 2013, the Board of Directors issued:
  - 892,000 employee warrants (BCE 2013-02) on July 8, 2013.
  - 328,000 non-employee warrants (BSA 2013-02) on July 8, 2013.
  - 193,800 employee warrants (BCE 2013-02) on April 9, 2014.
  - 33,000 non-employee warrants (BSA 2013-02) on April 9, 2014.
- with the authorization of the General Meeting of Shareholders on June 25, 2014, the Board of Directors issued 60,000 employee warrants (BCE 2014-06) on December 3, 2014.
- with the authorization of the General Meeting of Shareholders on June 29, 2015, the Board of Directors issued :
  - 121,000 non-employee warrants (BSA 2015-06) on July 7, 2015.
  - 733,298 employee warrants (BCE 2015-06) on July 7, 2015.

- with the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors issued:
  - 205,000 non-employee warrants (BSA 2016) on July 26, 2016.
  - 766,000 free shares (AGA 2016) on July 26, 2016.
  - 593,500 free shares (AGA 2016) on July 27, 2017.
  - 72,500 free shares (AGA 2016) on December 19, 2017.
  - 165,000 non-employee warrants (BSA 2016) on July 27, 2017.
  - 220,000 stock options (SO 2017) on July 27, 2017.
  - 300,000 stock options (SO 2017) on December 19, 2017.
  - 175,000 stock options (SO 2018) on March 14, 2018.
- with the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors issued:
  - 380,000 free shares (AGA 2018) on September 18, 2018.
  - 20,000 non-employee warrants (BSA 2018) on September 18, 2018.
  - 30,000 stock options (SO 2018) on September 18, 2018.
  - 135,000 free shares (AGA 2018) on December 19, 2018.
  - 610,000 free shares (AGA 2018) on July 23, 2019.
- with the authorization of the General Meeting of Shareholders on June 11, 2019, the Board of Directors issued:
  - 105,000 non-employee warrants (BSA 2018) on July 23, 2019.

18.1 Employee warrants (BCE)

Vesting schedule

All BCE granted may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 on the first anniversary of the date of grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the first anniversary of the date of grant; and
- at the latest within 10 years from the date of grant.

Details and main characteristics of the BCE granted to date

	BCE 2013-02	BCE 2013-02	BCE 2014-06	BCE 2015-06
Date of grant	July 8, 2013	April 9, 2014	December 3, 2014	July 8, 2015
Plan expiration date	July 7, 2023	April 8, 2024	December 2, 2024	July 7, 2025
Number of warrants initially granted	892,000	193,800	60,000	733,298
Share entitlement per warrant	1	1	1	1
Exercise price	€0.025	€0.025	€0.025	€3.275
Valuation method		Black & Scholes		
Expected volatility	42.50%	42.50%	75.21%	76.49%
Expected dividend	0.00%	0.00%	0.00%	0.00%
Fair value per warrant	€0.44	€0.44	€2.15	€5.56

Changes in the balances of BCE

	BCE 2013-02	BCE 2014-06	BCE 2015-06	Total
Balance outstanding at January 1, 2019	**123,720**	**60,000**	**490,916**	**674,636**
Granted during the period	—	—	—	—
Exercised during the period	—	—	—	—
Forfeited during the period	—	—	(8,334)	(8,334)
Balance outstanding at December 31, 2019	**123,720**	**60,000**	**482,582**	**666,302**
Of which exercisable	123,720	60,000	473,728	657,448

18.2 Non-employee warrants (BSA)

Vesting schedule

BSA 2013-02 and BSA 2015-06 granted may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 on the first anniversary of the date of grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the first anniversary of the date of grant; and
- at the latest within 10 years from the date of grant.

BSA 2016 granted may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 100% on the first anniversary of the date of grant; and
- at the latest within 10 years from the date of grant.

BSA 2017 granted may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 on the date of the grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the date of grant; and
- at the latest within 7 years from the date of grant.

BSA 2018 granted may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 on the date of the grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the date of grant; and
- at the latest within 7 years from the date of grant.

BSA 2019 granted may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 on the date of the grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the date of grant; and
- at the latest within 7 years from the date of grant.

	BSA 2013-02	BSA 2013-02	BSA 2015-06	BSA 2016	BSA 2017	BSA 2018	BSA 2019
Date of grant	July 8, 2013	April 9, 2014	July 8, 2015	July 26, 2016	July 27, 2017	September 18, 2018	July 23, 2019
Plan expiration date	July 7, 2023	April 8, 2024	July 7, 2025	July 25, 2023	July 27, 2024	September 18, 2025	July 23, 2026
Number of warrants initially granted	328,000	33,000	121,000	205,000	165,000	20,000	105,000
Exercise price	€0.025	€0.025	€3.275	€8.08	€5.04	€ 2.22	€1.45
Share entitlement per warrant	1	1	1	1	1	1	1
Valuation method				Black & Scholes			
Expected volatility	42.50%	42.50%	76.49%	62.46%	49.37%	58.02%	78.5%
Expected dividend	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Subscription price per warrant	€0.08	€0.08	€0.25	€0.65	€0.40	€0.18	€0.13
Fair value per warrant (subscription price deducted)	€0.36	€0.36	€5.31	€2.94	€1.64	€2.02	€1.83

Changes in the balances of BSA

	BSA 2013-02	BSA 2015-06	BSA 2016	BSA 2017	BSA 2018	BSA 2019	Total
Balance outstanding at January 1, 2019	**293,040**	**121,000**	**158,000**	**165,000**	**20,000**	**—**	**757,040**
Granted during the period	—	—	—	—	—	105,000	105,000
Exercised during the period	—	—	—	—	—	—	—
Forfeited during the period	—	—	—	—	—	—	—
Balance outstanding at December 31, 2019	**293,040**	**121,000**	**158,000**	**165,000**	**20,000**	**105,000**	**862,040**
Of which exercisable	293,040	118,479	158,000	140,938	11,250	37,188	758,894

18.3 Free shares (AGA)

Vesting schedule

In July 2016, the Company's Board of Directors granted an aggregate of 766,000 free shares (AGA 2016) as follows:

- 546,000 AGA 2016 were fully acquired by key managers, including Mr. Bernard Gilly, the Chief Executive Officer of the Company, subject to the achievement of the following performance criteria no later than July 2018:
  - 291,000 of these free shares were acquired at the completion of enrollment in RESCUE and REVERSE clinical trials in July 2017; and
  - 255,000 free shares were acquired at the enrollment of the first patient in a Phase I/II clinical trial of GS030 in RP in July 2018.
- 56,000 AGA 2016 were fully acquired in July 2017 (one year after their grant date).

The AGA 2016 were issued at their nominal value and are subject to a lock-up period of one year after their acquisition date.

In July 2017 and in December 2017, the Company's Board of Directors granted an aggregate of 666,000 additional AGA 2016 as follows:

- 544,500 AGA 2016 were acquired by key managers, including Mr. Bernard Gilly, subject to the achievement of the performance criteria described below:
  - 281,250 of these free shares were acquired upon receipt of the definitive results of the GS010 REVERSE clinical trial; and
  - the remaining 263,250 free shares were acquired upon completion of the enrollment of 50% of the patients of a Phase I/II clinical trial of GS030 in RP, on May 17,2019.
- 32,500 AGA 2016 were fully acquired on July 2018 (one year after their grant date).

The AGA 2016 were issued at their nominal value and are subject to a lock-up period of one year after their acquisition date.

In September 2018 and December 2018, the Company's Board of Directors granted an aggregate of 515,000 additional AGA 2018 as follows:

- 400,000 AGA 2018 (60,000 were cancelled), which may be fully acquired by key managers, including Mr. Bernard Gilly, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than September 2020:
  - 200,000 of these free shares will be acquired upon completion of the enrollment of the patients of a Phase I/II clinical trial of GS030 in RP; and
  - the remaining 200,000 free shares will be acquired upon of the production of the first PPQ Batch of GS010.
- 40,000 AGA 2018 (15,000 AGA were cancelled) were fully acquired on September 18, 2019 (one year after their grant date).

The AGA 2018 will be issued at their nominal value and will be subject to a lock-up period of one year after their acquisition date.

In July 2019, the Company's Board of Directors granted an aggregate of 610,000 additional AGA 2018 as follows:

- 572,500 AGA 2018 which may be fully acquired by key managers, including Mr. Bernard Gilly, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than July 2021:
  - 286,250 of these free shares will be acquired upon the filing with the European Medicines Agency (EMA) of the application for Market Authorization (MA) at the European level of GS010;
  - The remaining 286,250 of these free shares will be acquired upon completion of the enrollment of the patients of a Phase I/II clinical trial of GS030 in RP; and
- 37,500 (of which 5,000 were cancelled) AGA 2018 will be fully acquired in July 2020 (one year after their grant date).

Details and main characteristics of the AGA granted to date

	AGA 2016	AGA 2016	AGA 2016	AGA 2018	AGA 2018	AGA 2019
Date of grant	July 26, 2016	July 27, 2017	December 19, 2017	September 18, 2018	December 19, 2018	July 23, 2019
Number of Share Awards initially granted	766,000	593,500	72,500	380,000	135,000	610,000
Vesting period (in Years)	1	1	1	1	1	1
Grant date Fair-value	€8.08	€5.12	€5.55	€2.10	€4.04	€1.80
Performance conditions (1)	Yes	Yes	Yes	Yes	Yes	Yes

(1) Performance conditions concern only grants to key managers, other employees are only subject to a service condition.

Changes in the balances of AGA

	AGA 2016	AGA 2018	Total
Balance outstanding at January 1, 2019	**271,250**	**492,500**	**763,750**
Granted during the period	—	610,000	610,000
Vested during the period	(263,750)	(40,000)	(303,750)
Forfeited during the period	(7,500)	(57,500)	(65,000)
Balance outstanding at December 31, 2019	**—**	**1,005,000**	**1,005,000**

18.4 Stock options (SO)

Vesting schedule

The SO 2017 granted on December 19, 2017, may be exercised by the beneficiary on the basis of the following vesting schedule:

- Up to ¼ on the date of the grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the date of grant; and
- at the latest within seven years from the date of grant.

The SO 2017 granted on March 14, 2018, may be exercised by the beneficiary on the basis of the following vesting schedule:

- 25% of the Options shall vest on the first anniversary of the Vesting Commencement Date;
- the remaining 75% becoming exercisable up to 1/36 per month from the date of grant; and
- at the latest within seven years from the date of grant.

The SO 2018 granted on December 19, 2018, may be exercised by the beneficiary on the basis of the following vesting schedule:

- 25% of the Options shall vest on the first anniversary of the Vesting Commencement Date;
- the remaining 75% becoming exercisable up to 1/36 per month from the date of grant; and
- at the latest within seven years from the date of grant.

Details and main characteristics of the SO granted to date

	SO 2017	SO 2017	SO 2017	SO 2018
Date of grant	July 27, 2017	December 19, 2017	March 14, 2018	September 18, 2018
Plan expiration date	July 26, 2024	December 18, 2024	March 13, 2025	September 17, 2025
Number of warrants initially granted	220,000	300,000	175,000	30,000
Exercise price	€5.04	€5.55	€ 6.98	€ 2.19
Share entitlement per warrant	1	1	1	1
Valuation method		Black & Scholes		
Expected volatility	51.09%	50.36%	48.75%	58.02%
Expected dividend	0.00%	0.00%	0.00%	0.00%
Fair value per option	€2.09	€2.20	€ 2.63	€ 0.91

Changes in the balances of SO

	SO 2017	SO 2018	Total
Balance outstanding at January 1, 2019	**475,000**	**30,000**	**505,000**
Granted during the period	—	—	—
Exercised during the period	—	—	—
Forfeited during the period	(475,000)	(30,000)	(505,000)
Balance outstanding at December 31, 2019	**—**	**—**	**—**
Of which exercisable	—	—	—

18.5 Reconciliation with P&L share-based expenses

	As of December 31, 2018				As of December 31, 2019			
In thousands of euros	R&D	G&A	S&M	TOTAL	R&D	G&A	S&M	TOTAL
Non-Employee Warrants (BSA)	70	98	—	168	49	88	—	136
Employee Warrants (BCE)	5	141	—	146	(41)	19	—	(22)
Performance Shares (AGA)	335	887	340	1,561	766	695	121	1,582
Stock Options (SO)	540	6	—	547	(388)	(1)	—	(389)
Share-based payments expense	**950**	**1,132**	**340**	**2,422**	**385**	**801**	**121**	**1,307**

Note 19: Financial income and expenses

The financial income and expenses are broken down as follows:

	As of December 31,	
In thousands of euros	2018	2019
Income from cash equivalents	—	—
Foreign exchange gains	40	95
Other	4	1
Financial income	**44**	**96**
Foreign exchange losses	(43)	(115)
Accrued interests	(408)	(191)
Interest expenses from Lease	—	(179)
Amortized cost (Effective Interest Method)	—	(18)
Finance cost on employee benefits	(1)	(1)
Other	—	—
Financial expenses	**(452)**	**(504)**
Total	**(408)**	**(409)**

Foreign exchange gains and losses primarily arise from the purchase of services labeled in U.S. dollars.

The accrued interests correspond to the interest expenses on the conditional advances received from Bpifrance Financement. As mentioned in Note 11.2, the accrued interests have been calculated on the basis of a rate of 5.56%.

Interest expenses from Lease reflect interest on the lease liability deriving from the first application of IFRS 16 new standard.

Note 20: Income tax expense

As mentioned in Note 3.12 – Accounting Principles – Research Tax Credit, subsidies and conditional advances, the French Research Tax Credit is not included in the line item income taxes but included in the line item other income.

As the Group is generating tax losses, no income tax expense has been recognized. Moreover, in accordance with the principles described in Note 3.17, and with respect to the stage of development of the Company, no deferred tax assets have been recognized in the Financial Statements.

As of December 31, 2019, accumulated tax loss carryforwards since inception amounted to €144 million. This tax loss can be carried forward indefinitely and charged against future profits, in accordance with current French tax laws (CGI art. 209, I-al. 3 et BIC-XIV-2000s).

Reconciliation between the effective and nominal income tax expense

The following table shows the reconciliation between the effective and nominal tax expense at the statutory French rate of 28.00% as of December 31, 2019 (same as of December 31, 2018), excluding additional contributions:

	As of December 31,	
In thousands of euros	2018	2019
Income before taxes	**(33,453)**	**(30,710)**
Statutory tax rate	28.00%	28.00%
Nominal tax expense	9,367	8,599
Increase/decrease in tax expense arising from:	—	—
Research tax credit	1,210	(80)
Share-based compensation	(678)	(1,115)
Non-recognition of deferred tax assets related to tax losses and temporary differences	(9,899)	(7,400)
Other differences	—	—
Income tax expense	—	(4)
Effective tax rate	0%	0%

Note 21: Commitments

The following table discloses aggregate information about material contractual obligations and the periods in which payments are due as of December 31, 2019.

In thousands of euros	Total	Less than one year	One to three years	Four to five years	More than five years
Conditional advances	3,633	—	550	2,500	583
Pension and employee benefits	103	—	—	—	103
G&A operations related services	2,187	437	875	875	—
Corporate bond	4,621	889	3,732	—	—
Total	**10,544**	**1,326**	**5,157**	**3,375**	**686**

Commitments under service agreement – G&A operations

The Group entered into a services contract with *Passage de l'Innovation* in connection with human resources, legal and intellectual property services on May 1, 2017, which was amended on December 15, 2017, January 31, 2018 and December 18, 2018. According to the last amendment terms and conditions, the annual cost is fixed at €240 K and each party can terminate the contract after a six-month notice period.

Commitments related to R&D operations

The Company has signed various licensing and collaboration agreements:

- In October 2012, the Group entered into a license agreement with Inserm Transfert S.A. ("Inserm"), a French public scientific and technological institute. The Group paid a license fee of €40 K in 2013 upon the execution of the agreement, which has been recognized as research and development expenses in the statement of income. Upon completion of development milestones, the Group has to pay non-refundable fees up to €2,750 K in the aggregate. As of December 31, 2019, the residual commitments amount to €1,800 K. Upon commercialization of any product covered by the licensed patents, the Group will be obligated to pay a percentage of net sales as a royalty. The royalty rate varies depending on the amount of net sales.
- In December 2013, the Group entered into a license agreement for use of scientific data with the *Association Française contre les Myopathies*, ("AFM"), a non-profit association, the French Muscular Dystrophy Association, Genethon and Inserm Transfert, acting as a delegate of Inserm, a French public scientific and technological institute and the *Université Pierre et Marie Curie*, ("UPMC"), a French university. The Group paid a license fee of €10 K upon the execution of the agreement, which has been recognized as research and development expenses in the Consolidated Statement of Income. Upon completion of development milestones, the Group has to pay non-refundable fees up to €688 K. As of December 31, 2019, the residual commitments amounted to €450 K. Upon commercialization of any product covered by the license patents, the Group will be obligated to pay an annual royalty of 1% of net sales.
- In February 2013, the Group entered into a license agreement with Novartis. The Company issued 670,588 ordinary shares as consideration paid for the licenses. The amount of the intangible asset recognized was €275 K (see Note 4) and determined by reference to the fair value of the ordinary shares that were granted by the Company in exchange for the licenses. Upon commercialization of any product covered by the licenses, the Company will be obligated to pay a royalty of 5% of net sales.
- In February 2014, the Company entered into a non-exclusive license, development and commercialization agreement with Avalanche Technologies ("Avalanche" renamed "Adverum Biotechnologies"), a biotechnology company. The annual license fee payable by the Group is $30 K, which was a €26 K payment each year from 2014 to 2018 recognized as research and development expenses in the statement of income. Upon completion of development milestones, the Group has to pay specified non-refundable fees of up to $5,900 K. As of December 31, 2019, the residual commitments amount to $5,500 K. Upon commercialization of any product covered by the license patents, the Group will be obligated to pay a percentage of net sales as a royalty. The royalty rate varies depending on the amount of net sales.
- In January 2016, the Group entered into a license agreement with M.I.T., upon exercising an option right granted under the patent option agreement between M.I.T. and the Group, dated January 9, 2015. Under the terms of this license agreement, the Group recognized as a research and development expense and agreed to pay a license issue fee of $45 K, license maintenance fees up to $100 K per year and variable payments up to $7,300 K depending on the achievement of milestone events. As of December 31, 2019, the residual commitments amount to $6,700 K. The Group will also pay running mid-single-digit royalties on future net sales.
- In 2019, the Company entered into a non-exclusive license agreement with President and Fellows of Harvard College. Under the terms of this license agreement, we agreed to pay

a non-refundable license issuance fee of $25 K. In addition, we agreed to pay an annual license maintenance fee as from the first commercial sale of a licensed product ranging from $25 K to $75 K (creditable against running royalties), a milestone payment of $25 K upon achievement of marketing authorization for the first licensed product in any country, and a running royalty of less than 1% on net sales for a period of 15 years from the date of the first commercial sale (on a licensed product by licensed product basis).

- In 2019, GenSight Biologics entered into an exclusive license agreement with Sorbonne University, *Centre National de la Recherche Scientifique* ("CNSR"), *Institut National de la Santé et de la Recherche Médicale* and SATT Lutech. Under this license agreement, we paid the licensors a one-time license upfront payment of €30 K. We are also obliged to pay milestone payments upon achievement of certain development and regulatory milestone events. After the grant of a MA or BLA for the product, we are required to pay a fixed royalty fee for each first use of a product on a patient who has received the associated gene therapy treatment. In addition, we are required to pay an annual license maintenance fee creditable against the total paid amount of fixed royalty fee due on the same year.

For each of these licensing and collaboration agreements, based on the significant uncertainties in the development of the product candidates as well as the Group having sole discretion to decide whether it would like to proceed with the research and development activities, the Group has concluded, based on the stage of development of its product candidates, that it is remote that a payment will be made by the Group to the parties under these licensing and collaboration agreements.

Note 22: Relationships with related parties

The Group did not conclude any new significant transactions with related parties during the period.

Key management personnel compensation

The compensation amounts presented below, which were awarded to key management personnel which are members of the Board of Directors of the Group, were recognized as expenses during the period presented:

	As of December 31,	
In thousands of euros	2018	2019
Short-term employee benefits	829	864
Share-based payments benefits	837	467
Total	**1,666**	**1,332**

The methods and assumptions used for the measurement of share-based payments are described in Note 18.

Liabilities to key management personnel as of December 31, 2018 and 2019 are set forth below:

	As of December 31,	
In thousands of euros	2018	2019
Variable compensation	128	110
Total	**128**	**110**

Transactions with related parties:

Mr. Bernard Gilly, CEO of GenSight Biologics, is a shareholder (27.1%) of *Passage de l'Innovation* as of December 31, 2019. In 2015, the Company entered into an agreement with *Passage de l'Innovation* for the rental of its new premises. As described above, several amendments were signed on January, July, October 2018 and November 2019, as well as an amendment related to the service agreement in connection with human resources, legal and intellectual property services. The related amounts presented below were recognized as expenses during the period presented:

	As of December 31,	
In thousands of euros	2018	2019
Rent and services	792	766
Total	**792**	**766**

No liabilities are due to related parties as of December 31, 2018 and December 31, 2019, respectively.

Note 23: Earnings per share

The basic earnings per share is calculated by dividing the net income for the period attributable to the shareholders of the Group by the weighted average number of ordinary shares outstanding during the period. Preferred shares had the same rights and dividends as ordinary shares for purposes of calculating earnings per share. All preferred shares were converted on a one-for-one basis into ordinary shares upon completion of the IPO on Euronext Paris in July 2016.

All outstanding ordinary shares have been taken into consideration for purposes of calculating basic earnings per share. The weighted average number of ordinary shares was 24,466,559 and 28,382,184 for the years ended December 31, 2018 and 2019, respectively.

The diluted earnings per share is calculated by dividing the net income for the period attributable to shareholders of the Group by the weighted average number of shares outstanding plus any potentially dilutive shares not yet issued from share-based compensation plans (see Note 18).

Dilution is defined as a reduction of earnings per share or an increase of loss per share. When the exercise of outstanding share options and warrants decreases loss per share, they are considered to be anti-dilutive and excluded from the calculation of

loss per share. Thus, basic and diluted earnings (loss) per share are equal as all equity instruments issued, representing 2,700,426 and 3,869,644 potential additional ordinary shares, for the years ended December 31, 2018 and 2019, respectively, have been considered anti-dilutive.

In thousands of euros, except for earning (loss) per share	As of December 31, 2018	2019
Net income (loss) of the reporting period	(33,453)	(30,710)
Adjusted weighted average number of outstanding shares	24,466,559	28,382,184
Basic and diluted earnings (loss) per share	**€(1.37)**	**€(1.08)**

Note 24: Management of financial risks

The principal financial instruments held by the Group are cash and cash equivalents. The purpose of holding these instruments is to finance the ongoing business activities of the Group. It is not the Group's policy to invest in financial instruments for speculative purposes. The Group does not utilize derivatives.

The principal risks to which the Group is exposed are liquidity risk, foreign currency exchange risk, interest rate risk and credit risk.

Liquidity risk

Ultimate responsibility for liquidity risk management rests with the Board of Directors, which has established an appropriate liquidity risk management framework for management of the Group's short, medium and long-term funding and liquidity management requirements. The Group manages liquidity risk by maintaining adequate reserves, banking facilities and reserve borrowing facilities, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The note 11.2 details the Group's remaining contractual maturity for its non-derivative financial liabilities with agreed repayment periods.

As of December 31, 2019, the Group does not have sufficient net working capital to meet its obligations during the next 12 months. See Note 2.2 Going Concern.

Foreign currency exchange risk

The Group is exposed to foreign exchange risk inherent in certain services provided in the United States, which have been invoiced in U.S. dollars. The Group does not currently have revenues in dollars nor in any other currency. Due to the relatively low level of these expenditures, the exposure to foreign exchange risk is unlikely to have a material adverse impact on the results of operations or financial position of the Group. The Group's exposure to currencies other than the U.S. dollar is negligible. For the years ended December 31, 2018 and 2019, approximately 20% and 33%, respectively, of its purchases and other external expenses were made in U.S. dollars, generating a foreign exchange loss of €43 K and €115 K, respectively. In light of these insignificant amounts, the Group has not adopted, at this stage, a hedging mechanism in order to protect its business activity against fluctuations in exchange rates. As the Group further increases its business, particularly in the United States, the Group expects to face greater exposure to exchange rate risk and would then consider adopting an appropriate policy for hedging against these risks.

Interest rate risk

The Company has low exposure to interest rate risk. The Group borrow funds at fixed interest rates. The repayment flows of the advances from *Banque Publique d'Investissement* ("BPI France") and the borrowings are not subject to interest rate risk.

Credit risk

In order to minimize credit risk, the Group has adopted a policy of only dealing with creditworthy counterparties and obtaining sufficient collateral, where appropriate, as a means of mitigating the risk of financial loss from defaults. The Group's exposure and the credit ratings of its counterparties are continuously monitored and the aggregate value of transactions concluded is spread amongst approved counterparties.

The credit risk related to the Group's cash and cash equivalents is not significant in light of the quality of the co-contracting financial institutions.

The Group does not have significant credit risk exposure to any single customer or any group of counterparties having similar characteristics.

Fair value

The fair value of financial instruments traded on an active market is based on the market rate as of December 31, 2019. The market prices used for the financial assets owned by the Company are the bid prices in effect on the market as of the valuation date.

The nominal value, less the provisions for depreciation, of the accounts receivable and current debts, is presumed to approximate the fair value of those items.

Capital risk management

The Group manages its capital to ensure that entities in the Group will be able to continue as going concerns while maximazing the return to shareholders through the optimization of the debt and equity balance. The Group's overall strategy remains unchanged from 2018.

The capital structure of the Group consists of net debt (borrowings disclosed in notes 10 after deducting cash and bank balances) and equity of the Group (comprising issued capital,

reserves and retained earnings and non-controlling interests as disclosed in Note 10).

The Group is not subject to any externally imposed capital requirements.

Note 25: Auditor's fees

The auditors' fees paid by the Group in 2019 amounted to €322 K.

	2019			
	Becouze		Deloitte & Associés	
In thousands of euros	Amount	%	Amount	%
Audit certification	165	98%	148	97%
Other report for French legal purposes	5	2%	5	3%
Total	**169**	**100%**	**153**	**100%**

Note 26: Subsequent events

On January 28, 2020, the Company has granted a total of 1,020,000 free shares to its officers and employees at a fair market value per share of €3.72 at the grant date.

18.1.2 STATUTORY AUDITORS' REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019

This is a translation into English of the statutory auditors' report on consolidated the financial statements of GENSIGHT BIOLOGICS S.A. issued in French and it is provided solely for the convenience of English speaking users.
This statutory auditors' report includes information specifically required by French law, such as information about the appointment of the statutory auditors or verification of the management report and other documents provided to shareholders.
This report should be read in conjunction with, and construed in accordance with French law and professional auditing standards applicable in France.

To the Shareholders' Meeting of GENSIGHT BIOLOGICS S.A.,

Opinion

In compliance with the engagement entrusted to us by your bylaws and your Shareholders' Meeting, we have audited the accompanying consolidated financial statements of GENSIGHT BIOLOGICS S.A. for the year ended December 31, 2019. These financial statements were approved by the board of directors on March 11, 2020 on the basis of the information available at that date in the evolving context of the Covid-19 health crisis.

In our opinion, the consolidated financial statements give a true and fair view of the assets and liabilities and of the financial position of the Group as of December 31, 2019 and of the results of its operations for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union.

The audit opinion expressed above is consistent with our report to the Audit Committee.

Basis for Opinion

Audit Framework

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the "Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements" section of our report.

Independence

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from January 1, 2019 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 or in the French Code of ethics *(Code de déontologie)* for statutory auditors.

Material uncertainty regarding going concern

Without questioning the opinion expressed above, we draw attention to the note "2.2. Going concern" to the consolidated financial statements for the year ended December 31, 2019 which describes the material uncertainty resulting from events or conditions that may cast significant doubt on the Company's ability to continue as a going concern.

Emphasis of Matter

Without qualifying our opinion expressed above, we draw your attention to the Note 2.1 "Statement of compliance – Impact of initial application of IFRS 16 Leases" and the Note 6 "IFRS 16 – Leases" of the Consolidated Financial Statements which present the fact that the Company has opted for the simplified retrospective method for the first time adoption of IFRS 16 on January 1, 2019 and the impact of this new standard as of December 31, 2019.

Justification of Assessments – Key Audit Matters

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code *(Code de commerce)* relating to the justification of our assessments, and besides to the matter described in the "Material Uncertainty Related to Going Concern" section, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period, as well as our responses to those risks.

These matters were addressed in the context of our audit of the consolidated financial statements as a whole, approved in the circumstances mentioned above, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the consolidated financial statements.

Recording of research and development costs
(refer to notes "3.20 Use of estimates" and "17.1 Research and development expenses" to the notes to consolidated financial statements as of December 31, 2019)

Identified risks

Research and development costs represent a significant component of the Group's consolidated financial statements, considering Company' activity and its current development phase, as they account for 81% of total operating expenses. These expenses mainly include external subcontracting costs (including preclinical and clinical studies in particular) or product manufacturing as well as personnel costs.

There may be discrepancies between the achievement of subcontracting or manufacturing services and their related invoicing. The need of estimating the amount of services already achieved but not invoiced, or at the opposite, services already invoiced but not realized, leads to a risk of misevaluation of the invoices to be received or prepaid expenses regarding these external costs at year end.

The estimate of the amount of services already performed to be recognized at year end thus requires significant judgments from the management.

We therefore considered that the accounting of research and development expenses is a key audit matter.

Audit procedures implemented to deal with identified risks

As part of our audit, we reviewed the internal control procedures related to the accounting of subcontracting and manufacturing expenses in order to identify control activities implemented by Management and evaluate their design.

Our work were supplemented by procedures, on a sampling basis, of account payable confirmation requests and an analysis of subcontracting invoices received before and after year end, in order to identify which exercise they related to and evaluate the correct linkage with fiscal year.

Specific Verifications

We have also performed, in accordance with professional standards applicable in France, specific verifications required by laws and regulations of the Group information presented in the Board's Management Report approved on March 11, 2020. With regard to the events which occurred and the facts known after the date the financial statements were approved by relating to the impact of the Covid-19 crisis, the management indicated to us that they will be communicated to the annual general meeting called to approve the financial statements.

We have no matters to report as to its fair presentation and its consistency with the consolidated financial statements.

Report on Other Legal and Regulatory Requirements

Appointment of the Statutory Auditors

We were appointed as statutory auditors of GENSIGHT BIOLOGICS S.A. by the bylaws of April 17, 2012 for Deloitte & Associés and by the Shareholders' Meeting of May 19, 2016 for Becouze.

As at December 31, 2019, Deloitte & Associés was in the 7th year of total uninterrupted engagement and Becouze was in the 4th year of total uninterrupted engagement, including four years of joint work since securities of the Company were admitted to trading on a regulated market.

Responsibilities of Management and Those Charged with Governance for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with International Financial Reporting Standards as adopted by the European Union, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The consolidated financial statements were approved by the Board of Directors.

Statutory Auditors' Responsibilities for the Audit of the Consolidated Financial Statements

Objectives and audit approach

Our role is to issue a report on the consolidated financial statements. Our objective is to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As specified in Article L.823-10-1 of the French Commercial Code *(Code de commerce)*, our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.
- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the consolidated financial statements.
- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the consolidated financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.
- Evaluates the overall presentation of the consolidated financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation.

- Obtains sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. The statutory auditor is responsible for the direction, supervision and performance of the audit of the consolidated financial statements and for the opinion expressed on these consolidated financial statements.

Report to the Audit Committee

We submit a report to the Audit Committee which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the consolidated financial statements of the current period and which are therefore the key audit matters, that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) N° 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L.822-10 to L.822-14 of the French Commercial Code *(Code de commerce)* and in the French Code of Ethics *(Code de déontologie)* for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Paris and Bordeaux, April 8, 2020

The Statutory Auditors
French original signed by

Becouze	Deloitte & Associés
Fabien BROVEDANI	Stéphane LEMANISSIER

18.1.3 COMPANY'S ANNUAL FINANCIAL STATEMENTS (FRENCH GAAP) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2019

1. BALANCE SHEET

ASSETS

		12/31/2019			12/31/2018
In thousands of euros	Note	Gross	Deprec. Prov.	Net	Net
Non-current assets					
Intangible assets					
Software	1	18	12	6	1
Tangible assets	2				
Property, plant and equipment		1,207	615	592	729
Other tangible assets		516	422	94	147
Financial assets	3				
Other financial assets		630	—	630	580
Total non-current assets		**2,371**	**1,049**	**1,322**	**1,457**
Current assets					
Receivables	4				
Down payments		185	—	185	370
Accounts receivable		1,576	—	1,576	487
Other receivables		5,261	—	5,261	5,155
Loans and receivables		4,617	2,375	2,242	1,329
Cash	5				
Cash and cash equivalents		19,171	—	19,171	25,788
Prepaid expenses		1,959	—	1,959	3,037
Total current assets		**32,769**	**2,375**	**30,394**	**36,166**
Regularization accounts					
Foreign exchange differences – assets		6	—	6	4
TOTAL ASSETS		**35,146**	**3,424**	**31,722**	**37,627**

The attached note forms an integral part of the financial statements.

LIABILITIES AND SHAREHOLDERS' EQUITY

In thousands of euros	Note	12/31/2019	12/31/2018
Shareholders' equity:	**6**		
Share capital		821	620
Premiums related to the share capital		128,130	112,135
Legal reserve		—	—
Restricted reserves		174	174
Retained earnings		(89,769)	(57,581)
Net loss		**(29,323)**	**(32,189)**
Total Shareholders' equity		**10,033**	**23,159**
Provisions for liabilities and charges:			
Provisions for liabilities		28	4
Total provisions for liabilities and charges		**28**	**4**
Liabilities:	**7**		
Straight bonds		4,200	—
Convertible bonds		1,800	—
Refundable advances		3,633	3,441
Trade payables		10,034	9,237
Tax and social liabilities		1,886	1,749
Other liabilities		3	6
Total liabilities		**21,556**	**14,433**
Regularization accounts:			
Foreign exchange differences – liabilities		105	31
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		**31,722**	**37,627**

The attached note forms an integral part of the financial statements.

2. STATEMENTS OF INCOME (LOSS)

In thousands of euros	Note	12/31/2019	12/31/2018
Sales of products or services	10	700	–
Income		700	–
Operating revenues:			
Grants		–	24
Transferred expenses		3	54
Other revenues		264	250
Total operating revenues (I)		**967**	**328**
Operating expenses:			
Purchases of raw material		256	63
Other purchases and external expenses		27,709	28,736
Tax expenses		56	110
Payroll expenses		3,379	3,694
Social charges		1,504	1,145
Depreciation and amortization		284	243
Other expenses		414	660
Total operating expenses (II)		**33,602**	**34,651**
OPERATING LOSS (I-II)		**(32,635)**	**(34,323)**
Financial income:			
Foreign exchange gains		–	–
Other financial income		–	81
Total financial income (III)		**–**	**81**
Financial expenses:			
Foreign exchange losses		–	–
Depreciation and amortization		583	1,824
Interest expenses on borrowings and financial debt		211	408
Other financial expenses		103	36
Total Financial expenses (IV)		**897**	**2,268**
FINANCIAL INCOME (EXPENSES) (III-IV)	**11**	**(897)**	**(2,187)**
EARNING BEFORE TAX (I-II+III-IV)		**(33,532)**	**(36,510)**
EXTRAORDINARY INCOME (EXPENSES) (V-VI)		**–**	**(1)**
Income taxes	15	(4,210)	(4,322)
NET INCOME (LOSS)		**(29,323)**	**(32,189)**

The attached note forms an integral part of the financial statements.

3. NOTES TO THE FINANCIAL STATEMENTS

GOING CONCERN

The annual financial statements for the year ended December 31, 2019 have been prepared in accordance with French accounting rules in compliance with the principle of prudence and independence of exercises, and assuming the going concern.

Since its incorporation, the Company has funded its activities through several equity financings, grants, conditional advances and Research Tax Credit. In 2019, the Company started to generate revenue from the sale of LUMEVOQ™ (GS010) to the *CHNO des Quinze-Vingts* in Paris, since the National Drug Safety Agency (ANSM) granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™. To date, the Company continues to actively prepare for the launch of LUMEVOQ™ in Europe in 2021 and in the United States in 2022.

Current cash and cash equivalents on hand are not projected to be sufficient to support the Company's current operating plan for a period of 12 months following the date of issuance of the 2019 annual financial statements. Considering the cash position as of December 31, 2019 (amounting to €19.2 million), the reimbursement of the 2019 Research Tax Credit contemplated in 2020 for a consideration of €4.2 million and additional expected income related to the ATU in France cautiously forecasted at €7.0 million, the Company expects to cover its cash requirements until the end of November 2020.

We believe that the €7.0 million income from the ATU in France, representing 10 patients treated, is a cautious estimate. Any additional request approved would reduce the need for financing and extend the runway accordingly.

In order to meet these obligations and subject to the realization of a Qualifying Financing(1) of €10 million, the Company will be able to receive a second tranche of €4.0 million from the bond issuance with Kreos Capital. The Company will also explore other financing options through debt or equity in order to complete its working capital needs and to finance its operating expenses. In this respect, a third optional tranche of €2 million could be made available to the Company by Kreos Capital at a later date.

The financial statements have been prepared on a going concern basis assuming that the Company will either be successful in its additional financing objections or that the Company will modify its operating plans, in particular by delaying or limiting the scope of its research and development programs. However, no assurance can be given at this time as to whether the Company will be able to achieve these financing objectives. As such, there are material uncertainties regarding the Company's ability to continue as a going concern. As such, no adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should the Company not be able to continue as a going concern.

MAIN EVENTS OF THE FISCAL YEAR

On February 4, 2019 GenSight Biologics reports top-line results at Week 48 of the RESCUE Phase III clinical trial of GS010, which evaluates the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) occurred up to 6 months prior to study treatment.

On February 25, 2019, GenSight Biologics announced the completion of a capital increase of €8 million subscribed entirely by Sofinnova Crossover I SLP ("Sofinnova"). The purpose of this capital increase is to pursue the final stages of clinical development of GS010, and file for marketing authorization in Europe.

On April 17, 2019 the Company announced results from the second scheduled readout, at Week 72, of the RESCUE Phase III clinical trial evaluating the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) occurred up to 6 months prior to study treatment.

On May 7, 2019, GenSight Biologics announced that the independent Data Safety Monitoring Board (DSMB) completed its first safety review of the ongoing PIONEER Phase I/II clinical trial of GS030 combining gene therapy and optogenetics for the treatment of Retinitis Pigmentosa. The DSMB confirmed the absence of any safety issues for the first cohort of three subjects who received a single intravitreal injection of 5e10 vg combined with a wearable optronic visual stimulation device. The DSMB recommended moving forward as planned without any modification in the protocol and recruiting the second cohort of three subjects receiving an escalating dose of 1.5e11 vg.

On May 15, 2019 GenSight Biologics reported a first set of results from Week 96 of the REVERSE Phase III clinical trial. The trial evaluated the safety and efficacy of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 37 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) commenced between 6 and 12 months prior to study treatment.

On July 11, 2019 the Company announced that enrollment in REFLECT, a Phase III clinical trial of GS010 for the treatment of Leber Hereditary Optic Neuropathy (LHON), was successfully completed ahead of schedule.

(1) Qualifying Financing means a financing of the Company in the form of equity (or Non-Dilutive Payment or subordinated convertible bonds, or a combination of the above) from existing shareholders and/or new top tier investors reasonably satisfactory to Kreos, with a minimal amount of gross proceeds of €10 million, being specified that such amount may be reduced, up to a maximal amount of €2 million, by the proceeds susceptible to be received by the Company under *Autorisations Temporaires d'Utilisation payantes*.

On September 23, 2019 GenSight Biologics reported the first set of results from Week 96 of the RESCUE Phase III clinical trial. The trial evaluated the efficacy and safety of a single intravitreal injection of GS010 (rAAV2/2-ND4) in 39 subjects whose visual loss due to 11778-ND4 Leber Hereditary Optic Neuropathy (LHON) commenced up to 6 months prior to study treatment.

On October 9, 2019 the Company reported positive proof of GS010 DNA transfer from one eye to the other eye following unilateral intravitreal injection of primates. In a non-clinical study to investigate the local biodistribution of GS010, tissue samples from the non-injected eye of monkeys that had been unilaterally injected with GS010 were found to contain GS010 DNA three months after injection, indicating the expression of the therapeutic gene in the contralateral eye.

On December 9, 2019 GenSight announced that the French Competent Authority, the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM), granted a named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*.

On December 11, 2019 the Group reported results from the REALITY registry study and an analysis of REVERSE and RESCUE Phase III data, which further highlight the poor prognosis for patients with loss of vision due to Leber Hereditary Optic Neuropathy (LHON) associated with the ND4 mutation. The results confirm LHON experts' observations from their clinical practice and contrast sharply against the bilateral improvement observed in LUMEVOQ™ (GS010)'s Phase III studies.

On December 20, 2019 GenSight Biologics announced that it had obtained committed financing in the form of a bond financing of up to €12 million from Kreos Capital VI (UK) Limited ("Kreos") and issued a drawdown notice thereunder for the first tranche of €6 million (the "Kreos Transaction") concurrently with the completion of a capital increase of €9 million subscribed for by one of its main shareholders Sofinnova Crossover I SLP ("Sofinnova") and by a new strategic Chinese investor Strategic International Group Limited, a wholly owned subsidiary of 3SBio Inc. ("3SBio") (the "3SBio-Sofinnova Transaction").

EVENTS AFTER THE CLOSE OF THE FISCAL YEAR

On January 28, 2020, the Company has granted a total of 1,020,000 free shares to its officers and employees at a fair market value per share of €3.72 at grant date.

ACCOUNTING PRINCIPLES

Non-current assets

Tangible and intangible assets are recorded at the contribution value or at their original purchase price.

Depreciation of tangible assets is calculated using the straight-line method to take into account the economic depreciation of fixed assets.

At the closing of the accounts, whenever events or market developments suggest the need for impairment of intangible and tangible assets, expected future revenues of the activity are compared to the net value of its assets. If applicable, the corresponding assets are written down to bring them to their fair value.

Intangible assets

Research costs are recorded in the financial statements as expenses.

Development costs are recognized in the financial statements as intangible assets only if all the following criteria are met:

- It is technically feasible to complete the development of the project;
- Intention of the Company to complete the project and to utilize it;
- Capacity to utilize the intangible asset;
- Proof of the probability of future economic benefits associated with the asset;
- Availability of the technical, financial and other resources for completing the project; and
- Reliable evaluation of the development expenses.

Because of the risks and uncertainties related to regulatory authorizations and to the research and development process, the Company considers that the six criteria would be deemed fulfilled as from the grant of market authorization.

Intangible assets consist of patents, costs related to the acquisition of software licenses. They are depreciated using the straight-line method over their expected period of use.

Items	Depreciation period
Patents	20 years
Software	3 years

Tangible assets

Tangible assets are recorded at their acquisition cost or, if applicable, at their production cost.

Tangible assets are depreciated using the straight-line method over the estimated useful period of the property. Rented fixtures are depreciated over the term of their lifetime or over the term of the rental agreement, whichever is shorter.

The depreciation periods used are the following:

Items	Depreciation period
Fixtures and improvement in structures	9 years
Research and development equipments	5 to 10 years
Computer equipment	3 years
Office equipment and furniture	5 years

Financial assets

Investments

These items are recognized in the balance sheet at purchase cost excluding incidental expenses.

Their value is assessed annually by reference to their value in use which is mainly based on the current and forecast profitability of the subsidiary concerned and the share of equity owned. If the value in use falls below the net book value, a depreciation is recognized.

Security deposit

They are recorded at their original value.

Short-term investments

Marketable securities are held in order to meet short- term cash commitments rather than an investment objective or for other purposes. They are immediately convertible into a known amount of cash and subject to insignificant risk of changes in value. Short-term investments are stated at acquisition cost and consist of immediately mobilized term investments without penalty.

Receivables and payables

Receivables and payables are measured at their nominal value and are depreciated as a provision in order to take into account potential losses due to recovery difficulties.

Receivables and payables in foreign currencies are converted into euros based on exchange rate at the closing of year-end, the gap being carried over in an adjustment account for the asset or a liability depending on whether a loss or profit potential. In the case of a potential loss, a provision for foreign exchange loss is recognized.

Loans

Loans are booked at their nominal value. Related transaction costs are immediately expensed. Accrued interests are recognized as a liability at the interest rate provided in the contract.

Provisions for risks and expenses

The Company establishes provisions for risks and expenses in accordance with the definition given in the notice CRC 00-06 on liabilities, namely:

- A provision for risk and expenses corresponds to the commitments whose due dates and amounts are uncertain;
- A provision is recognized in the financial statement when the company has a legal or implicit obligation to a third party resulting from a past event, which is likely or certain to cause an outflow of resources to that third party, and provided that the future outflows of liquid assets can be estimated reliably.

Conditional advances

The company has benefited from a financial assistance in the form of non-refundable subsidies and conditional advances.

Subsidies are recognized in the financial statements where there exists reasonable assurance that:

- The company will comply with the conditions attached to the subsidies; and
- The subsidies will be received.

A public subsidy that is to be received either as a compensation for expenses or for losses already incurred or for immediate financial support of the company without associated future costs, is recognized in the financial statements as other income for the period in which the grant is classified as a receivable.

Funds received in the form of conditional advances are recognized as financial liabilities, including capitalized interests. The obligation to repay totally or partially the advance is based on the technical and commercial success of the funded program.

Details related to the conditional advances are provided in Note 7.

Use of estimates

The preparation of the Financial Statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, income and expenses during the reporting period. The Group bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company's actual results may differ from these estimates under different assumptions or conditions. There have been no significant changes from original estimates in any periods presented.

These estimates and judgments involve mainly:

- the estimate of the repayments of the conditional advances obtained by the Company from public institutions, such as Bpifrance Financement. The anticipated repayments of the conditional advances are analyzed at each reporting period (see Note 10), and the measurement of the conditional advances classified as financial liabilities based on the effective rate method;
- research and development expenses include estimates of the amount recognized over the year for subcontracts. At year-end closing, an analysis of the services already performed but not invoiced and / or already invoiced but not performed is carried out by the project managers and validated by the company's management;
- the estimate of the amount due to one of key suppliers with which contractual relationship ended during 2019 as mentioned in Note 7. The amount booked as a liability corresponds to Management best estimate of its future cash outflow;
- the estimate of the selling price for LUMEVOQ™ (GS010) to the CHNO of the *Quinze-Vingts*. The National Drug Safety Agency, granted to GenSight Biologics a Temporary Authorization for

Use ("ATU nominative"). Variable consideration under IFRS 15 are required to be estimated at contract inception. The Group assessed individual contracts to determine the estimated variable consideration and related constraints; and

- the estimate of the amount due to one of key suppliers with which contractual relationship ended during 2019 as mentioned in Note 7. The amount booked as a liability corresponds to Management best estimate of its future cash outflow.

NOTE 1 — INTANGIBLE ASSETS

Other Intangible assets break down as follows:

In thousands of euros	01/01/2019	Increase	Decrease	12/31/2019
Gross	**12**	**6**	**—**	**18**
Software	12	6	—	18
Depreciation	**11**	**1**	**—**	**12**
Software	11	1	—	12
NET	**1**	**5**	**—**	**6**

NOTE 2 — TANGIBLE ASSETS

Tangibles assets break down as follows:

In thousands of euros	01/01/2019	Increase	Decrease	12/31/2019
Gross	**1,654**	**69**	**—**	**1,723**
Technical equipment and installations	498	27	—	526
Leasehold improvement	679	2	—	681
	1,177	*29*	*—*	*1,207*
Office and computer equipment	160	31	—	191
Furniture	317	8	—	325
	477	*39*	*—*	*516*
Depreciation	**(779)**	**(259)**	**—**	**(1,037)**
Technical equipment and installations	(221)	(91)	—	(312)
Leasehold improvement	(227)	(76)	—	(303)
	(448)	*(167)*	*—*	*(615)*
Office and computer equipment	(121)	(32)	—	(153)
Furniture	(209)	(60)	—	(269)
	(331)	*(92)*	*—*	*(422)*
NET	**876**	**(190)**	**—**	**686**

NOTE 3 — FINANCIAL ASSETS

Financial assets break down as follows:

In thousands of euros	01/01/2019	Increase	Decrease	12/31/2019
Gross	**601**	**158**	**(129)**	**630**
Investments	—	—	—	—
Security deposits	73	132	—	205
Long-term deposits	247	26	—	273
Own shares	281	—	(129)	152
Depreciation	**—**	**—**	**—**	**—**
Security deposits	—	—	—	—
Long-term deposits	—	—	—	—
Own shares	—	—	—	—
TOTAL	**601**	**158**	**(129)**	**630**

The list of subsidiaries and affiliates is presented at the end of the present notes.

The increase in security deposits mainly derives from the advance payment of the last capital reimbursement of the straight bond contracted with Kreos Capital which have been set off against the subscription price of the Tranche A.

In the context of its initial public offering, GenSight Biologics implemented a liquidity agreement. As of December 31, 2019:

- Long-term deposits consisted of free cash available within this liquidity agreement;
- Own shares amount to €152 K and are composed of 85,502 shares valued at the year-end rate (€2.485), adjusted by unrealized gains of €61 K. During the year, the number of shares purchased amounts to 796,803 at an average purchase price of €1.76 and the number of shares sold amounts to 789,301 at an average selling price of €1.81.

NOTE 4 — RECEIVABLES

Breakdown of receivables is summarized in the following table:

In thousands of euros	Less than one year	More than one year	Total gross
Downpayments	185	—	185
Accounts receivable and related receivables	1,576	—	1,576
Other receivables	5,262		5,261
Research tax credit	*4,242*	*—*	*4,242*
VAT	*1,020*	*—*	*1,020*
Others	*—*	*—*	*—*
Loans and receivables	2,242	—	2,242
Prepaid expenses	1,959	—	1,959
NET	**11,224**	**—**	**11,224**

Prepayments are made of advances to suppliers.

As of December 31, 2019, the Company has receivables mainly resulting from the Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted to the CHNO of the *Quinze-Vingts* for €700 K as well as the service agreement contracted with its US-based subsidiary, amounting to €729 K.

The Company has a research tax credit amounting to €4,242 K.

In the context of the inception of its U.S.-based subsidiary, the parent company granted cash advances of approximately $400 K (€356 K) on a quarterly basis. The gross balance amounts to €4,617 K as of December 31, 2019. Due to the uncertainty of the recoverability of this loan, the Company has deemed reasonable to book a depreciation of €2,375 K, representing the net amount due by the GenSight Biologics Inc., taking into account the management fees and recharges between the two entities.

Prepaid expenses correspond mainly to advances on manufacturing contracts, rents, research contracts, insurance premiums and travel expenses.

NOTE 5 — CASH

As of December 31, 2019, the Cash and cash equivalent amount to €19,171 K (€25,788 K as of December 31, 2018).

NOTE 6 — SHAREHOLDERS' EQUITY

6.1 — Share capital

As of December 31, 2019, share capital amounts to €821 K and consists of 32,827,362 ordinary shares with a nominal value of €0.025.

Each ordinary share shall carry to holders a proportional part to the benefits and the net assets of the Company.

Share class and number of shares	01/01/2019	Capital Increase	12/31/2019	Share capital in € K
Ordinary shares	24,802,973	8,024,389	32,827,362	821
TOTAL	**24,802,973**	**8,024,389**	**32,827,362**	**821**

Capital increases in favor of categories of persons

On February 25, 2019, GenSight completed a capital increase of €8 million subscribed entirely by Sofinnova Crossover I SLP, by the issuance of 3,921,568 new shares with a nominal value of €0.025 each for a subscription price of €2.04 each (including premium).

On December 20,2019, GenSight completed a capital increase of €9 million subscribed by Sofinnova Crossover I SLP ("Sofinnova") and by Strategic International Group Limited, a wholly owned subsidiary of 3SBio Inc, by the issuance of 3,799,071 new shares with a nominal value of €0.025 each for a subscription price of €2.369 each. 3SBio and Sofinnova participated for subscription amounts of €5 million and €4 million respectively.

Capital increases resulting from the definitive acquisition of free shares (AGA)

On May 17, 2019, 263,750 free shares AGA 2016 with performance conditions granted to key managers have been acquired, due to the achievement of the second performance criteria.

On September 18, 2019, 40,000 free shares AGA 2018 have been fully acquired by holders.

6.2 — Non-employee share warrants (BSA)

The following table relates to warrants (BSA) to purchase ordinary shares as of December 31, 2019:

Type of warrants	BSA 2013-02	BSA 2013-02	BSA 2015-06	BSA 2016	BSA 2017	BSA 2018	BSA 2019
Number of warrants issued	260,040	33,000	121,000	158,000	165,000	20,000	105,000
Subscription price per warrant (euros)	0.0008	0.0008	0.10	0.65	0.40	0.18	0.13
Number of shares to be issued	260,040	33,000	121,000	158,000	165,000	20,000	105,000
Exercise price per share (euros)	0.025	0.025	0.025	8.080	5.040	2.220	1.450
Expiration date	07/08/23	04/09/24	07/07/25	07/25/23	07/27/24	09/18/25	07/23/26

6.3 — Employee share warrants (BCE)

The following table relates to warrants (BCE) to purchase ordinary shares as of December 31, 2019:

Type of warrants	BCE 2013-02	BCE 2014-06	BCE 2015-06
Number of warrants issued	123,720	60,000	482,582
Subscription price per warrant (euros)	—	—	—
Number of shares to be issued	123,720	60,000	482,582
Exercise price per share (euros)	0.025	0.025	3.275
Expiration date	07/08/23	12/03/24	07/07/25

6.4 — Free shares (AGA)

The following table relates to free shares (AGA) as of December 31, 2019:

Free shares	2018 AGA	2018 AGA	2019 AGA
Number of granted shares	265,000	135,000	605,000
Share value at grant (euros)	2.10	4.04	1,80
Acquisition date	09/18/2019	12/19/2019	07/23/2020

6.5 — Statement of changes in shareholders' equity

In thousands of euros	Share capital	Premiums related to the share capital	Restricted reserves	Reserves	Net income (loss)	Total Shareholders' equity
As of 01/01/2019	620	112,135	174	(57,581)	(32,189)	23,159
Capital increase	201	15,995	—	—	—	16,196
Capital increase related costs	—	—	—	—	—	—
Allocation of prior period income (loss)	—	—	—	(32,189)	32,189	—
Issue od share warrants	—	—	—	—	—	—
Net income (loss)	—	—	—	—	(29,323)	(29,323)
As of 12/31/2019	**821**	**128,130**	**174**	**(89,769)**	**(29,323)**	**10,032**

NOTE 7 — LIABILITIES

The breakdown of liabilities is provided by the following table:

In thousands of euros	Less than one year	Between one and five years	More than five years	Total
Straight bonds	889	3,311	—	4,200
Convertible bonds	—	1,800	—	1,800
Refundable advances	—	3,050	583	3,633
Trade payables	10,034	—	—	10,034
Tax and social liabilities	1,886	—	—	1,886
Due to employees	594	—	—	594
Social security and payroll contribution	633	—	—	633
VAT	604	—	—	604
Other taxes	54	—	—	54
Other debts	3	—	—	3
TOTAL	**14,697**	**8,161**	**583**	**23,441**

The Group terminated its contractual relationship with one of its key suppliers during the year. No financial compensation was required. In November 2019 GenSight received two invoices from this supplier for a total amount of USD2.6 million. The Company considers that the main part of services billed by this supplier have not been performed. As of December 31, 2019, discussions between this supplier and GenSight are still ongoing. The Group's legal counsels have advised that they do not consider that the claim has merit, and they have recommended that it be contested. The Company booked a liability for € 2.4 million offset by a credit note to be received for € 2.2 million, considering that only € 0.2 million could be due to this supplier.

In 2019, GenSight Biologics obtained committed financing in the form of a bond financing of up to €12 million from Kreos Capital VI (UK) Limited and issued a drawdown notice thereunder for the first tranche of €6 million, including a €4.2 million straight bond issuance and a €1.8 million convertible bonds issuance.

In 2014, the Company received a grant from Bpifrance Financement of both subsidies and conditional advances in relation to the development of its technology platform. The program will be funded according to a specified schedule set forth in the contract, subject to completion of milestones. As the program advances, the Company will provide Bpifrance Financement with interim progress reports and a final report when the funded project ends.

Based on these reports, the Company is entitled to conditional advances from Bpifrance Financement. Each award of an advance is made to help fund a specific development milestone. The total intended amount of the conditional advances is €5,686 K. The Company has committed to reimburse a total amount of €6,490 K (included accrued interests; the annual rate amounts to 1.44%). If the total advances actually paid by Bpifrance Financement are less than €5,686 K, the reimbursements will be reduced in proportion to the advances actually paid.

As per the agreement, the advances would be paid according to the following schedule, subject to completion of milestones:

- €678 K received in December 2014;
- €2,279 K received in July 2016 (1);
- €494 K initially expected to be received in the first half of 2018 (2);
- €853 K initially expected to be received in November 2018; and
- €986 K initially expected to be received in November 2019.

After review and analysis of the stage of completion of the remaining milestones, level of expenses that have been incurred as of December 31, 2018 and 2019, and given that the initial agreement was on November 30, 2019, the Group considers that it would not be able to complete the remaining key milestones on time and therefore should not receive any more conditional advance from Bpifrance Financement.

The advances already paid in 2017 and 2016 and the corresponding accrued interests are both recognized as non-current liabilities in the statement of financial position.

The updated repayment schedule for a total amount of €3,303 K (€2,957 K of cash received + €346 K of capitalized interests) of all of the conditional advances is as follows:

- €550 K on or before June 30, 2022;
- €1,000 K on or before June 30, 2023;
- €1,500 K on or before June 30, 2024; and
- €253 K on or before June 30, 2025;

Following the repayment of all of the conditional advances, the Company may be required to make additional payments over a period of two years of up to €1.4 million (€603 K the first year and €823 K the second year), depending on whether the Company reaches cumulative revenues, excluding taxes, of €80.0 million. These additional repayments should be done within 15 years following the first year of reimbursement, *i.e.* 2037. The obligation to repay these amounts is based on the technical and commercial success of the funded program, as determined by the revenues forecast or revenues deriving from direct or indirect exploitation of those products and results of its optogenetics technology platform. In the event Bpifrance Financement determines that the program is not successful, Bpifrance Financement will meet with the Company to assess the impact on the repayments and the repayment schedule.

The Company has decided to include the future cash flows resulting from the additional payments in the calculation of the EIR, based on the first sales projections of its second product.

NOTE 8 — RESEARCH AND DEVELOPMENT EXPENSES

As indicated in the accounting policies, R&D expenses are not capitalized but recorded as operating expenses. For fiscal year 2019, R&D expenses amounted to €27,705 K.

NOTE 9 — ACCRUED EXPENSES

The amount of accrued expenses is as follows:

In thousands of euros	Less than one year	More than one year	Total
Accounts payable, accrued expenses	7,323	—	7,323
Employees, accrued expenses	449	—	449
Employees, paid vacation	135	—	135
Social organizations, accrued expenses	182	—	182
Social organizations, paid vacation	56	—	56
Social organizations, other accrued expenses	395	—	395
Payable interests	3	—	3
TOTAL	**8,543**	**—**	**8,543**

(1) The estimated amount from the initial payment schedule was €2,675 K. The costs occurred by Company amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.
(2) The corresponding milestone was in November 2017.

NOTE 10 — INCOME

Total income as of December 31,2019 solely comes from the named patient Temporary Authorization for Use ("ATU nominative") for LUMEVOQ™ (GS010) granted by the National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) to the CHNO of the *Quinze-Vingts* on December 9, 2019.

Should our commercial price set at a lower price than the one used for the ATU, the Company will have to reimburses the Health Insurance for the overpayment received during the ATU phase.

NOTE 11 — FINANCIAL INCOME (LOSS)

Financial income (loss) as of December 31, 2019 is as follows:

In thousands of euros	12/31/2019	12/31/2018
Financial revenues	**—**	**81**
Foreign exchange gains	—	—
Other financial income	—	81
Financial expenses	**(897)**	**(2,268)**
Foreign exchange losses	—	—
Financial depreciation and amortization	(583)	(1,824)
Interest expenses on borrowings and financial debt	(211)	(408)
Other financial expenses	(103)	(36)
Financial Income (loss)	**(897)**	**(2,187)**

The financial depreciation and amortization mainly correspond to the depreciation booked on the cash advances granted by the Company to its U.S.-based subsidiary. Due to the uncertainty of the recoverability of this loan, the Company has deemed reasonable to book a depreciation of €2,375 K, representing the net amount due by the GenSight Biologics Inc., taking into account the management fees and recharges between the two entities.

Other financial expenses correspond to realized losses related to the liquidity contract.

NOTE 12 — EXTRAORDINARY INCOME (LOSS)

The extraordinary income is nil as of December 31, 2019.

NOTE 13 — HEADCOUNT

As of	12/31/2019	12/31/2018
Managers	25	28
NET	**25**	**28**

NOTE 14 — INCREASE AND REDUCTIONS NOT RECOGNIZED IN FUTURE TAX DEBT (IN BASE)

At the close of fiscal year 2019, the amount of deficit being indefinitely carried forward is as follows:

In thousands of euros	Basis	Potential corporate tax savings
Net Operating Losses	144,160	40,365

NOTE 15 — RESEARCH TAX CREDIT

The Company benefits from the provisions in Articles 244 *quater* B and 49 *septies* F of the French Tax Code related to the Research Tax Credit.

Changes in the Research Tax Credit over the last two periods are presented as follows:

- 2018: €4,322 K, reimbursed in 2019 (1).
- 2019: € 4,210 K.

NOTE 16 — TRANSACTIONS WITH RELATED PARTIES

The compensation granted to the Directors of the Company amounted to €864 K for fiscal year 2019.

Moreover, the CEO of GenSight Biologics was shareholder of the Company with which GenSight Biologics had a lease contract and a service agreement (in connection with Human Resources, legal and Intellectual Property services) in 2019. The related expenses during the period amounted to €766 K.

NOTE 17 — COMMITMENTS

17.1 — Commitments under operating leases

Commitments existing as of December 31, 2018 have not changed significantly at the end of the reporting period, with the exception of the following:

- On November 2019, the office lease contract the Group entered on January 2015 relating to its headquarters in Paris, France, has been amended. The last amendment consists especially in a decreased rent as the Group uses a smaller office space. The associated services (reception, IT, access to meeting rooms) have slightly increased.

(1) The amount of Research Tax Credit for FY18 received at the end of 2019 differed form the amount booked in the 2018 Financial Statement for €32 K.

The table below shows the minimum contractual future payments relating to those contracts as of December 31, 2019:

In thousands of euros	As of December 31, 2019
2020	495
2021	495
2022	495
2023	495
2024	251
2025	50
2026	50
2027	11
Total	**2,342**

17.2 – Commitments under service agreement – G&A operations

The Company did not sign an addendum to the services contract in connection with human resources, legal and intellectual property services. According to the contract terms and conditions, the annual cost is fixed at €240 K and each party can still terminate the contract after a six-month notice period.

17.3 — Commitments related to R&D operations

The Company has signed various licensing and collaboration agreements:

In 2012, the Company entered into a license agreement with a French public scientific and technological institute. The Company paid a license fee of €40 K in 2013 upon the execution of the agreement. Upon completion of development milestones, the Company has to pay non-refundable fees up to €2,750 K in the aggregate. As of December 31, 2019, the residual commitments amount to €1,800 K. Upon commercialization of any product covered by the licensed patents, the Company will be obligated to pay a percentage of net sales as a royalty. The royalty rate varies depending on the amount of net sales.

In 2013, the Company entered into a license agreement with a non-profit association. The Company paid a license fee of €10 K upon the execution of the agreement. Upon completion of development milestones, the Company has to pay non-refundable fees up to €688 K. As of December 31, 2019, the residual commitments amount to €450 K. Upon commercialization of any product covered by the license patents, the Company will be obligated to pay an annual royalty of 1% of net sales.

In 2013, the Company entered into a license agreement with Novartis. Upon commercialization of any product covered by the licenses, the Company will be obligated to pay a royalty of 5% of net sales.

In 2014, the Company entered into a non-exclusive license, development and commercialization agreement with a biotechnology company. The annual license fee payable by the Company is U.S.$30 K. Upon completion of development milestones, the Company has to pay specified non-refundable fees of up to U.S.$5,900 K. As of December 31, 2019, the residual commitments amount to U.S.$5,500 K. Upon commercialization of any product covered by the license patents, the Company will be obligated to pay a percentage of net sales as a royalty. The royalty rate varies depending on the amount of net sales.

In 2016, the Company entered into a license agreement with a U.S. academic research institute. Under the terms of this license agreement, the Company agreed to pay a license issue fee of $45 K, license maintenance fees up to $100 K per year and variable payments up to $7,300 K depending on the achievement of milestone events. As of December 31, 2019, the residual commitments amount to $6,700 K. The Company will also pay running mid-single-digit royalties on future net sales.

In 2019, the Company entered into a non-exclusive license agreement with a U.S. educational and charitable corporation. Under the terms of this license agreement, we agreed to pay a non-refundable license issuance fee of $25 K. In addition, we agreed to pay an annual license maintenance fee as from the first commercial sale of a licensed product ranging from $25 K to $75 K (creditable against running royalties), a milestone payment of $25 K upon achievement of marketing authorization for the first licensed product in any country, and a running royalty of less than 1% on net sales for a period of 15 years from the date of the first commercial sale (on a licensed product by licensed product basis).

In 2019, GenSight Biologics entered into an exclusive license agreement with 3 Scientific and Technological Public Institutes (EPST) and a private technology transfer company. Under this license agreement, we paid the licensors a one-time license upfront payment of €30 K. We are also obliged to pay milestone payments upon achievement of certain development and regulatory milestone events. After the grant of a MA or BLA for the product, we are required to pay a fixed royalty fee for each first use of a product on a patient who has received the associated gene therapy treatment. In addition, we are required to pay an annual license maintenance fee creditable against the total paid amount of fixed royalty fee due on the same year.

17.4 — Retirement commitments

The employee retirement commitment is not recorded in the accounts in accordance with the option offered by the French accounting regulations. This commitment amounted to €103 K as of December 31, 2019.

As part of the estimate of the retirement commitments, the following assumptions were used for all categories of employees:

- Social security contribution: 45% in 2018 and 2019;
- Salary increase: 3% in 2018 and 2019;

- Discount rate: iBoxx Corporates AA 10+ index, 0.77% and 1.30% in 2018 and 2019, respectively;
- Retirement age: 67;
- Terms of retirement: voluntary retirement;
- Life table: TGHF 2005;
- Collective agreement: *Convention Collective Nationale des Ingénieurs et des Cadres de la Métallurgie* (National Collective Agreement for Engineers and Executives in the Metalworking Industry); and
- Personnel turn-over: 29% (20-49), 0% above 50.

NOTE 18 — TABLE OF SUBSIDIARIES AND HOLDINGS

On April 28, 2017, GenSight Biologics created its first subsidiary, GenSight Biologics Inc., registered and located in the United States of America (State of Delaware). The Company doesn't have any other investment in a subsidiary as of December 2019.

	Capital (in euros)	Reserves and retained earnings brought forward	% interest	Book value of shares held (in euros)		Loans and advances granted not yet refunded (in thousands of euros)	Guarantees and security granted	Turnover excluding tax	Net income in last year (in thousands of euros)	Dividends booked during the year
				Gross	Net					
GenSight Biologics Inc.	0.44	(952)	100%	0.44	0.44	4,617	–	–	(803)	–

The capital reserves and retained earnings have been translated into thousands of euros on the basis of year-end exchanges rates, while profits and losses have been translated at average rate.

A provision of € 2,375 K has been booked on the loans and advances granted in GenSight Biologics SA's financial statements as of 2019.

GenSight Biologics SA draws up consolidated accounts in which its subsidiary GenSight Biologics Inc. is fully consolidated.

NOTE 19 – AUDITOR'S FEES

The auditors' fees paid by the Group in 2019 amounted to €322 K.

	2019			
	Becouze		Deloite & Associés	
In thousands of euros	Montant	%	Montant	%
Audit certification	165	98%	148	97%
Other reports for French legal purposes	5	2%	5	3%
TOTAL	**169**	**100%**	**153**	**100%**

Services other than the audit certification include in particular work relating to the issuance of reports on equity transactions.

18.1.4 STATUTORY AUDITORS' REPORT ON THE FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2019

This is a translation into English of the Statutory auditors' report on the financial statements of GENSIGHT BIOLOGICS S.A. issued in French and it is provided solely for the convenience of English speaking users.
This Statutory auditors' report includes information specifically required by French law, such as information about the appointment of the statutory auditors or verification of the management report and other documents provided to shareholders.
This report should be read in conjunction with and construed in accordance with French law and professional auditing standards applicable in France.

To the Shareholders' meeting of GENSIGHT BIOLOGICS S.A.,

Opinion

In compliance with the engagement entrusted to us by your bylaws and your Shareholders' Meeting, we have audited the accompanying financial statements of GENSIGHT BIOLOGICS S.A. for the year ended December 31, 2019. These financial statements were approved by the board of directors on March 11, 2020 on the basis of the information available at that date in the evolving context of the Covid-19 health crisis.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and of the financial position of the Company, as of December 31, 2019 and of the results of its operations for the year then ended in accordance with French accounting principles.

The audit opinion expressed above is consistent with our report to the Audit Committee.

Basis for Opinion

Audit Framework

We conducted our audit in accordance with professional standards applicable in France. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibilities under those standards are further described in the "Statutory Auditors' Responsibilities for the Audit of the Financial Statements" section of our report.

Independence

We conducted our audit engagement in compliance with independence rules applicable to us, for the period from January 1, 2019 to the date of our report and specifically we did not provide any prohibited non-audit services referred to in Article 5(1) of Regulation (EU) No 537/2014 or in the French Code of ethics *(Code de déontologie)* for statutory auditors.

Material uncertainty regarding going concern

Without questioning the opinion expressed above, we draw attention to the note "Going concern" to the financial statements for the year ended December 31, 2019 which describes the material uncertainty resulting from events or conditions that may cast significant doubt on the Company's ability to continue as a going concern.

Justification of Assessments – Key Audit Matters

In accordance with the requirements of Articles L.823-9 and R.823-7 of the French Commercial Code *(Code de commerce)* relating to the justification of our assessments, and besides to the matter described in the "Material Uncertainty Related to Going Concern" section, we inform you of the key audit matters relating to risks of material misstatement that, in our professional judgment, were of most significance in our audit of the financial statements of the current period, as well as our responses to those risks.

These matters were addressed in the context of our audit of the financial statements as a whole, approved in the circumstances mentioned above, and in forming our opinion thereon, and we do not provide a separate opinion on specific items of the financial statements.

Recording of research and development costs

(refer to note "Use of estimates" and Note 8 "Research and development expenses" to the notes to financial statements as of December 31, 2019)

Identified risks

Research and development costs represent a significant component of the Company' financial statements, considering Company' activity and its current development phase, as they account for more than 80 % of total operating expenses. These expenses mainly include external subcontracting costs (including preclinical and clinical studies in particular) or product manufacturing as well as personnel costs.

There may be discrepancies between the achievement of subcontracting or manufacturing services and their related invoicing. The need of estimating the amount of services already achieved but not invoiced, or at the opposite, services already invoiced but not realized, leads to a risk of misevaluation of the invoices to be received or prepaid expenses regarding these external costs at year end.

The estimate of the amount of services already performed to be recognized at year end thus requires significant judgments from the management.

We therefore considered that the accounting of research and development expenses is a key audit matter.

Audit procedures implemented to deal with identified risks

As part of our audit, we reviewed the internal control procedures related to the accounting of subcontracting and manufacturing expenses in order to identify control activities implemented by Management and evaluate their design.

Our work was supplemented by procedures, on a sampling basis, of account payable confirmation requests and an analysis of subcontracting invoices received before and after year end, in order to identify which exercise they related to and evaluate the correct linkage with fiscal year.

Specific Verifications

We have also performed, in accordance with professional standards applicable in France, specific verifications required by laws and regulations.

Information given in the Management Report and in the other documents provided to Shareholders with respect to the financial position and the financial statements

We have no matters to report as to the fair presentation and the consistency with the financial statements of the information given in the management report of of the Board of Directors approved on March 11, 2020 and in the other documents provided to the shareholders with respect to the financial position and the financial statements. With regard to the events which occurred and the facts known after the date the financial statements were approved by the Board of Directors relating to the impact of the Covid-19 crisis, the management indicated to us that they will be communicated to the annual general meeting called to approve the financial statements.

We attest the fairness and consistency with financial statements of the information provided related to payment terms required by article D.441-4 of the French Commercial Code *(Code de commerce)*.

Report on corporate governance

We attest that the Board of Directors' report on corporate governance sets out the information required by Articles L.225-37-3 and L.225-37-4 of the French Commercial Code *(Code de commerce)*.

Concerning the information given in accordance with the requirements of Article L. 225-37-3 of the French Commercial Code *(Code de commerce)* relating to remunerations and benefits received by or awarded to the directors and any other commitments made in their favour, we have verified its consistency with the financial statements, or with the underlying information used to prepare these financial statements and, where applicable, with the information obtained by your Company from controlled enterprises included in the scope of consolidation. Based on this work, we attest the accuracy and fair presentation of this information.

With respect to the information relating to items that your Company considered likely to have an impact in the event of a takeover bid or exchange offer, provided pursuant to Article L.225-37-5 of the French Commercial Code *(Code de commerce)*, we have agreed this information to the source documents communicated to us. Based on this work, we have no observation to disclose on this information.

Other Information

In accordance with French law, we have verified that the required information concerning the identity of the shareholders and holders of voting rights has been properly disclosed in the management report.

Report on Other Legal and Regulatory Requirements

Appointment of the Statutory Auditors

We were appointed as statutory auditors of GENSIGHT BIOLOGICS S.A. by the bylaws of April 17, 2012 for Deloitte & Associés and by the Shareholders' Meeting of May 19, 2016 for Becouze.

As at December 31, 2019, Deloitte & Associés was in the 7th year of total uninterrupted engagement and Becouze was in the 4th year of total uninterrupted engagement, including four years of joint work since securities of the Company were admitted to trading on a regulated market.

Responsibilities of Management and Those Charged with Governance for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with French accounting principles, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless it is expected to liquidate the Company or to cease operations.

The Audit Committee is responsible for monitoring the financial reporting process and the effectiveness of internal control and risks management systems and where applicable, its internal audit, regarding the accounting and financial reporting procedures.

The financial statements were approved by the Board of Directors.

Statutory Auditors' Responsibilities for the Audit of the Financial Statements

Objectives and audit approach

Our role is to issue a report on the financial statements. Our objective is to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with professional standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As specified in Article L.823-10-1 of the French Commercial Code *(Code de commerce)*, our statutory audit does not include assurance on the viability of the Company or the quality of management of the affairs of the Company.

As part of an audit conducted in accordance with professional standards applicable in France, the statutory auditor exercises professional judgment throughout the audit and furthermore:

- Identifies and assesses the risks of material misstatement of the financial statements, whether due to fraud or error, designs and performs audit procedures responsive to those risks, and obtains audit evidence considered to be sufficient and appropriate to provide a basis for his opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtains an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the internal control.
- Evaluates the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management in the financial statements.
- Assesses the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. This assessment is based on the audit evidence obtained up to the date of his audit report. However, future events or conditions may cause the Company to cease to continue as a going concern. If the statutory auditor concludes that a material uncertainty exists, there is a requirement to draw attention in the audit report to the related disclosures in the financial statements or, if such disclosures are not provided or inadequate, to modify the opinion expressed therein.
- Evaluates the overall presentation of the financial statements and assesses whether these statements represent the underlying transactions and events in a manner that achieves fair presentation

Report to the Audit Committee

We submit a report to the Audit Committee which includes in particular a description of the scope of the audit and the audit program implemented, as well as the results of our audit. We also report, if any, significant deficiencies in internal control regarding the accounting and financial reporting procedures that we have identified.

Our report to the Audit Committee includes the risks of material misstatement that, in our professional judgment, were of most significance in the audit of the financial statements of the current period and which are therefore the key audit matters that we are required to describe in this report.

We also provide the Audit Committee with the declaration provided for in Article 6 of Regulation (EU) N° 537/2014, confirming our independence within the meaning of the rules applicable in France such as they are set in particular by Articles L.822-10 to L.822-14 of the French Commercial Code *(Code de commerce)* and in the French Code of Ethics *(Code de déontologie)* for statutory auditors. Where appropriate, we discuss with the Audit Committee the risks that may reasonably be thought to bear on our independence, and the related safeguards.

Paris and Bordeaux, April 8, 2020

The Statutory Auditors
French original signed by

Becouze	Deloitte & Associés
Fabien BROVEDANI	Stéphane LEMANISSIER

18.1.5 DATE OF LATEST FINANCIAL INFORMATION

Our latest financial information is the half-year financial statements (French GAAP and IFRS) for the fiscal year ended December 31, 2019.

18.2 INTERIM AND OTHER FINANCIAL INFORMATION

Not applicable.

18.3 AUDITING OF HISTORICAL ANNUAL FINANCIAL INFORMATION

In accordance with provisions of Article 19 of the Prospectus Regulation (EU) 2017/1129, the Company's annual consolidated financial statements (IFRS) for the fiscal year ended December 31, 2017, the Company's annual consolidated financial statements (IFRS) for the fiscal year ended December 31, 2018 and the statutory auditor's report on the Company's annual consolidated financial statements (IFRS) for the fiscal year ending December 31, 2017 and the statutory auditor's report on the Company's annual consolidated financial statements (IFRS) for the fiscal year ending December 31, 2018 are incorporated by reference in this Universal Registration Document. These information are included in the Documents registered with the AMF on April 27, 2018 under number R.18-036 and on December 20, 2019 under number D. 19-1035.

These Registration Documents may be consulted on the Company's (http://www.gensight-biologics.com) and on the AMF's website.

18.4 *PRO FORMA* FINANCIAL INFORMATION

Not applicable.

18.5 DIVIDEND POLICY

We have never declared or paid any cash dividends on our ordinary shares. We currently intend to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

Subject to the requirements of French law and our bylaws, dividends may only be distributed from our distributable profits, plus any amounts held in our available reserves, which are those reserves other than the legal and statutory reserves and the revaluation surplus. The declaration and payment of any dividends in the future will be determined by the Board of Directors, in our discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, and contractual restrictions, including restrictions contained in any agreements governing any indebtedness the Company may incur.

18.6 LEGAL AND ARBITRATION PROCEEDINGS

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business.

As of the date of this Universal Registration Document, to our knowledge, there are no governmental, legal or arbitral proceedings (including any proceedings of which we are aware, that are pending or with which we are threatened), likely to have, or having had in the course of the last twelve months, a material adverse effect on our operations, financial position or results. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

18.7 SIGNIFICANT CHANGE IN FINANCIAL POSITION

To our knowledge, there has been no material change in our financial position since December 31, 2019, other than those described in this Universal Registration Document.

ADDITIONAL INFORMATION

19.1 SHARE CAPITAL

19.1.1 AMOUNT OF ISSUED CAPITAL

As of the date of this Universal Registration Document, our share capital is equal to €820,684.05, divided into 32,827,362 shares, with nominal value of €0.025 per share, fully authorized, subscribed and paid-up.

19.1.2 SECURITIES NOT REPRESENTING SHARE CAPITAL

As of the date of this Universal Registration Document, we have not issued any securities not representing the share capital.

19.1.3 SHARES CONTROLLED BY THE COMPANY, TREASURY SHARES AND PURCHASE BY THE COMPANY OF ITS OWN SHARES

Our Combined General Shareholders' Meeting of June 11, 2019 authorized our Board of Directors to implement a buyback program of our shares, according to the provisions of Article L.225-209 of the French Commercial Code.

The maximum number of shares that can be purchased is 5 % of the share capital of the Company (at any time whatsoever, such percentage applying to a capital, which shall be adjusted based on the transactions subsequently affecting it).

Objectives of the buybacks:

- to ensure the buoyancy of the secondary market or the liquidity of the Company shares through the intermediary of an investment service provider by way of a liquidity agreement in compliance with the code of ethics of the AMAFI (French Financial Markets' Association) admitted by the regulations, it being specified that in this context, the number of shares taken into account for the calculation of the limitation referred to hereabove corresponds to the number of shares purchased, following the deduction of the number of shares, which have been re-sold;
- to keep the purchased shares and to subsequently put them up for exchange or as payment in the context of any external growth transactions;
- to ensure the coverage of share purchase option schemes and/or share schemes allocated on a free of charge basis (or similar schemes) in favor of the salaried employees and/or the corporate officers of the Group as well as any share allocations pursuant to a company or group savings scheme (or similar scheme) in respect of a company profit sharing scheme and/or any other forms of allocation of shares to the salaried employees and/or to the corporate officers of the Group;
- to ensure the coverage of securities giving right to the allocation of shares of the Company in the context of the regulations in force;
- to carry out the possible cancellation of the acquired shares, in accordance with the authorization granted or to be granted by the Extraordinary General Meeting.

The maximum purchase price is €24 per share. In case of a transaction affecting the share capital, and notably of a share consolidation or split, or allocation of bonus shares to the shareholders, the above-mentioned price will be adjusted to the same proportion (a coefficient of the ratio between the number of shares comprising the share capital before the transaction and the number of shares after the transaction).

The maximum amount of the funds intended for the program of the repurchase of the shares shall amount to €34,469,448.

During the fiscal year ended December 31, 2019, this buyback program was used exclusively within the scope of a liquidity agreement with the objective of stimulating trading or liquidity of the Company's shares, stipulated with Oddo & Cie as investment services provider.

Number of shares purchased	796,803
Average purchase price	1.7597
Number of shares sold	789,301
Average selling price	1.8096
Total amount of negotiation costs	25,000
Number of shares used in 2019	—
Number of shares owned as of December 31, 2019	85,502
Value at average purchase price	150,484
Nominal value	2,137.55

19.1.4 FREE SHARES

(a) Free shares granted by the Company

We have granted free shares (*Attributions Gratuites d'Actions*, or AGA) since July 26, 2016.

As of the date of this Universal Registration Document, 1,219,500 of the granted shares have been definitively acquired, including 1,091,000 performance shares and 128,500 non-performance shares.

AGA 2016 granted on July 26, 2016

With the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors granted 766,000 free shares (AGA 2016) on July 26, 2016, as follows:

- 546,000 AGA 2016 were fully acquired by Key Managers, including Mr. Gilly, and were subject to the achievement of the following performance criteria:
  - 291,000 of these free shares were acquired at the completion of enrollment in RESCUE and REVERSE clinical trials; and
  - the remaining 255,000 free shares were acquired at the enrollment of the first patient in a Phase I/II clinical trial of GS030 in RP, on July 24, 2018.
- 56,000 AGA 2016 were fully acquired in July 26, 2017 (one year after their grant date).

The AGA 2016 were issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

The Board of Directors held on July 27, 2017 acknowledged the definitive acquisition of 347,000 free shares and decided accordingly to increase the capital increase of €8,675.

The Board of Directors held on July 24, 2018 acknowledged the definitive acquisition of 255,000 free shares and decided accordingly to increase the capital increase of €6,375.

AGA 2016 granted on July 27, 2017

With the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors granted 593,500 free shares (AGA 2016) on July 27, 2017, including:

- 505,000 AGA 2016 were fully acquired by Key Managers, including Mr. Gilly, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than July 27, 2019:
  - 245,000 of these free shares were acquired upon receipt of the definitive results of the GS010 REVERSE clinical trial on July 27, 2018; and,
  - the remaining 227,500 free shares have been acquired upon completion of the enrollment of 50% of the patients of a Phase I/II clinical trial of GS030 in RP on May, 17, 2019.
- 32,500 AGA 2016 were fully acquired on July 27, 2018 (one year after their grant date).

The AGA 2016 were issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

The Board of Directors held on July 24, 2018 acknowledged the definitive acquisition of 245,000 free shares and decided accordingly to increase the capital increase of €6,937.5.

The Board of Directors held on June 11, 2019 acknowledged the definitive acquisition of 227,500 free shares and decided accordingly to increase the capital increase of €5,687.5.

AGA 2016 granted on December 19, 2017

With the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors granted 72,500 free shares (AGA 2016) on December 19, 2017.

The AGA 2016 may be fully acquired by one Key Manager, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than July 27, 2019:

- 36,250 of these free shares were acquired after the one year acquisition period and upon receipt of the definitive results of the GS010 REVERSE clinical trial on December 19, 2018; and
- the remaining 36,250 free shares were acquired upon completion of the enrollment of 50% of the patients of a Phase I/II clinical trial of GS030 in RP on May 17, 2019.

The AGA 2016 were issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

The Board of Directors held on December 19, 2018 acknowledged the definitive acquisition of 36,250 free shares and decided accordingly to increase the capital increase of €906.25.

The Board of Directors held on June 11, 2019 acknowledged the definitive acquisition of 36,250 free shares and decided accordingly to increase the capital increase of €906.25.

AGA 2018 granted on September 18, 2018

With the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors granted 380,000 free shares (AGA 2018) on September 18, 2018, including:

- 325,000 AGA 2018 (of which 95,000 were cancelled) may be fully acquired by Key Managers, including Mr. Gilly, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than September 18, 2020:
  - 112,500 of these free shares will be acquired upon completion of the enrollment of the patients of a Phase I/II clinical trial of GS030 in RP; and

— the remaining 112,500 free shares will be acquired upon completion of the production of the first PPQ Batch of GS010;

- 40,000 AGA 2018 were fully acquired on September 18, 2019 (one year after their grant date).

The AGA 2018 will be issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

The Board of Directors held on September 25, 2019 acknowledged the definitive acquisition of 40,000 free shares and decided accordingly to increase the capital increase of €1,000.

AGA 2018 granted on December 19, 2018

With the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors granted 135,000 free shares (AGA 2018) on December 19, 2018.

The AGA 2018 may be fully acquired by one Key Manager, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than September 18, 2020:

- 67,500 of these free shares will be acquired upon completion of the enrollment of the patients of a Phase I/II clinical trial of GS030 in RP; and
- the remaining 67,500 free shares will be acquired upon completion of the production of the first PPQ Batch of GS010.

The AGA 2018 will be issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

AGA 2018 granted on July 23, 2019

With the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors granted 610,000 free shares (AGA 2018) on July 23, 2019.

- 572,500 AGA 2018 (of which 25,000 have been cancelled) may be fully acquired by Key Managers, including Mr. Gilly, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than July 23, 2021:
  — 273,750 of these free shares will be acquired upon the filing with the European Medicines Agency (EMA) the application for market authorization (MA) at the European level of the GS010;
  — 273,750 of these free shares will be acquired upon completion of the enrollment of the patients of a Phase I/II clinical trial of GS030 in RP; and
- 37,250 AGA 2018 (of which 5,000 have been cancelled) will be fully acquired on July 23, 2020 (one year after their grant date).

The AGA 2018 will be issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

AGA 2018 granted on January 28, 2020

With the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors granted 1,020,000 free shares (AGA 2018) on January 28, 2020.

- 567,500 AGA 2018 may be fully acquired by Key Managers, including Mr. Gilly, subject to (i) a one year acquisition period from the date of grant and (ii) achievement of the performance criteria described below no later than January 28, 2022:
  — 283,750 of these free shares will be acquired upon the approval with the European Medicines Agency (EMA) of the application for market authorization (MA) at the European level of the GS010;
  — 283,750 of these free shares will be acquired upon the filing with the Food and Drug Administration (FDA) of the application for Biologics License Application (BLA) for the GS010.
- 452,500 AGA 2018 will be fully acquired on January 28, 2021 (one year after their grant date).

(b) Conditions governing the free shares granted by the Company

Free shares are granted to employees only. The beneficiary will definitively acquire the shares for free after an "acquisition period," given that he/she is still within the Company at this time. Then a "retain period" is applied before shares can be disposed.

(c) Free shares holders

The table below sets forth the free shares granted by us to our executive officers and directors as of the date of this Universal Registration Document :

Name	Grant Date	Number of free shares	Performance condition
Bernard Gilly	07/26/2016	250,000	Yes
	07/27/2017	200,000	Yes
	09/18/2018	45,000	Yes
	07/23/2019	220,000	Yes
	01/28/2020	490,000	Yes
Thomas Gidoin	07/26/2016	150,000	Yes
	07/27/2017	90,000	Yes
	09/18/2018	45,000	Yes
	07/23/2019	150,000	Yes
	01/28/2020	250,000	Yes
Magali Taïël	12/19/2018	135,000	Yes
	07/23/2019	65,000	Yes
	01/28/2020	140,000	Yes
Total		**2,230,000**	

19.1.5 OTHER SECURITIES GIVING ACCESS TO SHARE CAPITAL

As of the date of this Universal Registration Document, the total number of ordinary shares that can be issued by full exercise of all of the securities giving access to the capital and instruments issued to date amounts to 4,824,644, or a maximum dilution of 14.70% on the basis of the capital and voting rights existing to date and 12.81% on the basis of the capital and the fully diluted voting rights.

The following table summarizes the instruments giving access to share capital as of the date of this Universal Registration Document:

	Number of shares warrants for founders, share warrants or free shares	Exercice Price range in Euro
BCE	666,302	0,025 – 3,275
BSA	1,396,561	0,025 – 8,080
AGA	1,960,000	–
OCA	801,781	–
Total outstanding instruments giving access to capital as of the date of this Universal Registration Document	**4,824,644**	

19.1.5.1 Warrants

(a) Warrants granted by the Company

We have granted share-based warrants in the form of share warrants for founders (*Bons de Souscription de Parts de Créateur d'Entreprise*, or BCE) and share warrants (*Bons de Souscription d'Actions*, or BSA).

As of the date of this Universal Registration Document, 666,302 share warrants for founder (BCE) will give right to 666,302 ordinary shares with nominal value of €0.025 at an average exercise price of €2.379 per share.

As of the date of this Universal Registration Document, 1,396,561 share warrants (BSA) will give right to 1,396,561 ordinary shares with nominal value of €0.025 at an exercise price of €2,799 per share.

BCE 2013-02 warrants and BSA 2013-02 warrants

With the authorization of the General Meeting of Shareholders on February 5, 2013, the Board of Directors issued 892,000 BCE 2013-02 warrants with an exercise price of €0.025 per share, and 328,000 BSA 2013-02 warrants with an exercise price of €0.025 per share on July 8, 2013.

With the authorization of the General Meeting of Shareholders on February 5, 2013, the Board of Directors issued 193,800 BCE 2013-02 warrants, with an exercise price of €0.025 per share and 33,000 BSA 2013-02 warrants, with an exercise price of €0.025 per share on April 9, 2014.

The BCE 2013-02 and BSA 2013-02 warrants are exercisable on the basis of the following vesting schedule:

- up to 1/4 of the BCE 2013-02 and BSA 2013-02 warrants on the first anniversary of the date of grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the first anniversary of the date of grant; and
- at the latest within 10 years from the date of grant.

BCE 2014-06 warrants

With the authorization of the General Meeting of Shareholders on June 25, 2014, the Board of Directors issued 60,000 BCE 2014-06 warrants on December 3, 2014, with an exercise price of €0.025 per share.

The BCE 2014-06 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 of the BCE 2014-06 warrants on the first anniversary of the date of grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the first anniversary of the date of grant; and
- at the latest within 10 years from the date of grant.

BCE 2015-06 warrants and BSA 2015-06 warrants

With the authorization of the General Meeting of Shareholders on June 29, 2015, the Board of Directors issued 733,298 BCE 2015-06 warrants, with an exercise price of €3.275 per share, and 121,000 BSA 2015-06 warrants, with an exercise price of €3.275 per share on July 8, 2015.

The BCE 2015-06 and BSA 2015-06 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 of the BCE 2015-06 and BSA 2015-06 warrants on the first anniversary of the date of grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the first anniversary of the date of grant; and
- at the latest within 10 years from the date of grant.

BSA 2016 warrants

With the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors issued 205,000 BSA 2016 warrants, with an exercise price of €8.08 per share on July 26, 2016.

The BSA 2016 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- 100% of the BSA 2016 warrants on the first anniversary of the date of grant; and
- at the latest within 7 years from the date of grant.

With the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors issued 165,000 BSA 2016 warrants, with an exercise price of €5.04 per share on July 27, 2017.

The BSA 2016 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 of the BSA 2016 warrants on the first anniversary of the date of grant;
- the remaining 75% becoming exercisable up to 1/36 per month from the first anniversary of the date of grant; and
- at the latest within 7 years from the date of grant.

BSA 2018 warrants

With the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors issued 20,000 BSA 2018 warrants, with an exercise price of €2.22 per share on September 18, 2018.

The BSA 2018 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 as from the date of the grant;
- the remaining 75% on the basis of 1/36th per month as from the Date of Grant (*i.e.* as from September 18, 2018), at the end of each month; and
- at the latest within 7 years from the date of grant.

BSA 2019 warrants

With the authorization of the General Meeting of Shareholders on June 11, 2019, the Board of Directors issued 105,000 BSA 2019 warrants, with an exercise price of €1.45 per share on July 23, 2019.

The BSA 2019 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 as from the date of the grant;
- the remaining 75% on the basis of 1/36th per month as from the Date of Grant (*i.e.* as from July 23, 2019), at the end of each month; and
- at the latest within 7 years from the date of grant.

See also Section 13.4.1, "History of Share Warrants for Founders (BCE)", and Section 13.4.2, "History of Share Warrants (BSA)" of this Universal Registration Document.

BSA 2019 KREOS-A

With the authorization of the General Meeting of Shareholders on June 11, 2019, the Board of Directors issued 534,521 BSA2019 KREOS-A warrants, with an exercise price of €2.245 per share on December 19, 2019.

The period of validity of the BSA2019-KREOS-A Warrants shall start upon their issuance and shall expire on the occurrence of the earlier of the following two events: (i) the tenth anniversary of the grant date, or (ii) the acceptance by the shareholders of the Borrower of a third-party bona fide offer for all outstanding shares in the Issuer.

See also Section 13.4.1, "History of Share Warrants for Founders (BCE)", and Section 13.4.2, "History of Share Warrants (BSA)" of this Universal Registration Document.

(b) Conditions governing the warrants granted by the Company

Share warrants for founders (BCE)

Share warrants for founders entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our Board of Directors and at least equal to the fair market value of an ordinary share on the date of grant. Share warrants for founders may only be issued by companies meeting certain criteria, which we will not meet following the listing of our shares on Euronext Paris.

Share warrants for founders are not transferable and may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by laws of descent or distribution and may be exercised, during the lifetime of the beneficiary, only by the beneficiary.

Share warrants (BSA)

Share warrants need to be subscribed for a price which is determined by the Board on the date of grant, in addition to any exercise price payable by a holder upon the exercise of any share warrant.

Share warrants may not be transferred to any person subject to certain exceptions detailed in our BSA plan.

(c) Warrants holders

The table below sets forth the warrants granted by us to our executive officers and directors as of the date of this Universal Registration Document:

Name	Grant Date	Type of Grant	Number of Ordinary Shares Underlying Awards (#)(1)	Exercise Price (€)	Expiration Date
Bernard Gilly	07/08/2013	BCE	300,000	0.025	07/07/2023
	07/08/2015	BCE	161,000	3.275	07/07/2025
José-Alain Sahel	07/08/2013	BSA	280,000	0.025	07/07/2023
	07/08/2015	BSA	48,000	3.275	07/07/2025
	07/26/2016	BSA	120,000	8.08	07/25/2023
	07/27/2017	BSA	80,000	5.04	07/26/2024
	07/23/2019	BSA	40,000	1.45	07/23/2026
Peter Goodfellow	04/09/2014	BSA	33,000	0.025	04/08/2024
	07/08/2015	BSA	7,000	3.275	07/07/2025
	07/26/2016	BSA	7,000	8.08	07/25/2023
	07/27/2017	BSA	10,000	5.04	07/26/2024
Thomas Gidoin	07/08/2015	BCE	160,000	3.275	07/07/2025
Michael Wyzga	07/08/2015	BSA	40,000	3.275	07/07/2025
	07/26/2016	BSA	31,000	8.08	07/25/2023
	07/27/2017	BSA	15,000	5.04	07/26/2024
	09/18/2018	BSA	10,000	2.22	09/18/2025
	07/23/2019	BSA	20,000	1.45	07/23/2026
Simone Seiter	07/27/2017	BSA	30,000	5.04	07/26/2024
	09/18/2018	BSA	5,000	2.22	09/18/2025
	07/23/2019	BSA	15,000	1.45	07/23/2026
Natalie Mount	07/27/2017	BSA	30,000	5.04	07/26/2024
	09/18/2018	BSA	5,000	2.22	09/18/2025
Maritza McIntyre	07/23/2019	BSA	30,000	1.45	07/23/2026
Kreos Capital (Expert Fund) LP	12/19/2019	BSA	534,521	2.245	12/19/2029
Total			**2,011,521**		

(1) Each BCE and BSA warrant entitles its holder to subscribe to one ordinary share, with a nominal value of €0.025 each, at an exercise price of €0.025, €3.275, €8.08, €1.45, € 2.245.

19.1.5.2 Stock Options

With the authorization of the General Meeting of Shareholders on May 31, 2017, the Board of Directors issued 220,000 SO 2017, with an exercise price of €5.040 per share on July 27, 2017. These have been fully forfeited as of the date of this Universal Registration Document.

With the authorization of the General Meeting of Shareholders on May 31, 2017, the Board of Directors issued 300,000 SO 2017, with an exercise price of €5.55 per share on December 19, 2017. These have been fully forfeited as of the date of this Universal Registration Document.

With the authorization of the General Meeting of Shareholders on May 31, 2017, the Board of Directors issued 175,000 SO 2017, with an exercise price of €6.98 per share on March 14, 2018. These have been fully forfeited as of the date of this Universal Registration Document.

With the authorization of the General Meeting of Shareholders on April 12, 2018, the Board of Directors issued 30,000 SO 2018, with an exercise price of €2.19 per share on September 18, 2018. These have been fully forfeited as of the date of this Document.

The beneficiaries would be the salaried employees or some of them, or certain categories of the personnel, of the Company and, as appropriate, companies or economic interest groups which are bound to it under the conditions of Article L.225-180 of the Commercial Code and the corporate officers that meet the conditions provided by Article L.225-185 of the Commercial Code.

19.1.5.3 Convertible Bonds

On December 20, 2019, the Company issued, with the authorization of the General Meeting of Shareholders on June 11, 2019, a drawdown notice thereunder for the first tranche of €6 million (the **"Kreos Transaction"**), including 1.8 million euros in the form of convertible bonds

The Convertible Bonds (nominal value of €1) will bear an annual interest of 9.25%. Each Convertible Bond A and Convertible Bond B will arrive to maturity 42 months after their issuance. The Convertible Bonds might be converted into ordinary shares at any time from their issuance date to their maturity date at a price of €2.245 reflecting a 10% discount to the volume weighted average price of the Company's shares on the regulated market of Euronext Paris over the three last trading days before pricing, *i.e.*, December 16, 17 and 18, 2019.

19.1.6 TERMS GOVERNING ANY RIGHT OF ACQUISITION AND/OR ANY OBLIGATION ATTACHED TO SUBSCRIBED BUT NOT PAID-UP CAPITAL

The table below sets forth the resolutions regarding issuance of shares currently in force:

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Delegation of powers given to the Board of Directors in order to issue ordinary shares [1] giving right, as the case may be, to ordinary shares or the allocation of debt securities (of the company or a company of the group), and/or securities giving a right to ordinary shares (of the company or a company of the group) without preferential subscription rights by public offering in accordance with the provisions of articles L.225-129-2, L.225-136 and L.228-92 of the Commercial Code (*15th resolution*).	Capital increase: Maximum **75% of the share capital** at the date of the 2018 Shareholder's Meeting *i.e.* **€454,391.69** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until June 12, 2020	Capital increase: **100% of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€724,707.28** Debt instruments giving access to equity securities: **€50,000,000**	–	Capital increase: **€537,397.95** Debt instruments giving access to equity securities: **€50,000,000**
Delegation of powers given to the Board of Directors in order to issue ordinary shares giving right, as the case may be, to ordinary shares or the allocation of debt securities (of the company or a company of the group), and/or securities giving a right to ordinary shares (of the company or a company of the group) without preferential subscription rights as remuneration for the securities contributed in the context of a public exchange offering in accordance with the provisions of articles L.225-129-2, L.225-135, L.225-148 and L.228-92 of the Commercial Code (*16th resolution*).	Capital increase: Maximum **20% of the share capital** at the date of the Shareholder's Meeting *i.e.* **€121,171.12** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until June 12, 2020		–	

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Delegation of powers given to the Board of Directors in order to issue ordinary shares [1] giving right, as the case may be, to ordinary shares or the allocation of debt securities (of the company or a company of the group), and/or securities giving a right to ordinary shares (of the company or a company of the group) without preferential subscription rights by an offer referred to at section II of article L.411-2 of the Monetary and Financial Code in accordance with the provisions of articles L.225-129-2, L.225-135, L.225-136 and L.228-92 of the Commercial Code *(17th resolution)*.	Capital increase: Maximum **20% of the share capital** at the date of the Shareholder's Meeting *i.e.* **€121,171.12** and limited to 20% of the share capital per year Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until June 12, 2020	Capital increase: **100% of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€724,707.28** Debt instruments giving access to equity securities: **€50,000,000**	–	Capital increase: **€537,397.95** Debt instruments giving access to equity securities: **€50,000,000**
Authorization given to the Board of Directors, for each of the issue of ordinary shares [2] or securities giving right to the capital decided pursuant to the application of the fifteenth and seventeenth resolutions set out hereabove, to derogate from the conditions for the determination of the price provided for by the fifteenth and seventeenth resolutions in accordance with the provisions of article L.225-136, 1° of the Commercial Code *(18th resolution)*.	Capital increase: Maximum **10 % of the share capital** of the company (such as it stands as at the date of the implementation of this authorization hereof) per twelve-month period at the time of the issue.			–	
Delegation given to the Board of Directors in order to increase the capital through the issue of ordinary shares and/or securities giving right to the capital, subject to a limitation of 10 % of the capital in view of remunerating contributions in kind of shares or securities giving right to the capital in accordance with the provisions of articles L.225-129-2, L.225-147 and L.228-92 of the Commercial Code *(20th resolution)*.	Capital increase: **10% of the share capital** at the date of the Shareholder's Meeting *i.e.* **€60,585.56** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until June 12, 2020		–	
Authorization given to the Board of Directors with a view to the granting of options for the subscription and/or purchase of shares to members of the salaried work force (and/or certain corporate officers) in accordance with the provisions of articles L.225-177 to L.225-185 of the Commercial Code *(22nd resolution)*.	**5% of the share capital** at the date of the 2018 Shareholder's Meeting *i.e.* **€30,292.78** **1,211,711** options	38 months *i.e.* until June 12, 2021		Date of use by the Board of Directors: September 18, 2018 Number of options issued: **30,000** corresponding to a potential capital increase of **€750**	

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Authorization given to the Board of Directors with a view to allocating free of charges shares to members of the salaried work force and/or certain corporate officers in accordance with the provisions of articles L.225-197-1 and L.225-197-2 of the Commercial Code *(23rd resolution)*.	**10% of the share capital** at the date of the 2018 Shareholder's Meeting *i.e.* **€60,585.56** **2,423,422** free shares	38 months *i.e.* until June 12, 2021	Capital increase: **100% of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€724,707.28** Debt instruments giving access to equity securities: **€50,000,000**	Date of use by the Board of Directors: September 18, 2018 Number of free shares issued: **380,000** corresponding to approximately 1.938% of the share capital as of the date of the decision of the Board of Directors and consisting of a potential capital increase of **€9,500** Date of use by the Board of Directors: December 19, 2018 Number of free shares issued: **135,000** corresponding to approximately 0.545% of the share capital as of the date of the decision of the Board of Directors and consisting to a potential capital increase of **€3,375** Date of use by the Board of Directors: July 23, 2019 Number of free shares issued: **580,000** corresponding to approximately 2.52% of the share capital as of the date of the decision of the Board of Directors and consisting of a potential capital increase of **€14,500** Date of use by the Board of Directors: January 28, 2020 Number of free shares issued: **1,020,000** corresponding to approximately 3.11% of the share capital as of the date of the decision of the Board of Directors and consisting of a potential capital increase of **€25,500**	Capital increase: **€537,397.95** Debt instruments giving access to equity securities: **€50,000,000**

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Delegation of authority to be given to the Board of Directors in order to issue common shares giving, where applicable, access to common shares or the award of debt securities (for the company or a company in the group) and/or securities entitling to common shares (in the company or a company in the group) with the elimination of the preemptive right to the benefit of categories of persons fulfilling certain characteristics[3], duration of the delegation of authority, maximum par value of the capital increase[4], issue bonus, option of limiting the amount of subscriptions or distributing unsubscribed shares *(21st resolution)*	Capital increase: Maximum **60 % of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€434,824.4** Debt instruments giving access to equity securities: **€50,000,000**	18 months *i.e.* until December 12, 2020	Capital increase: **100% of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€724,707.28** Debt instruments giving access to equity securities: **€50,000,000**	Date of use by the Board of Directors: December 19, 2019 Capital increase: **€94,976.78** consisting of the issue of **3,799,071** new ordinary shares, at a price of €2.369 per share, with a nominal value of €0.025 (issue premium of €2.344) Number of Convertible Bonds issued: **1,800,000**, consisting of a potential issue of 801,781 new shares, corresponding to a potential capital increase of **€20,044.53**	Capital increase: **€537,397.95** Debt instruments giving access to equity securities: **€50,000,000**
Delegation of authority to be given to the Board of Directors in order to issue share purchase warrants, warrants for the subscription and/or the purchase of new and/or existing shares, and/or warrants for the subscription and/or acquisition of new and/or existing redeemable shares, with the cancellation of the preemptive rights of categories of persons [5] [6], maximum par value of the capital increase, duration of delegation of authority, exercise price in accordance with the provisions of articles L.225-129-2, L.225-138 and L.228-91 of the Commercial Code *(23rd resolution)*	Capital increase: Maximum **5 % of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€36,235.35** **1,436,227** share warrants	18 months *i.e.* until December 12, 2020		Date of use by the Board of Directors: July 23, 2019 Number of warrants issued: **105,000** corresponding to approximately **0.36%** of the share capital as of the date of the decision of the Board of Directors and consisting to a potential capital increase of **€2,625** Date of use by the Board of Directors: December 19, 2019 Number of warrants issued: **534,521** corresponding to approximately **1.63%** of the share capital as of the date of the decision of the Board of Directors and consisting to a potential capital increase of **€13,363.03**	

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Delegation of authority to be given to the Board of Directors for issuing common shares giving, where applicable, access to common shares or the award of debt securities (for the company or a company in the group) and/or securities giving access to common shares (in the company or a company in the group) with the maintenance of the preemptive right, duration of the delegation of authority, maximum par value of the capital increase, option of offering unsubscribed shares to the public *(20th resolution)*	Capital increase: Maximum **40 % of the share capital** at the date of the 2019 Shareholder's Meeting *i.e.* **€289,882.9** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until August 11, 2021	–	–	Capital increase: **€289,882.9** Debt instruments giving access to equity securities: **€50,000,000**

(1) The issue price should at least be equal to the minimum required by the legal and regulatory provisions applicable at the time when the Board of Directors shall implement the delegation (for reference, to date the weighted average of the listed prices of the share on the regulated Euronext Paris market for the three trading sessions preceding the determination of the subscription price for the increase in capital decreased by a maximum discount of 5 %).
(2) The issue price of the ordinary shares shall at least be equal, at the choice of the Board of Directors (i) either to the weighted average of the Company share price on the Euronext Paris regulated market on the date preceding the determination of the issue price, which may be decreased by a maximum discount of 15 %, (ii) or the average of 5 consecutive listed prices of the Company share on the Euronext Paris regulated market chosen amongst the thirty trading sessions preceding the determination of the issue price, which may be decreased by a maximum discount of 15 %.
(3) The present delegation shall be made in favor of the following categories of persons:
(i) individual or legal entities (including companies), investment companies, trusts, investment funds, or other investment vehicles of any form whatsoever, whether French or foreign generally investing in the pharmaceutical, bio-technological, ophthalmological, neurodegenerative diseases or medical technologies sectors; and/or
(ii) companies, institutions or entities of any form whatsoever, whether French or foreign conducting a significant part of their business in those sectors; and/or
(iii) financial service providers, being French or foreign with an equivalent status, capable of guaranteeing that an increase in capital will be successfully placed with the persons referred to in (i) and (ii) hereabove and, in this context, subscribing to the issued securities.
(4) The issue price should at least be equal to the average weighted by the volumes (in the central order book and not including blocks and off market) of the price of the Company's shares on the Euronext Paris regulated market for the last 3 trading sessions preceding the determination of the issue price, such average subject to amendment as the case may be in order to take into account the differences in the entitlement to dividends date and may be decreased as the case may be by a maximum discount of 15%.
(5) The issue price of the warrant shall equal to at least 8% of the market value of an ordinary share on the date of attribution.
(6) The price for the subscription and/or purchase of the shares to which the warrants shall give right shall at least be equal to the weighted average of the closing prices of the Company's shares for the last 20 trading sessions preceding the date of the decision to issue warrants, deducted by any issue price of the warrant.

19.1.7 SHARE CAPITAL OF THE COMPANY THAT IS THE SUBJECT OF AN OPTION OR OF AN AGREEMENT TO PUT IT UNDER OPTION

To our knowledge, as of the date of this Universal Registration Document, our share capital is not the subject of any option or any agreement to put it under option.

19.1.8 HISTORY OF THE COMPANY'S SHARE CAPITAL SINCE ITS INCEPTION

All the figures (number of shares and amount in €) in the table below are adjusted in order to take into account the reverse stock split which took place on August 17, 2015. All share warrants attached to the Series A preferred shares indicated in the table below (ABSA n°1 and ABSA FBIMR) were cancelled on July 7, 2015.

Date	Nature of Operation	Number of shares issued	Nominal value of the share (in €)	Issue price per share (in €)	Share premium (in €)	Issue price (in €)	Number of shares representing the share capital	Capital increase (in €)	Share capital (in €)
April 2012	Inception (issuance of ordinary shares)	1,520,000	0.025	0.025	–	38,000.00	1,520,000	38,000.00	38,000.00
February 5, 2013	Share capital increase (issuance of ordinary shares)(1)	268,235	0.025	0.025	–	6,705.88	1,788,235	6,705.88	44,705.88
February 5, 2013	Share capital increase (issuance of Series A preferred shares with warrants attached called ABSA n°1)	1,428,571	0.025	2.800	3,964,285.08	3,999,999.36	3,216,806	35,714.28	80,420.15

Date	Nature of Operation	Number of shares issued	Nominal value of the share (in €)	Issue price per share (in €)	Share premium (in €)	Issue price (in €)	Number of shares representing the share capital	Capital increase (in €)	Share capital (in €)
February 5, 2013	Share capital increase (issuance of Series A preferred shares)	14,630	0.025	2.800	40,598.25	40,964.00	3,231,436	365.75	80,785.90
March 20, 2013	Share capital increase (issuance of Series A preferred shares with warrants attached called ABSA n°1)	2,364,286	0.025	2.800	6,560,892.54	6,619,999.69	5,595,722	59,107.15	139,893.05
March 20, 2013	Share capital increase (issuance of Series A preferred shares with warrants attached called ABSA n°1)	2,635,714	0.025	2.800	7,314,107.46	7,380,000.31	8,231,436	65,892.85	205,785.90
March 20, 2013	Series A-related costs	–	–	–	(337,065.56)	–	8,231,436	–	205,785.90
July 8, 2013	Subscription of warrants (BSA2013-02)	–	–	–	656.00	656.00	8,231,436	–	205,785.90
December, 19, 2013	Share capital increase (issuance of Series A preferred shares with warrants attached called ABSA FBIMR)	523,253	0.025	3.225	1,674,408.96	1,687,490.29	8,754,689	13,081.33	218,867.23
April 9, 2014	Subscription of warrants (BSA2013-02)	–	–	–	66.00	66.00	8,754,689	–	218,867.23
December 31, 2014	Reversal of share premium to reserves	–	–	–	(174,161.35)	–	8,754,689	–	218,867.23
February 11, 2015	Share capital increase (issuance of ordinary share through exercise of BCE2013-02 and BSA 2013-02)	229,560	0.025	0.025	–	5,739.00	8,984,249	5,739.00	224,606.23
June 30, 2015	Share capital increase (issuance of Series B preferred shares)	4,624,871	0.025	6.950	32,027,233.06	32,142,854.84	13,609,120	115,621.78	340,228.00
July 7, 2015	Series B-related costs	–	–	–	(1,305,561.25)	–	13,609,120	–	340,228.00
July 8, 2015	Subscription of warrants (BSA2015-07)	–	–	–	30,250.00	30,250.00	13,609,120	–	340,228.00
July 31, 2015	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	2	0.025	0.025	–	0.05	13,609,122	0.05	340,228.05
July 13, 2016	Share capital increase (Euronext IPO)	5,000,000	0.025	8.000	39,875,000.00	40,000,000.00	18,609,122	125,000.00	465,228.05
July 13, 2016	Euronext IPO-related costs		–	–	(3,571,365.00)	–	18,609,122	–	465,228.05
August 10, 2016	Share capital increase (Euronext IPO – Overallotment option)	655,859	0.025	8.000	5,230,475.53	5,246,872.00	19,264,981	16,396.48	481,624.53

Date	Nature of Operation	Number of shares issued	Nominal value of the share (in €)	Issue price per share (in €)	Share premium (in €)	Issue price (in €)	Number of shares representing the share capital	Capital increase (in €)	Share capital (in €)
August 10, 2016	Euronext IPO overallotment option-related costs	–	–	–	(236,109.24)	–	19,264,981	–	481,624.53
September 3, 2016	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	112,000	0.025	0.025	–	2,800.00	19,376,981	2,800.00	484,424.53
October 6, 2016	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	31,720	0.025	0.025	–	793.00	19,408,701	793.00	485,217.53
October 6, 2016	Share capital increase (issuance of ordinary share through exercise of BCE2015-07)	1,000	0.025	3.275	3,250.00	3,275.00	19,409,701	25.00	485,242.53
October 31, 2016	Subscription of warrants (BSA2016-07)	–	0.025	–	133,250.00	133,250.00	19,409,701	–	485,242.53
January 11, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	117,320	0.025	0.025	–	2,933.00	19,527,021	2,933.00	488,175.53
January 11, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2015-07)	13,432	0.025	3.275	43,654.00	43,989.80	19,540,453	335.80	488,511.33
May 5, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2015-07)	50,000	0.025	3.275	162,500	163,750	19,590,453	1,250	489,761.33
May 31, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	193,800	0.025	0.025		4,845	19,784,253	4,845	494,606.33
June 27, 2017	Share capital increase (Euronext PIPE)	3,750,000	0.025	6.00	22,406,250	22,500,000	23,534,253	93,750	588,356.33
June 27, 2017	Euronext PIPE related costs				(1,778,450.20)		23,534,253		588,356.33
June 29, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2015-06)	7,332	0.025	3.275	23,829	24,012.30	23,541,585	183.3	588,539.63
June 29, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	76,120	0.025	0.025		1,903	23,617,705	1,903	590,442.63

Date	Nature of Operation	Number of shares issued	Nominal value of the share (in €)	Issue price per share (in €)	Share premium (in €)	Issue price (in €)	Number of shares representing the share capital	Capital increase (in €)	Share capital (in €)
July 3, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	31,720	0.025	0.025		793.00	23,649,425	793	591,235.63
July 26, 2017	Share capital increase (issuance of ordinary share through acquisition of AGA (Performance Tranche 1) 2016)	291,000	0.025	0.025	(7,275)		23,940,425	7,275	598,510.63
July 26, 2017	Share capital increase (issuance of ordinary share through acquisition of AGA2016)	56,000	0.025	0.025	(1,400)		23,996,425	1,400	599,910.63
September 18, 2017	Share capital increase (issuance of ordinary share through exercise of BCE2013-02)	237,798	0.025	0.025		5,944.95	24,234,223	5,944.95	605,855.58
October 2017	Subscription of warrants (BSA2017)	–	0.025	–	66,000	66,000	24,234,223	5,944.95	605,855.58
July 24, 2018	Share capital increase (issuance of ordinary share through acquisition of AGA2016)	255,000	0.025	0.025	(6,375)		24,489,223	6,375	612,230.58
July 27, 2018	Share capital increase (issuance of ordinary share through acquisition of AGA2016)	277,500	0.025	0.025	(6,937.5)		24,766,723	6,937.50	619,168.08
December 14, 2018	Subscription of warrants (BSA2018)	–	0.025	–	3,600	3,600	24,766,723	–	619,168.08
December 19, 2018	Share capital increase (issuance of ordinary share through acquisition of AGA2016)	36,250	0.025	0.025	(906.25)		24,802,973	906.25	620,074.33
February 25, 2019	Share capital increase	3,921,568	0.025		7,901,959.52	7,999,998.72	28,724,541	98,039.2	718,113.53
February 25, 2019	Capital increase related costs	–	–	–	(94,360)	–	28,724,541	–	718,113.53
May 17, 2019	Share capital increase (issuance of ordinary share through acquisition of AGA2017)	263,750	0.025	–	(6,593.75)	–	28,988,291	6,593.75	724,707.28
September 19, 2019	Share capital increase (issuance of ordinary share through acquisition of AGA2018)	40,000	0.025	–	(1,000)	–	29,028,291	–	725,707.28

Date	Nature of Operation	Number of shares issued	Nominal value of the share (in €)	Issue price per share (in €)	Share premium (in €)	Issue price (in €)	Number of shares representing the share capital	Capital increase (in €)	Share capital (in €)
December 15, 2019	Subscription of warrants (BSA2018)		0.025		13,650	13,650	29,028,291	–	725,707.28
December 19, 2019	Share capital increase	3,799,071	0.025	2.369	8,905,022.42	8,999,999.2	32,827,362	94,976.78	820,684.05
December 19, 2019	Capital increase related costs				(723,683.4)				
December 19, 2019	Subscription of warrants (BSA2019 Kreos-A)	–	0.025	–	1.00	1.00	32,827,362	–	820,684.05
TOTAL		**32,827,362**			**128,141,695.32**	**136,365,091.97**		**820,684.05**	

(1) The Company issued 268,235 ordinary shares for the benefit of Novartis in payment for intellectual property rights (see 18.1.2, "License Agreement with Novartis Pharma AG"). In compliance with IFRS 2, the acquired license was valued at the fair value of issued shares, as assessed by an independent expert, at €1.025 per share.

19.1.9 FACTORS LIKELY TO HAVE AN IMPACT IN THE EVENT OF A PUBLIC OFFERING

Pursuant to Article L.225-37-5, we call to your attention to the following points likely to have an impact in the event of a public offering:

The capital structure as well as the known direct or indirect holdings of the Company and all related matters are described in Section 16.1 of this Universal Registration Document.

There are no statutory restrictions on the exercise of double voting rights, apart from abstentions from voting that may be requested by one or more shareholders holding at least 2.5% of the share capital absent a declaration of a breach of the statutory thresholds (Article 12.2 of the Company's bylaws).

There is no statutory restriction on the transfer of shares.

There is no instrument containing special control rights.

There are no control mechanisms provided in a potential shareholding system for personnel with control rights not exercised by the said personnel.

The rules for nominating and removing members of the Board of Directors are the legal and statutory rules provided for in Article 16 of the Company's bylaws.

With regards to authority of the Board of Directors, current delegations are described in paragraph 19.1.3 of this Universal Registration Document (share purchase program) and in the table of delegations for capital increases appearing in Paragraph 19.1.6 of this same document.

The Company's bylaws are changed in accordance with the legal and regulatory provisions.

No significant agreement is entered into by the Company that is changed or that terminates in the event of a change of control.

There are no private agreements providing for severance payments in the event of cessation of duties of members of the Board of Directors or employees if they resign or are laid off without real and serious cause or if their employment is terminated due to a public offering. Details of the severance likely to be paid to the chief executive officer are provided above, as well as in Sections 13.1 and 13.7 of this Universal Registration Document (Table 11).

19.2 CONSTITUTIVE DOCUMENTS AND BYLAWS

19.2.1 CORPORATE PURPOSE (ARTICLE 2 OF THE BYLAWS)

Our corporate purpose in France and abroad includes:

- the research and development in the treatment of ophthalmic pathologies and neurodegenerative diseases of any kind;
- the technical development, including by way of clinical trials, the production and marketing of any product and material enabling the treatment of ophthalmic pathologies and neurodegenerative diseases;
- any services and activities in relation thereto;
- the acquisition, operation or sale of any process, patent or other intellectual property rights in relation thereto;
- the participation, by any means, whether directly or indirectly, in any operation that could be connected to the activities described above by way of incorporation, contribution,

subscription or acquisition of the shares, merger or creation, acquisition, leasing including any management leasing, of any business; and

- more generally, all commercial, industrial, real estate, civil and financial transactions, including any guarantee or security, loan, cash transaction in particular the transactions set out in article L.511-7 of the French Monetary and Financial Code, relating directly or indirectly to any of the aforementioned corporate purposes or any similar or related purpose.

19.2.2 ADMINISTRATIVE AND MANAGEMENT BODIES

19.2.2.1 Board of Directors (Articles 15, 16, 17, 18, 20 and 21 of the bylaws)

Composition of the Board of Directors, and of the directors

The Company is governed by a Board of Directors composed of at least three members and at most 18 members elected by the ordinary shareholders' meeting pursuant to and subject to the exceptions stated by law.

The Board of Directors should reflect a balanced representation of women and men.

During the term of the Company, directors are appointed, renewed or dismissed under the conditions provided for by applicable laws and regulations and by the Company's bylaws.

Directors are appointed for a three-year term, by way of exception and in order to exclusively allow for the implementation or the maintenance of the staggering of the mandates, the ordinary shareholders' meeting may appoint one or several members of the Board of Directors for a term of two years or one year. Directors are eligible for re-election. They can be dismissed at any time by the general shareholders' meeting.

No person who is more than 75 years old may be a director. The number of directors who are also party to employment contracts with us may not exceed one-third of the directors in office. Directors are subject to applicable laws and regulations regarding plurality of offices.

Directors may be individual or legal entities. At the time they are elected, legal entities must appoint a permanent representative who is subject to the same conditions and obligations, and who incurs the same civil and criminal responsibilities as he were a director in his own name, without prejudice to the joint liability with the legal entity he represents.

The office of permanent representative is given for the duration of the term of office of the legal entity he represents. If the legal entity revokes the appointment of its permanent representative, it must immediately notify the Company, by registered mail, of this dismissal and the name of its new permanent representative. This is also required in the event of the death or resignation of the permanent representative.

The shareholders' meeting can allocate to the directors, as directors' attendance fees (*jetons de présence*), a fixed annual amount. The distribution between the directors is determined by the Board of Directors. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special and temporary assignments. The Board of Directors may also authorize the reimbursement of reasonable travel and accommodation expenses, as well as other expenses incurred by directors in the corporate interest.

There are no directors' share ownership requirements.

Deliberations of the Board of Directors

The Board of Directors meets as often as necessary in the Company's interest. The Chairman convenes these meetings. If the Board of Directors has not met in more than two months, at least one-third of its members may request that the Chairman convene it to discuss a particular agenda. The Chief Executive Officer may also request that the Chairman convenes the Board of Directors to discuss a particular agenda. Decisions are taken by a majority of members present or represented. In the event of a tie, the vote of the meeting's Chairman does prevail.

The Board of Directors can only deliberate if at least half of the directors attend the meeting in the manners provided for in our bylaws. In compliance with legal and regulatory provisions, the internal regulations may provide that are considered present for the quorum and the majority, the directors participating to the Board meeting by videoconference or telecommunication means in compliance with technical specifications laid down by the legislative and regulatory provisions in force.

Any director may authorize another director to represent him at a meeting of the Board of Directors, each director may hold only one proxy per meeting.

The deliberations of the Board are recorded in minutes signed by the Chairman of the meeting and by at least one director who participated in the meeting. In case the Chairman of the meeting is prevented from signing, at least two directors can sign it.

The Board of Directors sets up in its internal regulation its operating procedures in accordance with the law and the bylaws.

Powers of the Board of Directors

The Board of Directors determines the direction of the Company's business and ensures its implementation. Subject to the powers expressly granted to the shareholders' meeting, and within the limits of the Company's purpose, the Board of Directors decides any question concerning the proper functioning of the Company and, through its decisions, settles matters concerning it.

It may decide to create committees responsible for studying issues that it itself or its Chairman may submit to them for analysis. The composition and powers of each of these committees, which operate under its responsibility, are set by the Board of Directors by internal regulations.

Directors' voting powers on proposal, arrangement or contract in which any director is materially interested

Pursuant to Article L.225-38 of the French Commercial Code, any agreement entered into (directly or through an intermediary) between us and any director that is not entered into (1) in the ordinary course of our business and (2) upon standard market terms is subject to the prior authorization of the Board of Directors (it being specified that the interested director cannot vote on such decision). The same provision applies to agreements between us and another company, provided that the company is not one of our wholly owned subsidiaries, if one of our directors is the owner or a general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of our directors has an indirect interest.

19.2.2.2 Chairman (Article 17 of the bylaws)

The Board of Directors elects a Chairman from among the members who are natural persons. No person who is more than 75 years old may be a Chairman.

The Chairman represents the Board of Directors. He organizes and manages its work, and reports on such work to the general shareholders' meeting. He oversees the proper functioning of the Company's governing bodies and ensures, in particular, that the directors are able to carry out their duties.

19.2.2.3 Chief Executive Officer (Article 19 of the bylaws)

At the option of the Board of Directors, the Company may be managed either by the Chairman or by another individual appointed by the Board of Directors (among its members or outside) and given the title of Chief Executive Officer. No person who is more than 75 years old may be a Chief Executive Officer.

The Chief Executive Officer is granted the broadest powers to act in all circumstances in the Company's name. He exercises these powers within the limits of the Company's purpose and subject to the powers that the law and the bylaws grant expressly to the shareholders' meeting or the Board of Directors. The Chief Executive Officer represents the Company in its relations with third-parties.

On the recommendation of the Chief Executive Officer, the Board of Directors may appoint, among its members or outside, one or more individuals in charge of assisting the Chief Executive Officer, who holds the title of Deputy Chief Executive Officer. No person who is more than 70 years old may be a Deputy Chief Executive Officer.

There may be no more than five Deputy Chief Executive Officer.

The term of office of the Deputy Chief Executive Officer or of the Deputy Chief Executive Officers is determined at the time they are appointed, but this term may not exceed the term of office on the Board, if applicable.

The Chief Executive Officer may be dismissed at any time by the Board of Directors. This is also true for the Deputy Chief Executive Officers, on the recommendation of the Chief Executive Officer. If dismissal is decided without grounds, it may result in damages, except when the Chief Executive Officer assumes the position of Chairman of the Board of Directors.

When the Chief Executive Officer ceases or is prevented from performing his duties, the Deputy Chief Executive Officers retain their duties and powers, unless decided otherwise by the Board, until the appointment of the new Chief Executive Officer.

The Board of Directors determines the compensation of the Chief Executive Officer and the Deputy Chief Executive Officers.

19.2.3 RIGHTS, PREFERENCES AND RESTRICTIONS ATTACHING TO ORDINARY SHARES

19.2.3.1 Form of Shares (Article 11 of the bylaws)

Fully paid-up shares are in registered or bearer form, at the shareholder's discretion, under the conditions defined by the regulations in force.

The Company may at any time verify the identity of the holders of bearer shares in accordance with applicable laws and regulations.

19.2.3.2 Rights and Obligations Attached to Shares (Articles 12 and 14 of the bylaws)

Each share gives a right to a share of the profits and corporate assets in proportion to the percentage of capital it represents. Moreover, it gives the right to vote and to representation at shareholders' meetings under the conditions set by law and the bylaws.

By derogation to Article L.225-123 paragraph 3 of the French Commercial Code, the bylaws do not grant double voting rights to the shares of the Company.

Shareholders are liable for losses only up to the amount of their contributions.

The rights and obligations attached to a share remain with the share when it is transferred.

Ownership of a share legally implies compliance with the bylaws and the resolutions of the shareholders' meeting.

Whenever it is necessary to hold several shares to exercise a right, individual shares or a number of shares less than the number required give no rights to their owners against the Company; in this case, it is the responsibility of the shareholders to combine the number of shares necessary.

19.2.3.3 Indivisibility of the Shares - Beneficial Ownership (Article 13 of the bylaws)

Shares are indivisible with respect to the Company

Co-owners of indivisible shares are represented at shareholders' meetings by one of the owners or by a single agent. If they disagree, the agent shall be designed by court at the request of one of the co-owners.

If there is a beneficial owner, the share registration must show the existence of the beneficial ownership. Except where otherwise stipulated in an agreement notified to the Company by registered mail with return receipt, the voting right belongs to the beneficial owner in ordinary shareholders' meetings and to the bare owner in extraordinary shareholders' meetings.

19.2.3.4 Transfer of Shares (Article 12 of the bylaws)

Shares are freely negotiable, except where otherwise stipulated by laws or regulations. They are registered in an account and are transferred, with respect to the Company, by a transfer between accounts, under the conditions defined by the laws and regulations in force.

19.2.4 MODIFICATION OF SHAREHOLDERS' RIGHTS

The rights of shareholders may be modified in accordance with applicable laws and regulations. The bylaws do not contain any particular provisions with respect to modification of the rights of shareholders that are more stringent than the law.

19.2.5 GENERAL SHAREHOLDERS' MEETINGS (ARTICLES 24 TO 31 OF THE BYLAWS)

Notice and place of meeting

Shareholders' meetings shall be called and shall deliberate on the terms provided by law.

Meetings shall be held either at the registered office or at another place stated in the notice of the call to a meeting.

Agenda

The meeting agenda is provided on the notices and letters of meeting; it is decided by the author of the notice.

The meeting may deliberate only on items indicated on the agenda; however, in all circumstances it may dismiss one or more directors and replace them.

One or more shareholders representing at least the percentage of capital required by law, and acting under the statutory conditions and within the statutory time periods, have the option to require the inclusion of proposed resolutions on the agenda.

Access to meetings

Any shareholder has the right to attend shareholders' meetings and participate in the deliberations personally or through an agent.

Any shareholder may participate at meetings in person or through his agent, under the conditions defined by the regulations in force, with proof of his identity and the ownership of his shares in the form of accounting registration under the conditions defined by the laws and regulations in force.

On the decision of the Board of Directors published in the notice of meeting to use such telecommunications methods, shareholders who attend the meeting *via* videoconference or other telecommunication or electronic transmission methods, including the Internet, which allow identification under the conditions required by the regulations in force, are deemed present for the calculation of quorum and majority.

On a decision by the Board of Directors, any shareholder may vote remotely or give his proxy pursuant to the regulations in force using a form prepared by the Company and sent to the Company under the conditions defined by the regulations in force, including electronic or broadcast transmission methods.

This form must be received by the company under the regulatory conditions to be counted.

Attendance sheet, officers (bureau), minutes

At each meeting, an attendance sheet containing the information required by law shall be kept.

Meetings are chaired by the Chairman of the Board of Directors or, in his absence, by a director specifically delegated for this purpose by the Board. If not, the meeting shall elect a Chairman.

The duties of tellers *(scrutateurs)* are performed by the two members of the meeting who are present and accept the duties and who have the largest number of votes.

The officers *(bureau)* name the secretary, who does not have to be a shareholder.

The mission of the officers *(bureau)* is to verify, certify and sign the attendance sheet, to ensure the proper conduct of discussion, to settle incidents at meetings, to count the votes cast, and to ensure the meeting is properly conducted and that minutes are prepared.

Minutes are prepared and copies or excerpts of the resolutions are issued and certified as required by law.

Ordinary shareholders' meeting

The ordinary shareholders' meeting is a meeting called to make all decisions that do not amend the bylaws. It meets at least once a year within six months after the closing of each fiscal year to approve the financial statements for the year and the financial statements unless an extension is granted under the conditions provided for by law.

On the first notice of meeting, it may legally deliberate only if the shareholders present or represented, or voting by mail and electronically, hold at least one-fifth of the voting shares. On the second notice of meeting, no quorum is required.

It rules by a majority of the votes held by the shareholders present, represented or who have voted by mail or means of distance communication.

Extraordinary shareholders' meeting

Only the extraordinary shareholders' meeting is authorized to amend all provisions of the bylaws. It may not, however, increase shareholders' commitments, subject to operations resulting from a legally performed consolidation of shares without the approval of each shareholder.

It legally deliberates only if the shareholders present, represented or who have voted by mail or electronically, hold at least one quarter of the voting shares on the first notice of meeting, and one-fifth of the voting shares on the second notice. If the second quorum is not reached, the second meeting may be moved to a date no more than two months from the date on which it was called.

The meeting rules by a two-thirds majority of the votes of the shareholders present, represented or voting by mail or means of distance communication.

However, under no circumstances may the extraordinary shareholders' meeting increase the commitments of the shareholders or damage the equality of their rights unless this is done by unanimous vote of the shareholders.

Decisions are made by a two-thirds majority of the votes held by the shareholders present, represented by proxy, or voting by mail. Abstentions will have the same effect as "no" vote.

19.2.6 STIPULATIONS THAT ALLOW DELAYING, DEFERRING OR PREVENTING A CHANGE IN CONTROL OF THE COMPANY

There are no provisions either in the Company's bylaws or in any internal charter or internal rules that could have the effect of delaying, postponing or preventing a change of control of the Company.

19.2.7 DECLARATION OF THRESHOLDS (ARTICLE 12 OF THE BYLAWS)

In addition to the thresholds provided for by applicable laws and regulations, any natural person or legal entity who comes to hold or ceases to hold, acting alone or in concert within the meaning of Article L.233-10 of the French Commercial Code, directly or indirectly, a number of shares representing at least 2.5% of the share capital or voting rights, including beyond the reporting thresholds provided for by laws and regulations, must inform the Company of the total number of shares and voting rights of the Company that such person holds, by registered letter with return receipt requested sent to the Company's registered office within four trading days after crossing such threshold(s). Such person shall also indicate the number of securities giving access to the capital and the voting right potentially attached thereto, as well as any other information provided for by law.

The notification shall be repeated in the conditions stated above each time an additional fraction of 2.5% of the share capital or voting rights is crossed upward or downward.

In the event of failure to comply with the notification requirements described above, shares exceeding the fraction that should have been notified will be deprived of voting rights at shareholders' meetings if, at such meetings, the notification failure has been recorded and if one or more shareholders jointly holding at least 2.5% of the share capital so request. Loss of voting rights shall be applicable in all shareholders' meetings that would be held up until two years following proper notification.

19.2.8 PARTICULAR STIPULATIONS GOVERNING MODIFICATIONS OF THE SHARE CAPITAL

As the bylaws do not provide any specific stipulations, the share capital may be increased, decreased or amortized by any methods or means authorized by law.

MATERIAL CONTRACTS

As of the date of this Universal Registration Document, we are a party to the following material contracts:

20.1 COLLABORATION, PARTNERSHIP AND RELATED AGREEMENTS

Agreements Relating to GS010

- Partnership agreement relating to the research, development and commercialization of GS010 between Genethon and the Company dated February 1, 2013, as amended from time to time.

In February 2013, we entered into a partnership agreement with Genethon to research, develop and commercialize selected research and development projects for gene therapy products within specific ocular indications using technology licensed by the Company under a license agreement with Inserm Transfert dated October 12, 2012. For more details, see Section 5.5.4, "Collaboration, Partnership and Related Agreements" of this Universal Registration Document.

Agreements Relating to GS030

Sight Again Program

- Consortium agreement relating to the research and development of complimentary therapeutic remedies between Pixium Vision S.A., or Pixium Vision, *Fondation Voir et Entendre* and the Company dated July 11, 2014.

In July 2014, we entered into a consortium agreement with Pixium Vision and FVE. For more details, see Section 5.5.4, "Collaboration, Partnership and Related Agreements" of this Universal Registration Document.

- Master agreement relating to the Sight Again Program between Bpifrance Financement, Pixium Vision and the Company dated December 16, 2014.

In December 2014, we entered into a master agreement relating to the Program with Bpifrance Financement, Pixium Vision and FVE setting forth the characteristics of the Program, to fix the amount and conditions for awarding funding granted by Bpifrance Financement as well as to clarify the principles and arrangements for monitoring the implementation of the Program by Bpifrance Financement. Pursuant to an amendment dated November 26, 2015, the product candidate known as GS020 has been replaced by the product candidate GS030 for the purpose of the agreement. For more details, see Section 5.5.4, "Collaboration, Partnership and Related Agreements" of this Universal Registration Document.

- Financial aid agreement related to the Sight Again Program between Bpifrance Financement and the Company dated December 16, 2014.

In December 2014, we entered into a financial aid agreement relating to the Program with Bpifrance Financement setting forth the amounts and conditions upon which Bpifrance Financement shall grant financial aid to the Program. Pursuant to an amendment dated November 26, 2015, the product candidate known as GS020 has been replaced by the product candidate GS030 for the purpose of the agreement. For more details, see Section 5.5.4, "Collaboration, Partnership and Related Agreements" of this Universal Registration Document.

20.2 IN-LICENSE AGREEMENTS

Agreements Relating to GS010

- License agreement relating to patents used in connection with GS010 with Inserm Transfert S.A. and the Company dated October 12, 2012.

On October 12, 2012, we entered into a license agreement with Inserm Transfert S.A. (acting as delegate of Inserm). For more details, see Section 5.5.5, "Intellectual Property" of this Universal Registration Document.

- License agreement relating to scientific data used in connection with GS010 with *Association Française contre les Myopathies*, Inserm Transfert S.A. and the Company dated December 2, 2013.

On December 2, 2013, we entered into a license agreement for use of scientific data with the AFM, Genethon and Inserm Transfert, acting as a delegate of Inserm and on behalf of the UPMC. For more details, see Section 5.5.5, "Intellectual Property" of this Universal Registration Document.

- License agreement for the use of Harvard Master CellBank relating to GS010 dated June 18, 2019.

For more details, see Section 5.5.5, "Intellectual Property" of this Universal Registration Document.

Agreements Relating to GS030

- License agreement relating to patents used in connection with GS030 with Adverum Biotechnologies (formerly Avalanche Biotechnologies) and the Company dated February 23, 2014.

On February 23, 2014, we entered into a non-exclusive license agreement with Adverum. For more details, see Section 5.5.5, "Intellectual Property" of this Universal Registration Document.

Massachusetts Institute of Technology

- License agreement relating to patents used in connection with GS030.

On January 6, 2016, we entered into a license agreement with M.I.T., upon exercising an option right granted under the patent option agreement between M.I.T. and us, dated January 9, 2015. This license agreement has been amended in April 2017, whereby the Company will provide the M.I.T. with a written research and development plan no later than July 1, 2018. For more details, see Section 5.5.5, "Intellectual Property" of this Universal Registration Document.

- License agreement relating to patents used in connection with GS030.

On May 6, 2019, we entered into a license agreement with Sorbonne Université, CNRS, Inserm and SATT Lutech.

For more details, see Section 5.5.5, "Intellectual Property" of this Universal Registration Document.

20.3 MANUFACTURING AGREEMENT

- Services agreement with Brammer Bio dated October 10, 2017.

In order to secure the commercial grade manufacturing when GenSight will be ready for submitting the marketing authorization application, GenSight has reconsidered its partnership with Novasep Henogen, and has decided to move on with Brammer Bio. Brammer Bio acquired in 2017 additional facilities dedicated to Phase III and commercial production for Gene Therapy. These facilities are currently under cGMP production, which would allow the manufacture of the consistency lots for our product candidate GS010 in 2019.

Hence, on October 10, 2017, we entered into a master services agreement with Brammer Bio for the manufacturing and control of our product candidate GS010. The performance of the services under the agreement is split into two work statements. The first work statement (WS1) has been contracted for the process transfer and establishment at Brammer Bio (part A) and the process characterization (part B), with completion timeframes ranging from 6 months to 10 months. The second work statement (WS2) was contracted in August 2018 for the process performance qualification (PPQ) which includes the manufacture of 3-PPQ batches (part C) eligible to market. Each work statement will terminate upon completion of the deliverables.

- Services agreement with Lonza dated February 10, 2014.

GenSight has conducted for its second lead product GS030 a process development program with Lonza (8066 El Rio St-Houston – TX 77054 – USA) on a scale that will support nonclinical safety evaluation, clinical trials and potentially commercial needs with full GMP compliance. Lonza is an established supplier to the pharmaceutical industry with global manufacturing expertise in viral-based therapeutics. Lonza facility in Houston is FDA-inspected and the personnel has a broad experience in the manufacture and release of batches of Phase I through Phase III clinical trial materials for use in the U.S., Europe and Japan. In the frame of several Statement Of Work (SOWs) agreed between 2015 and 2017, Lonza has executed the development of the manufacturing process up to 100L batch – scale, as well as the manufacture and the control of the GS030 – product required for preclinical and Phase I/II clinical studies.

By the end 2017, Lonza has completed the construction of a new Biotech facility in Pearland (Kirby Drive – Pearland –TX) dedicated to the production of clinical and commercial Cell and Gene Therapy products. The facility is designed to accommodate process development unit, quality control laboratories, USP/ DSP manufacturing suite and fully segregated fill-and-finish suite and is expected to double the company's current capacity for the production of vectors for virally modified therapeutics. GenSight is considering further partnership with Lonza in Pearland for process scale-up to 250L and manufacture of the GS030-product required for the Phase III clinical studies. GenSight and Lonza signed on January 29, 2019 and amendment to the Manufacturing Services Agreement to continue the term of their collaboration.

In October 2019, GenSight has decided to terminate the service agreement with Lonza.

DOCUMENTS AVAILABLE

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DOCUMENTS AVAILABLE

Copies of this Universal Registration Document and our bylaws are available free of charge at our registered office.

All such legal and financial documents relating to us and made available to shareholders in accordance with applicable regulations may be viewed at our registered office.

Once our shares have been admitted to trading on Euronext Paris, regulated information pursuant to the AMF General Regulations will be available on our website (http://www.gensight-biologics.com).

GLOSSARY

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GLOSSARY

AAA	Adeno Associated Virus
AMD	Age-Related Macular Degeneration
ANSM	*Agence nationale de securité du médicament et des produits de santé*
ATIS	Asynchronous Time-Based Image Sensor
ATMP	Advanced Therapeutic Medicinal Product
ATP	Adenosine TriPhosphate
BCVA	Best corrected visual acuity
BLA	Biological License Application
BPCIA	Biologics Price Competition and Innovation Act
CBER	Center for Biological Evaluation & Research
CDER	Center for Drug Evaluation & Research
CAT	Committee for Advanced Therapies
CE	European Conformity
cGMP	Certified Good Manufacturing Practices
CHMP	Committee on Human Medicinal Products
CMC	Chemistry, Manufacturing and Controls
CMO	Contract Manufacturing Organization
CMS	Center for Medicare & Medicated Services
Cox10	Cytochrome c oxidase assembly homolog 10
CRO	Contract Research Organization
CTA	Clinical Trial Application
DNA	Deoxyribonucleic acid
DSMB	Data Safety Monitoring Board
EEA	European Economic Area
EMA	European Medicines Agency
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
GA	Geographic Atrophy
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GTP	Good Tissue Practices
HCT/Ps	Human Cells, Tissues, and Cellular and Tissue-Based Products
HITECH	Health Information Technology for Economic and Clinical Health Act
HIPAA	Health Insurance Portability and Accountability Act
IBC	Institutional Biosafety Committee
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IND	Investigational New Drug
IOP	Intraocular pressure
IRB	Institutional Review Board
IVT	Intravitreal
LCA	Leber congenital amaurosis
LHON	Leber hereditary optic neuropathy
MAA	Marketing Access Authorization
MIT	Massachusetts Institute of Technology
MTS	Mitochondrial Targeting Sequence
mtDNA	Mitochondrial ribonucleic acid
mRNA	Messenger RNA
MTS	Mitochondrial Targeting Sequence
NDA	New Drug Application
ND4	NADH dehydrogenase 4
NIH	National Institutes of Health
NHP	Non-human primate
OCT	Optical coherence tomography
PDCO	Paediatric Committee
PDUFA	Prescription Drug User Fee Act
PHS	Public Health Service
PMA	PreMarket Approval
PPACA	Patient Protection and Affordable Care Act
RAC	Recombinant DNA Advisory Committee
rAAV	Recombinant adeno-associated Virus
REMS	Risk Evaluation and Mitigation Strategy
RGC	Retinal Ganglion Cells
RNA	Ribo Nucleic Acid
RP	Retinitis Pigmentosa
SOP	Standard operating procedure
SPC	Supplementary Protection Certificate
USPTO	United States Patent & Trademark Office
UTR	UnTranslated Region
VEP	Visual evoked potential
Wt	Wild type

ANNEXES

ANNEX 1.
OTHER INFORMATION RELATING TO THE FINANCIAL STATEMENTS OF GENSIGHT BIOLOGICS S.A. PARENT COMPANY

1. AGED TRADE ACCOUNT PAYABLES

In accordance with the French law on the Modernization of the Economy of August 4, 2008 and the resulting Articles L.441-6-1 and D.441-4 of the French Commercial Code, the aging of the balance of trade accounts payable by GenSight Biologics S.A. parent company at year-end is as follows:

	Not yet due	0 to 30 days	31 to 60 days	61 to 90 days	> 90 days	Total overdues
Number of invoices						204
Amount of trade account payable (tax included)	1,799	285	247	1	365	998
% of total purchases (tax included of the period)	5.72%	0.91%	0.79%	0.00%	1.16%	2.86%

2. AGED TRADE ACCOUNTS RECEIVABLES

In accordance with the French law on the Modernization of the Economy of August 4, 2008 and the resulting Articles L.441-6-1 and D.441-4 of the French Commercial Code, the aging of the balance of trade accounts receivables by GenSight Biologics S.A. parent company at year-end is as follows:

	0 day	0 to 30 days	31 to 60 days	61 to 90 days	> 90 days	Total
Number of invoices	—	—	—	—	—	—
Total amount of invoices concerned including VAT	—	—	—	—	—	—
Percentage of revenue for the financial year including VAT	—	—	—	—	—	—

3. FIVE YEARS FINANCIAL SUMMARY

	2019	2018	2017	2016	2015
A – CAPITAL AT YEAR-END (in thousands of euros)					
1. Share capital	821	821	606	485	340
2. Number of ordinary shares outstanding	32,827,362	24,802,973	24,234,223	19,409,701	2,017,798
3. Number of series A shares outstanding	–	–	–	–	6,966,454
4. Number of series B shares outstanding	–	–	–	–	4,624,870
B – OPERATIONS AND RESULTS OF THE YEAR (in thousands of euros)					
1. Net revenue	700	–	–	–	1
2. Earnings before tax, employee profit-sharing, depreciation, amortization and provisions	(33,250)	(36,218)	(22,478)	(20,138)	(14,820)
3. Income tax expense / (income)	(4,210)	(4,322)	(3,692)	(2,930)	(2,874)
4. Employee profit-sharing due for the year		–	–	–	–
5. Earnings after tax, employee profit-sharing, depreciation, amortization and provisions	(29,322)	(32,188)	(19,045)	(17,398)	(12,074)
6. Distributed earnings (during the year)	–	–	–	–	–
C – EARNINGS PER SHARE (in euros)					
1. Earnings per share after tax, employee profit-sharing, but before depreciation, amortization and provisions	(0.9)	(1.29)	(0.78)	(0.89)	(1.07)
2. Earnings after tax, employee profit-sharing, depreciation, amortization and provisions	(0.9)	(1.30)	(0.79)	(0.90)	(1.07)
3. Net dividend per ordinary share	–	–	–	–	–
D – PERSONNEL					
1. Average number of employees in the year	27	32	33	27	23
2. Total payroll for the year (in Keuros)	3,318	3,630	3,315	3,084	2,629
3. Amounts paid with respect to employee benefits during the year (Social Security, staff benefits, etc.) (in KEuros)	1,600	1,209	2,231	1,117	916

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