2016

REGISTRATION DOCUMENT

GenSight BIOLOGICS

GenSight Biologics S.A.

Corporation *(société anonyme)* with a share capital of €488,511.33

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

2016
REGISTRATION DOCUMENT

INCLUDING
THE ANNUAL FINANCIAL REPORT
AND THE MANAGEMENT REPORT

In accordance with its General Regulation *(Règlement Général)* and, in particular Article 212-23 thereof, the *Autorité des marchés financiers* (the "AMF") registered this Registration Document on April 28, 2017 under number R.17-036. This document may not be used in the context of any securities offering unless completed by a Securities Note in respect of which the AMF has granted a visa. The Registration Document has been prepared by the issuer, and its signatories therefore assume responsibility for its contents.

This registration was granted after the AMF had verified that the document is complete and comprehensible and that the information it contains is coherent, in accordance with the provisions of Article L.621-8-1-I of the French Monetary and Financial Code. It does not imply that the AMF has verified the accounting and financial information presented herein. The Registration Document is publicly available on the website of the AMF (www.amf-france.org). Copies of the Registration Document may also be obtained free of charge at GenSight Biologics S.A.'s registered office at 74, rue du Faubourg Saint-Antoine – 75012 Paris, France, as well as on the website of GenSight Biologics S.A., (www.gensight-biologics.com).

CONCORDANCE TABLE

The concordance table below makes it possible to identify in this 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).

	Section(s) of the Registration Document
1. CERTIFICATION OF THE PERSON ASSUMING RESPONSIBILITY FOR THE ANNUAL FINANCIAL REPORT	Section 1.2
2. COMPANY'S ANNUAL FINANCIAL STATEMENTS – FRENCH STANDARDS (FRENCH-GAAP)	Section 20.1.3
3. COMPANY'S ANNUAL FINANCIAL STATEMENTS – INTERNATIONAL FINANCIAL REPORTING STANDARDS (IFRS)	Section 20.1.1
4. MANAGEMENT REPORT	
4.1. Information on the Company's business	
• Presentation of the business (in particular progress achieved and difficulties encountered) and results of the Company	Sections 3, 6, 9, 10 and 20
• Analysis of business development, results and financial position and in particular debt of the Company and the Group	Sections 3, 9 and 10
• Outlook of the Company and the Group	Section 12
• Key financial and non-financial indicators of the Company and the Group	Section 3
• Post-closing events of the Company and the Group	Section 20.1
• 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 4.6
• Principal risks and uncertainties incurred by the Company and the Group	Section 4
• Information on R&D of the Company and the Group	Sections 6, 11 and 20.1
4.2. Legal, financial and tax information on the Company	
• Choice made on one of the two methods for exercising executive management in the event of a modification	N/A
• Shareholder structure and changes thereto	Section 18.1.2
• 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 21.1.3
• Employee stock ownership plans	Sections 9.3, 15.8, 20.1 and 21.1.4
• Items having a potential impact in the event of public offerings:	
i. Capital structure of the Company;	i. 21.1.8.1
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;	ii. 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;	iii. 18.1.2
iv. Holders of any securities conferring special rights of control and descriptions thereof;	iv. 18.2 – 18.3
v. Control mechanisms provided for in a potential employee stock ownership system where control rights are not exercised by the latter;	v. N/A
vi. Shareholders' agreements known to the Company and which may result in share transfer and voting rights restrictions;	vi. 18.2

	Section(s) of the Registration Document
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;	vii. 21.2.2
viii. Powers of the Board of Directors for the issuance and buybacks of shares;	viii. 21.1.3 and 21.1.6
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;	ix. 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.	x. 19.2.2
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• Reference to possible adjustments:	
– for securities giving access to the capital and stock options in the case of share buybacks;	
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• Amount of expenses and charges not deductible from taxable income	N/A
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• Injunctions or fines for anticompetitive practices	N/A
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• 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 15
• 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;	
– 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
• Summary of dealings in own shares of the Company by executives and related parties	Section 14.1.5
• In the case of performance share grants, reference to information according to which the Board of Directors' decision was made to:	
– either prohibit executive manager from disposing of the restricted stock units freely granted to them prior to ceasing to exercise their functions;	
– or to impose lockout obligations to registered holders for the shares until they cease to occupy their functions (by specifying accordingly the portion to be covered by these provisions)	Section 15.5
4.4. CSR information of the Company	
• Consideration of the employment-related and environmental consequences of the business and social commitments in favor of sustainable development, preventing discrimination and promoting diversity	Sections 8.2 and 17.2
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5. STATUTORY AUDITORS' REPORT ON THE COMPANY'S ANNUAL FINANCIAL STATEMENTS – FRENCH STANDARDS (FRENCH-GAAP)	Section 20.1.4

	Section(s) of the Registration Document
6. STATUTORY AUDITORS' REPORT ON THE COMPANY'S ANNUAL FINANCIAL STATEMENTS – INTERNATIONAL FINANCIAL REPORTING STANDARDS (IFRS)	Section 20.1.2
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8. CHAIRMAN'S REPORT ON INTERNAL CONTROL AND RISKS MANAGEMENT	Section 16.5.2
9. STATUTORY AUDITOR'S REPORT ON THE CHAIRMAN'S REPORT ON INTERNAL CONTROL AND RISKS MANAGEMENT	Section 16.5.3

This Registration Document does not include the resolutions that will be published in the French *Bulletin des Annonces Légales Obligatoires* in accordance with applicable legislation and submitted to the shareholders' meeting called to approve the financial statements for the fiscal year ended December 31, 2016 which will be held by the end of June 2017.

NOTE

In this 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 Registration Document describes the Company as of the date hereof.

This Registration Document includes our annual financial statements prepared in accordance with French accounting standards for the fiscal year ended December 31, 2016. In accordance with provisions of Article 28 of the Commission Regulation (EC) No 809/2004 of April 29, 2004, as amended, the Company's annual financial statements prepared in accordance with French accounting standards for the fiscal years ended December 31, 2014 and 2015 and the statutory auditor's reports on the Company's annual financial statements prepared in accordance with French accounting standards for the fiscal years ended December 31, 2014 and 2015 included in the Base Prospectus registered with the AMF on May 24, 2016 under number I.16-049 are incorporated by reference in this Registration Document.

This Registration Document also includes our 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, 2016. In accordance with provisions of Article 28 of the Commission Regulation (EC) No 809/2004 of April 29, 2004, as amended, the Company's annual financial statements (IFRS) for the fiscal years ended December 31, 2014 and 2015 and the statutory auditor's report on the Company's annual financial statements (IFRS) for the fiscal years ended December 31, 2014 and 2015 included in the Base Prospectus registered with the AMF on May 24, 2016 under number I.16-049 are incorporated by reference in this Registration Document.

The Base Prospectus may be consulted on the Company's website (www.gensight-biologics.com) and on the AMF's website (www.amf-france.org).

Unless otherwise indicated the selected financial information and comments on the financial statements presented in this Registration Document have been prepared on the basis of the 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 Registration Document.

Forward-looking Statements

This 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 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 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 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 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 Registration Document contains, in particular in Section 6, "Business Overview," information relating to our markets and to our competitive position. Unless otherwise indicated, the information contained in this 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 4, "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. Furthermore, additional risks that have not yet been identified or that are not considered material by us at the date of the visa on this Registration Document could produce adverse effects.

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PERSONS RESPONSIBLE

1.1 NAME AND POSITION OF THE PERSON RESPONSIBLE FOR THE REGISTRATION DOCUMENT

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

1.2 CERTIFICATION OF THE PERSON RESPONSIBLE FOR THE REGISTRATION DOCUMENT

I hereby certify, having taken all reasonable measures to this effect, that the information contained in this Registration Document is, to the best of my knowledge, in accordance with the facts and contains no omission likely to affect our import.

I certify that, to the best of my knowledge, the financial statements were prepared in accordance with applicable accounting standards and that they give a fair view of the assets, financial position and results of the Company. I further certify that the management report contained in this Registration Document, as mentioned in the concordance table of this Registration Document, provides a faithful representation of the development of the business, results and financial position of the Company, as well as a description of the principal risks and uncertainties it faces.

I have obtained from the statutory auditors a letter of completion of their work *(lettre de fin de travaux)* in which they state that they have verified the information relating to the financial situation and accounts presented in this Registration Document, and have read the Registration Document in its entirety.

April 26, 2017

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

1.3 NAME AND POSITION OF THE PERSON RESPONSIBLE FOR FINANCIAL INFORMATION

Thomas Gidoin,
Chief Financial Officer of GenSight Biologics S.A.
74, rue du Faubourg Saint-Antoine – 75012 Paris, France
Tel: +33 (0)1 76 21 72 20

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STATUTORY AUDITORS

2.1 STATUTORY AUDITORS

Deloitte & Associés

Represented by Dominique Valette

Immeuble Higashi – 106, cours Charlemagne – 69002 Lyon, France

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

45, rue Boissière – 75116 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 was approved by the general shareholders' meeting of the Company on April 17, 2012 , 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, 2018 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.

2.2 ALTERNATE STATUTORY AUDITORS

BEAS (substitute to Deloitte & Associés)

195, avenue Charles de Gaulle – 92200 Neuilly-sur-Seine, France

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

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).

BEAS was appointed substitute statutory auditor by our general shareholders' meeting on April 17, 2012 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, 2018. 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.

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

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SELECTED 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 Registration Document includes our annual financial statements prepared in accordance with French accounting standards for the fiscal year ended December 31, 2016. Only these annual financial statements are legally binding. These financial statements are presented in Section 20.1.3, "Company's Annual Financial Statements (French GAAP) for the Fiscal Year Ending December 31, 2016" of this Registration Document.

The Company, which does not have any subsidiaries or any investment interests, has prepared, in addition to its annual financial statements in compliance with the French accounting standards, on a voluntary basis, corporate financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2016 presented in this Registration Document in Section 20.1.1, "Company's Annual Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2016."

Unless otherwise indicated, the selected financial information as of and for the fiscal year ended December 31, 2016 has been derived from our financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2016. These financial statements for the fiscal year ended December 31, 2016 have been audited by Deloitte & Associés and Becouze, statutory auditors. The statutory auditors' report on the financial statements as of and for the fiscal year ended December 31, 2016 is included in Section 20.1.2, "Statutory Auditors' Report on the Company's Annual Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2016" of this Registration Document.

The information in this section should be read together with (i) our financial statements contained in Section 20.1.1, "Company's Annual Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2016" of this Registration Document, (ii) our analysis of our results presented in Section 9, "Operating and Financial Review," and (iii) our analysis of our liquidity and capital resources presented in Section 10, "Capital Resources."

3.1 SELECTED FINANCIAL INFORMATION

STATEMENTS OF INCOME (LOSS) DATA

	Year ending December 31	
	2015 €	2016 €
Operating income	3,559,998	3,000,665
Operating expenses:		
Research and development	10,722,104	18,529,135
General and administrative	6,499,188	6,490,216
Total operating expenses	17,221,292	25,019,351
Operating income (loss)	(13,661,294)	(22,018,686)
Financial income (loss)	7,674	(62,977)
Net income (loss)	(13,653,620)	(22,081,663)
Basic and diluted earnings (loss) per share[(1)]	(1.21)	(1.36)
Number of shares used for computing basic and diluted earnings (loss) per share	11,239,666	16,252,765

(1) See Note 21 to our financial statements as of December 31, 2016 for further details on the calculation of basic and diluted earnings (loss) per share.

STATEMENTS OF FINANCIAL POSITION DATA

	Year ending December 31	
	2015 Actual €	2016 Actual €
Cash and cash equivalents	30,059,909	53,982,212
Short-term investments	–	–
Total assets	36,310,275	59,230,624
Total shareholders' equity	29,326,426	53,340,317
Total non-current liabilities	690,399	2,995,415
Total current liabilities	6,293,450	2,894,892
Total liabilities	6,983,849	5,890,307
Total liabilities and shareholders' equity	36,310,275	59,230,624

STATEMENTS OF CASH FLOWS

	Year ending December 31	
	2015 €	2016 €
Cash flows from operating activities		
Net profit (loss)	(13,653,620)	(22,081,663)
Reconciliation of net profit (loss) and the cash used for operating activities:		
Amortization and depreciation	138,650	202,712
Retirement pension obligations	29,348	31,498
Expenses relating to share-based payments	1,531,876	4,634,525
Other financial items	(11,929)	(144)
Operating cash flows before change in working capital	**(11,965,676)**	**(17,213,072)**
Accounts receivable	502,961	(2,920)
Other receivables	(3,360,623)	972,759
Accounts payable	3,283,459	(3,458,603)
Other current liabilities	(554,675)	60,045
Change in working capital	**(128,877)**	**(2,428,718)**
Net cash flows from operating activities	**(12,094,554)**	**(19,641,790)**
Cash flows from investment activities		
Acquisitions of property, plant, and equipment	(699,427)	(188,177)
Acquisitions of intangible assets	(7,517)	(1,047)
Acquisitions of non-current financial assets	(79,545)	7,770
Sales of property, plant, and equipment	–	11,000
Purchase of short-term investments	1,403,938	–
Net cash flows from investment activities	**617,449**	**(170,454)**
Cash flows from financing activities		
Conditional advances received	–	2,300,258
Treasury shares	115,622	(145,227)
Warrants issuance	–	140,118
Capital increases, net of transaction costs	30,751,921	41,439,398
Net cash flows from financing activities	**30,867,543**	**43,734,547**
(Decrease)/Increase in cash and cash equivalents	**19,390,438**	**23,922,303**
Cash and cash equivalents at the beginning of the period	10,669,471	30,059,909
Cash and cash equivalents at the close of the period	**30,059,909**	**53,982,211**

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RISK FACTORS

Investors should carefully consider all of the information set forth in this 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 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. Investors should note that there may be other risks that have not yet been identified as of the date of this Registration Document, or the occurrence, as of the date hereof, we do not consider likely to have a material adverse effect on our business, results of operations, financial condition and prospects.

Among these important risks are the following:

- Currently, no gene therapy product has been approved for sale in the United States and only two such products have been approved in the European Union. Our product candidates are based on gene therapy technology, which makes it difficult to predict the timing and cost of development and subsequent regulatory approval for our product candidates.
- We have never generated revenue from product sales and have incurred operating losses since inception. We expect to continue to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We may need to raise additional capital in the future, which may not be available on acceptable terms, or at all.
- We have not completed the evaluation of our lead product candidate, GS010, in clinical trials and our second lead product candidate, GS030, is being evaluated in preclinical studies.
- 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.
- We face significant competition in an environment of rapid technological change and our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours.
- We rely on third-parties to conduct, supervise and monitor our clinical studies. If these third-parties do not meet our deadlines or otherwise conduct the 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.
- The commercial success of our product candidates depends upon their degree of market acceptance by physicians, patients, third-party payors and others in the medical community.
- We may choose in the future to enter into collaborations with third-parties for the development and commercialization of our product candidates. If we are unable to enter into such collaborations on acceptable terms, or if these collaborations are not successful, our business could be adversely affected.
- We may be unable to establish sales and marketing capabilities.
- 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.
- 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 do not own any issued patents and our rights to develop and commercialize our product candidates are limited by the terms and conditions of intellectual property licenses granted to us by others.

4.1 RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENT

We have never generated revenue from product sales and have incurred operating losses since inception. We expect to continue to incur losses for the foreseeable future and may never achieve or maintain 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 our products sales and we have incurred operating losses since inception. Our net loss was €13.7 million and €22.1 million for the fiscal years ended December 31, 2015 and 2016 respectively.

Our capacity to generate revenues from product sales and to achieve profitability will depend on our ability, alone or with 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 GS010, GS030 or any other product candidates and we may never obtain such approvals or be able to commercialize any of our current or any future product candidates. We do not anticipate generating revenues from product sales for the next several years. Our ability to generate future revenues from product sales will depend heavily 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 trial for

our lead product candidate GS010 and preclinical studies and clinical trials for our second lead product candidate GS030;

- initiating additional preclinical studies, clinical trials or other studies of our other product candidates;
- identifying and validating new product candidates that combine gene therapy approaches with our key platform technologies;
- 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;
- completing and submitting applications to, and obtaining regulatory approval from, other regulatory authorities;
- launching and commercializing product candidates for which we obtain marketing approval by establishing a sales force, marketing and distribution infrastructure or, in regions where we choose to do so, collaborating with a commercialization partner;
- setting a commercially viable price for any products for which we may receive approval;
- obtaining and maintaining adequate coverage and reimbursement from government and third-party payors for our product candidates;
- maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for our product candidates;
- 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 as a viable treatment option and satisfying any post-marketing requirements;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- acquiring or in-licensing other product candidates and technologies;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- 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.

Our limited operating history may make it difficult for you to evaluate our business to date and to assess our future viability.

We began our operations in April 2012. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring our technology, identifying potential product candidates, undertaking preclinical studies and clinical trials of our most advanced product candidates, and establishing collaborations. We have not yet demonstrated the ability to complete Phase III trials of our product candidates, obtain marketing approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a development-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company that is also capable of supporting commercial activities. We may not be successful in such a transition.

We may need to raise additional capital in the future, which may not be available on acceptable terms, or at all.

Our operations have consumed significant cash since inception. To date, we have financed our activities primarily through private placements, funding received from Bpifrance Financement and research tax credits *(crédit d'impôt recherche)*, or CIR. 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, 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

Medical 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 future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- pricing and reimbursement levels for commercial sale of our products and the amount of any revenues we would receive from such sales; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Furthermore, upon listing on the regulated market of Euronext Paris, or Euronext Paris, we expect to incur additional costs associated with operating as a public company.

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 rights of our current shareholders.

4.2 RISKS RELATED TO THE DISCOVERY AND DEVELOPMENT AND REGULATORY APPROVAL OF OUR PRODUCT CANDIDATES

No gene therapy product has been approved in the United States for sale and only two such products have been approved in the European Union and it is therefore difficult to predict the timing and cost of development and of subsequent regulatory approval for our product candidates.

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, or 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, there can be no assurance as to the length of the study period, the number of patients regulatory agencies will require to be enrolled in the studies in order to establish the safety, efficacy, purity and potency of human gene therapy products, or that the data generated in these studies will be acceptable to such regulatory agencies to support marketing approval.

The regulatory approval process of the FDA, the EMA and other regulatory authorities are lengthy, time-consuming and inherently unpredictable, and we may be unable to obtain regulatory approval for our product candidates.

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 Registration Document, only two gene therapy products, uniQure N.V.'s Glybera (granted under exceptional circumstances) and GlaxoSmithKline plc's Strimvelis, have received marketing authorization 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.

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. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The clinical trial requirements of the FDA, the EMA and other regulatory authorities and the criteria used to

determine the safety and efficacy of a new product candidate can vary substantially according to the type, complexity, novelty and intended use and market of such 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, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA, the EMA or other national authorities to change the requirements for approval of any of our product candidates. Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy medicinal products and require that we comply with these new guidelines.

In addition, in June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as Brexit). A significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations. The effects of Brexit will depend on any agreements the United Kingdom makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could lead to legal uncertainty and potentially divergent national laws and regulation as the United Kingdom determines which European Union laws to replace or replicate.

As a result of the regulatory review process or changes in regulatory positions and interpretations, we may be required to perform additional studies, which would increase our development costs, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product to market could decrease our ability to generate sufficient product revenue.

The complexity of a combination product that includes a biological product and a medical device presents additional, unique development and regulatory challenges, which may adversely impact our development plans and our ability to obtain regulatory approval of GS030.

GS030 relies on the combination of two components: a gene therapy to restore light sensitivity in retinal cells, and biomimetic goggles that stimulate the reengineered retinal cells by projecting light-amplified images onto the retina. Developing and obtaining regulatory approval, in the United States and in the European Union, for combination products such as GS030 pose unique challenges because they involve components that are regulated under different types of regulatory requirements, and, in the United States, by different FDA evaluation Centers. As a result, such products raise regulatory, policy and review management challenges. For example, in the European Union, GS030 has been classified by the EMA Committee for Advanced Therapies, or CAT, as an advanced therapy medicinal product, or ATMP, even though it consists of two components, as its primary mode of action is linked to the gene therapy component. Because the biomimetic goggles are not incorporated in, or combined with, the drug product itself, they are considered an external device. In the United States, because divisions from both the Center for Biological Evaluation and Research, or CBER, and FDA's Center for Devices and Radiological Health must review our submissions concerning GS030, the regulatory review and approval process for GS030 may be lengthened. In addition, differences in regulatory requirements for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees, pricing and reimbursement, and post-approval modifications.

To be successful in developing and commercializing GS030, we would need to address a number of scientific, technical and regulatory challenges. We have limited experience in the development of biologic-device combinations and may not be successful in developing GS030. Given our limited experience in developing devices, we expect to rely in part on third-parties for the design and manufacture of the biomimetic goggles. As a result, we have entered into a consortium agreement and related agreements for the financing and conduct of research and development activities with Pixium Vision S.A., or Pixium Vision, and *Fondation Voir et Entendre*, or FVE, a scientific foundation that funds scientific programs in the field of ophthalmic diseases. See Section 11.4, "Collaboration Agreements" of this Registration Document.

Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.

Results from preclinical studies or previous clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial clinical trials.

We have no clinical data demonstrating either the safety or efficacy of GS030 in humans, and we have no clinical data demonstrating efficacy of GS010 in humans. There can be no assurance that the results demonstrated in the Phase I/II clinical studies for GS010 will result in success in our planned clinical trials. In addition, we cannot assure you that we will be able to achieve the same or similar success in our preclinical studies and clinical trials of our other product candidates.

There is a high failure rate for drugs, biological products and devices proceeding through clinical trials. Companies in the pharmaceutical, medical devices and biotechnology industries frequently suffer significant setbacks in late-stage clinical trials, even after earlier clinical trials have shown promising results. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Only a small percentage of medical products under development result in the submission of a new product application to the FDA, the EMA or other regulatory agencies, and even fewer are approved for commercialization. Any such delays or rejections could materially and adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to identify or discover additional product candidates.

The success of our business depends primarily upon our ability to 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. Our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or 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. Research programs to identify new product candidates require substantial technical, financial and human resources and we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Additionally, as a result of our limited resources, we may decide to forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We may find it difficult to conduct our clinical trials, in particular with respect to patient enrollment, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on how quickly we can recruit patients and complete required follow-up periods. If patients are unwilling to participate in our gene therapy studies because of negative publicity from adverse events related to the biotechnology or gene therapy fields, competitive clinical trials for similar patient populations, clinical trials in products employing our vectors or our platform or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidates may be delayed. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve adequate diversity, to complete our clinical trials in a timely manner. In particular, our current product candidates are being developed to treat rare conditions with limited patient pools. The eligibility criteria of our clinical trials will further limit the pool of available trial participants.

Patient enrollment is affected by factors including:

- size of the patient population and process for identifying subjects;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of gene therapy-based approaches to treat diseases;
- availability of competing therapies and clinical trials;
- severity of the disease under investigation;
- availability of genetic testing for potential patients;
- proximity and availability of clinical trial sites for prospective subjects;
- ability to obtain and maintain subject consent;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or the EMA or other regulatory authorities. In addition to risks related to patient enrollment, our ability to successfully initiate and complete a clinical trial in any other country is subject to numerous risks unique to conducting business in other countries, including:

- inability to find contract research organizations, or CROs, qualified local consultants, physicians and partners, or difficulty in establishing or managing relationships with such persons;
- difficulty in making patients and patients' communities aware of the existence of the clinical trials;
- different standards for the conduct of clinical trials;

- absence in some countries of regulatory authorities with sufficient expertise for review of gene therapy protocols; and
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

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 trials 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 clinical trials;
- delays in reaching a consensus with 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 institutional review board, or 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 subjects to participate in our clinical trials;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event or after a negative finding following an inspection of our clinical trial operations or trial sites;
- failure by us, any CROs we engage or any other third-parties to adhere to clinical trial requirements;
- failure to perform in accordance with Good Clinical Practices, or GCP, or applicable regulatory requirements in the United States, the European Union or other countries;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by any third-parties we contracted to perform certain of those functions;
- delays in having subjects complete a trial or return for post-treatment follow-up;
- clinical trial sites or subjects dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- the occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- the occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

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.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our product candidates.

We have not completed the evaluation of our lead product candidate, GS010, in clinical trials and our second lead product candidate, GS030, is being evaluated in preclinical studies.

We initiated Phase III clinical trials in GS010 and preclinical studies in GS030 in the fourth quarter of 2015. However, neither GS010 nor GS030, nor our other product candidates have ever been fully evaluated in human clinical studies, and we may experience unexpected results in the future. We or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates containing our proprietary vectors are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of development, including after commencement of any of our clinical trials.

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.

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. While new recombinant vectors have been developed to reduce these side effects, gene therapy is still a relatively new approach 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. 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 side effects caused by the product candidate, 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 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 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.

We may be unable to obtain orphan drug designation for our product candidates other than GS010 and GS030, and may be unable to obtain exclusivity for any of our product candidates. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively

small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, orphan designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in the drug or biologic product.

Generally, if a medicinal product with an orphan drug designation receives the first marketing approval for a particular indication, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for a product that constitutes the similar drug treating the same indication, except if significant differences exist regarding, for example, principal molecular structural features, therapeutic indications or safety and efficacy. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for the same product for the same indication, except in limited circumstances, for the applicable exclusivity period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the United States can be extended by six months if the BLA sponsor submits sufficient pediatric data. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation contained an untrue, material fact or omitted material information or, under certain circumstances, if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

GS010 and GS030 have been granted orphan drug designation by the FDA and the EMA for the treatment of Leber hereditary optic neuropathy, or LHON, and for the treatment of Retinitis Pigmentosa, or RP, respectively. If we request orphan drug designation for our other product candidates, there can be no assurances that the FDA or the EMA will grant any of our product candidates such designation. Additionally, the designation of any of our product candidates as an orphan product does not guarantee that any regulatory agency will accelerate regulatory review of, or approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications prior to our product candidates receiving exclusive marketing approval.

Even if we were to obtain orphan drug exclusivity for a product candidate, such as for GS010 and GS030, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or
- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

PRIME designation by the EMA or breakthrough therapy designation by the FDA may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that any product candidates will receive marketing approval in the United States.

We may, in the future, apply for the Priority Medicine, or PRIME, designation for our product candidates in the European Union. To be accepted for PRIME, a medicine must show its potential to benefit patients with unmet medical needs based on early clinical data. Drugs that receive PRIME designation are eligible for accelerated assessment at the time of application for an MAA.

Similarly, we may, in the future, apply for breakthrough therapy designation for our product candidates in the United States. A breakthrough therapy product candidate is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that such product candidate may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA seeks to ensure the sponsor of a breakthrough therapy

product candidate receives: (i) intensive guidance on an efficient drug development program; (ii) a proactive, collaborative and cross-disciplinary review; and (iii) a rolling review process whereby the FDA may consider reviewing portions of a BLA before the sponsor submits the complete application. Product candidates designated as breakthrough therapies by the FDA may be eligible for priority review if supported by clinical data.

Both PRIME designation and designation as a breakthrough therapy is within the discretion of the EMA and the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for PRIME designation or designation as a breakthrough therapy, the EMA or the FDA may disagree. The receipt of either a PRIME designation or a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional EMA or FDA procedures and does not assure approval by the EMA or the FDA. In addition, even if any of our product candidates are granted PRIME designation or breakthrough therapy designation, the FDA or the EMA may later decide that it no longer meets the conditions for such designation.

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 more narrow 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.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping and submission of safety, RMP and other post-market information. In the European Union, our product candidates will be subject to the regulatory oversight of the CAT, which makes recommendations to the Committee for Medicinal Products for Human Use, or CHMP, for recommendation of approval by the European Commission. In the United States, any regulatory approvals that we receive for our product candidates also may be subject to REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. FDA and EMA guidance advises that patients treated with some types of gene therapy undergo follow-up observations for potential adverse events for as long as 15 years. If a previously unknown safety issue is discovered with a product after approval, the FDA, the EMA or other regulatory authorities may require revisions to the labeling or approved indications of the product or withdraw approval of the product entirely. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and other applicable federal and state laws. In addition, product manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA, the EMA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, requirements and adherence to commitments made in the BLA, Common Technical Document, or CTD, or other marketing application.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable other marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;

- refuse to permit the import or export of products; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

In addition, the FDA or EMA's policies, and those of equivalent other regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We face significant competition in an environment of rapid technological change and our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours.

The biotechnology and pharmaceutical industries, including the gene therapy field, are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.

We are aware of several companies focused on developing gene therapies for various indications, including bluebird bio, Inc., Applied Genetic Technologies Corporation, Asklepios BioPharmaceutical, Inc., Audentes Therapeutics, Inc., Adverum Biotechnologies, Inc., (formerly Avalanche Biotechnologies, Inc.), or Adverum, Dimension Therapeutics, Inc., NightstaRx Ltd, Spark Therapeutics Inc. and uniQure N.V., as well as several companies addressing other methods for modifying genes and regulating gene expression. Advances in gene therapy technology made by a competitor may be used to develop therapies that could compete against any of our product candidates. In addition, our individual product candidates face competition from companies outside the gene therapy approach who are using other treatment methods to address the same target indications, such as companies developing retinal implants or other stem cell approaches. See Section 6.9, "Competition" of this Registration Document.

Many of our potential competitors have substantially greater financial, technical and other resources, such as larger research and development, clinical, marketing and manufacturing departments. 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 opportunities 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 or earlier 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 product candidates uneconomical or obsolete.

Furthermore, 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. For example, Bernard Gilly is currently non-executive Chairman of the Board of Directors of Pixium Vision, a company working on a retinal implant technology that targets patients with an advanced stage of RP with no photoreceptors, whereas gene therapy targets patients earlier in the disease with some residual vision and photoreceptors. See Section 14.1.2, "Biographical Information About the Members of the Board of Directors and Officers of the Company" and Section 6.7, "Our Second Product Candidate: GS030 for the Treatment of RP—Existing Therapies for the Treatment of RP" of this Registration Document.

In addition, as a result of the expiration or successful challenge of the patent rights that we license from third-parties, we could face more litigation with respect to the validity or scope of patents. The availability of our competitors' products could limit the demand and the price we are able to charge for any products that we may develop and commercialize.

Even if we obtain and maintain approval for our product candidates from the FDA or the EMA, we may never obtain approval for our product candidates outside of the United States or the European Union.

Approval of a product candidate in the United States by the FDA or in the European Union by the EMA does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority does not ensure approval by the FDA, the EMA or regulatory authorities in other countries. Sales of our product candidates outside of the United States and the European Union will be subject to different regulatory requirements governing clinical trials and marketing approval. Even if the FDA or the EMA grants marketing approval for a product candidate, comparable regulatory authorities of other countries also must approve the

manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States and the European Union, including additional preclinical studies or clinical trials. In many countries outside the United States and the European Union, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. We also intend to submit a marketing authorization application to the EMA for approval of our product candidates in the European Union, but obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Even if a product candidate is approved, the FDA or the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining such regulatory approvals and compliance with such other regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects will be adversely affected.

4.3 RISKS RELATED TO THIRD PARTIES

We rely on third-parties to conduct, supervise and monitor our clinical studies. If these third-parties do not meet our deadlines or otherwise conduct the 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 clinical trials and to perform data collection and analysis. Such third-parties play a significant role in the conduct of these 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 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. 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, GLP 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. 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. 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.

We may choose in the future to enter into collaborations with third-parties for the development and commercialization of our product candidates. If we are unable to enter into such collaborations on acceptable terms, or if these collaborations are not successful, our business could be adversely affected.

We may seek to enter into collaborations in the future with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates, whether in specific geographic regions or worldwide, due to substantial capital costs required to develop the product candidates or manufacturing constraints. We may not be successful in our efforts to establish such strategic partnerships or other alternative arrangements for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third-parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. In addition, we may be restricted under existing collaboration agreements from entering into future agreements with potential collaborators.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates.

Even if we are able to enter into such collaborations, our ability to generate revenues from these arrangements would depend on our and our collaborators' abilities to successfully perform the functions assigned to each of us in these arrangements. Our relationships with such collaborators may pose several risks, including the following:

- collaborators have significant discretion in determining the efforts and the amount and timing of resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our shareholders about the status of such product candidates;
- collaborators could independently develop, or develop with third-parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;

- collaborators may infringe the intellectual property rights of third-parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Moreover, an unsuccessful outcome in any clinical trial for which our collaborator is responsible could be harmful to the public perception and prospects of our gene therapy platform. If any collaborations we enter into do not result in the successful development and commercialization of products, or if a collaborator terminates its agreement with us, we would not receive any future research funding or milestone or royalty payments under such collaboration. If we did not receive the funding we expected under such agreements, our development of product candidates could be delayed and we could need additional resources to develop our product candidates. In addition, if a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus apply to the activities of any of our collaborators.

Relationships with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates, or those like them, may require us to incur additional expenses, issue securities that dilute our existing shareholders or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Our ability to reach a definitive collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of several factors. If we license rights to product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture.

Our reliance on third-parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on the Novasep Group, or Novasep (through its subsidiary Henogen S.A.), Lonza Houston Inc., or Lonza, Genethon, and other third-parties to manufacture all or part of our product candidates and to perform quality testing, and because we collaborate with various organizations and academic institutions for the advancement of our gene therapy platform, we must share our proprietary technology and confidential information with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements limit the rights of the third-parties to use or disclose our confidential information. Despite these confidentiality agreements, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based on our know-how and trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

4.4 RISKS RELATED TO MANUFACTURING

Gene therapies are complex and difficult to manufacture, which could cause delays in our development or commercialization programs.

As of the date of this Registration Document, we have contracts with Novasep, Lonza and Genethon to manufacture clinical supplies of our product candidates, and we expect to continue to rely on third-parties for our manufacturing needs. 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.

We rely on Novasep, Lonza, Genethon and other third-parties to conduct manufacturing for our clinical trials, and these third-parties may not perform satisfactorily.

We currently rely, and expect to continue to rely to a significant degree, on Novasep, Lonza, Genethon and other third-parties for the production of our clinical trial materials and we can control only certain aspects of their activities.

Under certain circumstances, Novasep, Lonza and Genethon are 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 Novasep, Lonza and Genethon 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 Novasep, Lonza or Genethon do 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 Novasep, Lonza or Genethon, 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 Novasep, Lonza or Genethon, 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 or EMA action, including injunction, recall, seizure or partial or total suspension of product manufacture.

Failure to comply with regulatory requirements related to manufacturing could result in suspension or delay of commercial sales.

In the future, we may rely on third-parties' manufacturing facilities for commercial supplies of our product candidates and the facilities and quality systems of such parties must pass an inspection for compliance with the applicable regulations as a condition of regulatory approval. The preparation of therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of outside agents or other contaminants, or to inadvertent changes in the properties or stability of product candidates that may not be detectable in final product testing. We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the FDA's and the EMA's cGMP requirements.

In addition, the regulatory authorities may, at any time following approval of a product for sale, audit the manufacturing facilities for such product. If any such inspection or audit identifies a failure to comply with applicable regulations, or if a violation of product specifications or applicable regulations occurs independent of such an inspection or audit, the relevant regulatory authority may require remedial measures that may be costly or time-consuming to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon a third-party manufacturer or us could materially harm our business, financial condition, results of operations and prospects.

If any of our third-party manufacturers fails to comply with applicable cGMP regulations, the FDA, the EMA and other regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition, results of operations and prospects to be materially harmed.

Additionally, if supply from our third-party manufacturer is interrupted, there could be a significant disruption in commercial supply of our products. We do not currently have a backup manufacturer of our product candidate supply for clinical trials. An alternative manufacturer would need to be qualified, through a supplement to its regulatory filing, which could result in further delay. The regulatory authorities also may require additional trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and could result in a delay in our desired clinical and commercial timelines.

Any contamination in the manufacturing process for our product candidates could result in delays in our clinical development or marketing schedules.

Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage.

Most of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material contamination, recall or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially and adversely affect our development timelines.

Interruptions in the supply of product or inventory loss may adversely affect our operating results and financial condition.

Our product candidates are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict government standards for the manufacture and storage of our products, subjects us to production risks. While product batches released for use in clinical trials undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Our product candidates must be stored and transported at temperatures within a certain range. If these environmental conditions deviate, our product candidates' remaining shelf-lives could be impaired or their efficacy and safety could be adversely affected, making them no longer suitable for use.

The occurrence, or suspected occurrence, of production and distribution difficulties can lead to lost inventories and, in some cases, product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. Any interruption in the supply of finished products or the loss thereof could hinder our ability to timely distribute our products and satisfy customer demand. Any unforeseen failure in the storage of the product or loss in supply could delay our clinical trials and, if our product candidates are approved, result in a loss of our market share and negatively affect our business, financial condition, results of operations and prospects.

4.5 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

We may be unable to establish sales and marketing capabilities.

We currently have no sales and marketing 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 in Europe and the United States and will seek partnership agreements in Asia for sales 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 compete with many companies that currently 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 and sales functions, we may be unable to compete successfully against these more established companies.

Market opportunities for our product candidates may be smaller than anticipated.

Our understanding of both the number of people who have the diseases targeted by our product candidates, as well as the subset of people with such diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations and market research and may prove to be incorrect. Further, new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products or patients may become increasingly difficult to identify and access. In addition, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may not achieve profitability despite obtaining significant market share.

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 payers 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.

Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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. In both the European Union and Canada there is an increasing emphasis on cost-containment initiatives, which may put pricing pressure on us. In the European Union, reimbursement of products are mostly governed by national states and governmental entities. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional other price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in many markets outside the United States, the reimbursement for our products may be reduced compared to the United States and may be insufficient to generate commercially reasonable product revenues.

In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. Currently, no gene therapy product has been approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services, or CMS, the agency responsible for administering the Medicare program. It is difficult to predict what CMS will decide with respect to coverage and

reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these types of products. Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European Union member states. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Increasing efforts by government and third-party payors in the United States, the Europe Union and elsewhere to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Payors increasingly are considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states in the United States have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. 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.

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 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.

Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our product candidates.

Gene therapy remains a novel technology, and, to date, no gene therapy product has been approved in the United States and only one gene therapy product has been approved in the European Union under exceptional circumstances. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. Our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments for which greater clinical data may be available. For example, earlier gene therapy trials led to several well-publicized adverse events, including cases of leukemia and death seen in trials using other vectors. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy products, even if not ultimately attributable to the relevant product candidates, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for any approved product candidates, and a decrease in demand for any such product candidates.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving

humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal-testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

If we obtain approval to commercialize our product candidates outside of the United States or the European Union, we would be subject to additional risks associated with international operations.

If approved, we intend to commercialize GS010 and GS030 initially in the United States and the European Union. Because of the orphan nature of LHON and RP, we believe a targeted sales and marketing organization would be able to reach specialized ophthalmology centers and their patients in the United States. We plan to deploy a similar commercialization strategy in the European Union. We intend to find partners for Asia and the rest of the world. We expect that we will be subject to additional risks in commercializing our product candidates outside the United States or the European Union, including:

- different regulatory requirements for approval of drugs and biologics from country to country;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular other economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- other currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from natural disasters including earthquakes, typhoons, floods and fires.

4.6 RISKS RELATED TO OUR BUSINESS OPERATIONS

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.

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our gene therapy platform. Research programs to identify new product candidates require substantial technical, financial and human resources. Although certain of our product candidates are currently in clinical or preclinical development, we may fail to identify other potential product candidates for clinical development for several reasons. For example, our research may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects, may be commercially impracticable to manufacture or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area when it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 or clinical studies or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

Members of our management team have served, and may in the future serve, in management or directorship capacities at companies engaged in similar areas of research and development, or that have product candidates or products targeting the same indications as our product candidates. As a result, such members of management may face actual, potential or perceived conflicts of interest, in particular when we enter into contractual arrangements with such companies. Bernard Gilly is currently non-executive Chairman of the Board of Directors of Pixium Vision, a company working on retinal implant technology targeting RP patients at an advanced stage of the disease with no photoreceptor left, whereas gene therapy is targeting patients earlier in the disease with some residual vision and photoreceptors. See Section 14.1.2 "Biographical Information About the Members of the Board of Directors and Officers of the Company" and Section 6.7, "Our Second Product Candidate: GS030 for the Treatment of RP – Existing Therapies for the Treatment of RP" of this Registration Document. We have entered into a consortium agreement and related agreements for the financing and conduct of research and development activities with Pixium Vision and FVE, a scientific foundation that funds scientific programs in the field of ophthalmic diseases. See Section 11.4, "Collaboration Agreements" of this Registration Document.

If we are unable to manage our expected growth, we may not achieve our research and development plans in line with our timing expectations or at all.

To be successful in executing our business strategy, we expect that we will need to expand our resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of any of our product candidates that are approved for sale. Future growth would impose significant added responsibilities on members of management. The expansion of our operations may lead to significant costs and may divert our management and business development resources. It is likely that our management, finance and development personnel, management and information technology systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and product candidates will require us to continue to develop more robust business processes and to improve our systems and procedures in each of these areas, and to recruit, train and retain sufficient numbers of qualified personnel. We may be unable to successfully implement these tasks on a larger scale. Any inability to manage growth could delay or prevent the execution of our research, development and growth plans or disrupt our operations, and have a material adverse effect on our business.

Healthcare legislative reform measures in the United States may limit reimbursement of our future products.

In the United States, there have been, and continue to be, several legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addresses a new method by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Additionally, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biologic products that are demonstrated to be "highly similar" or "biosimilar or interchangeable" with an FDA-approved biologic product. This new pathway could allow competitors to reference data from biologic products already approved after 12 years from the time of approval. This could expose us to potential competition by lower-cost biosimilars even if we commercialize a product candidate faster than our competitors.

Additional changes in the United States that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the PPACA and the passage of additional laws and regulations

may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program.

For each U.S. state that does not choose to expand its Medicaid program, there likely will be fewer insured patients overall, which could impact the sales, business and financial condition of manufacturers of branded prescription drugs. Where patients receive insurance coverage under any of the new options made available through the PPACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on that resulting drug utilization, a decision that could impact manufacturer revenues. The U.S. federal government also has announced delays in the implementation of key provisions of the PPACA. The implications of these delays for our and our partners' business and financial condition, if any, are not yet clear.

We expect that additional U.S. state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that U.S. federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures in the United States.

We or our employees, principal investigators, consultants, and commercial partners may violate U.S. federal and state and European Union healthcare fraud and abuse laws, false claims laws and health information privacy laws.

In the European Union, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States, such as the U.K. Bribery Act 2010 and the French law number 2011-2012 of December 29, 2011 relating to the strengthening of drug safety and health products (*Loi n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé)*, or the French Sunshine Act. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection and use of personal health data in the European Union is governed by the provisions of the Data Protection Directive. This directive imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. The draft Data Protection Regulation currently going through the adoption process is expected to introduce new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. If the draft Data Protection Regulation is adopted in its current form it may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

In the United States, if we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various U.S. federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act and Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the U.S. federal government and the U.S. states in which we conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The PPACA amends the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The PPACA provides and recent government cases against pharmaceutical and medical device manufacturers support the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers;
- federal transparency laws, including the federal Physician Payment Sunshine Act, that require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- U.S. state law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge in the United States under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other U.S. government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In both the United States and the European Union, and elsewhere we are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include failure to comply with the FDA, the EMA, or other applicable regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with applicable healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA, the EMA or other regulatory authorities, which could result in sanctions and cause serious harm to our reputation.

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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations

relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biologic and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third-parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in the European Union, which is undergoing a continued severe economic crisis. In addition, the withdrawal of the United Kingdom from the European Union as a result of Brexit will take effect either on the effective date of the withdrawal agreement or, in the absence of agreement, two years after the United Kingdom provides a notice of withdrawal pursuant to the EU Treaty. The U.K. government delivered a notice of withdrawal on March 29, 2017. It is likely that the withdrawal of the United Kingdom from the European Union will involve a process of lengthy negotiations between the United Kingdom and European Union member states to determine the future terms of the United Kingdom's relationship with the European Union. This could lead to a period of considerable uncertainty, particularly in relation to global financial markets which in turn could adversely affect our ability to raise additional capital. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We and our third-party collaborators may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations or the operations of our suppliers' manufacturing facilities and have a material adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our suppliers' manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we or our collaborators have in place currently are limited and may not prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations and delays in our research and development work, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any breach of our data security, especially a breach resulting in the unauthorized use or disclosure of

protected health information, personally identifiable information or other data subject to privacy laws, could damage our reputation and/or result in monetary damages or other liabilities. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Related-party transactions may be challenged by tax authorities.

Many of the jurisdictions in which we conduct or may in the future conduct business have detailed transfer pricing rules which require that all transactions with related parties be priced using arm's-length pricing principles. Contemporaneous documentation must exist to support this pricing. The taxation authorities in these jurisdictions could challenge our arm's-length related-party transfer pricing policies. International transfer pricing is an area of taxation that depends heavily on the underlying facts and circumstances and generally involves a significant degree of judgment. If any of these taxation authorities are successful in challenging our transfer pricing policies, our income tax expense may be adversely affected and we could also be subjected to interest and penalty charges. Any increase in our income tax expense and related interest and penalties could have a significant impact on our future earnings and future cash flows.

4.7 FINANCIAL RISKS

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, 2015, we recorded CIR in the amount of €2,874,069, which was reimbursed in cash in 2016. For the year ended December 31, 2016, we recorded CIR in the amount of €2,929,874 which has not been received at the date of this Registration Document.

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.

We may not be able to carry forward future losses as a result of legislative or regulatory changes in corporate taxation in France.

As of December 31, 2016, taking into account the net loss recorded during the year, our accounts showed a loss to carry forward of €51,264,135. As of the date of this Registration Document, this loss can be carried forward indefinitely and charged against future profits, in accordance with current French tax laws.

In France, for financial years ending as from December 31, 2012, the set off of these losses is capped at €1 million plus 50% of profits exceeding this cap. The unused balance of losses can be carried forward to following financial years, and set off under the same conditions with no time limit.

We may not be able to set off prior losses against future profits, in whole or in part, in the event of legislative or regulatory changes in corporate taxation, which could have an adverse effect on our results.

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 performance shares (*attributions gratuites d'actions*, or AGA). As of December 31, 2016, 1,572,776 BCE, 619,040 BSA and 766,000 AGA have been allotted (giving the right to subscribe for or acquire, respectively, 1,572,776, 619,040 and 766,000 new shares.) See Section 21.1.5.1, "Warrants" of this Registration Document.

As of December 31, 2016, the exercise of all BCE and all BSA and the definitive acquisition of all AGA allotted and outstanding will thus allow for a subscription or acquisition of 2,957,816 new ordinary shares, generating a dilution of 13.22% based on fully diluted capital.

Moreover, the exercise of delegations of authority granted to the Board of Directors by the extraordinary and ordinary general meeting of May 19, 2016 to carry out one or more capital increases could lead to additional dilution. See Section 21.1.5, "Other Securities Giving Access to Share Capital" of this 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.

4.8 LEGAL RISKS AND RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We do not own any issued patents and our rights to develop and commercialize our product candidates are limited by the terms and conditions of intellectual property licenses granted to us by others.

Although in 2016 we filed one patent application in the United States and two patent applications in the European Union, we do not currently own any issued patents, and we are heavily reliant upon licenses to certain patent rights and other intellectual property from third-parties 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 approved, 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 competitive 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 that we license from third-parties. For example, pursuant to our intellectual property license agreement with Adverum Biotechnologies, Inc., or Adverum, Adverum retains control of such activities. 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 we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products 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 limit the extent to which we can prevent competitors from developing and commercializing competitive products relating to those technologies.

We also in-license certain patents owned by the Regents of the University of California pursuant to 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 that we license 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.

We or our licensors may be unable to obtain and maintain adequate patent protection for our products 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 file 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 the 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, these indications. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We cannot be certain that any patents will be granted with respect to any of the pending patent applications that we own or are licensed to us or any patent applications that we or our licensors may file in the future. In addition, we cannot be certain that any of the existing patents that we in-license or that we may in-license or own in the future will adequately protect our technology and our product candidates and methods of manufacturing the same and effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In the European Union, variation in the application of laws relating to the patentability of biotechnological inventions, including the application of specific exclusions to patentability means we cannot be certain that we or our licensors can effectively protect our technology in order to prevent competitors from developing and commercializing competitive products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.

We may not be aware of all third-party intellectual property rights potentially relating to our 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 products similar or identical to ours.

Our intellectual property licenses with third-parties may be subject to disagreements over contract interpretation.

The agreements under which we currently license intellectual property or technology from third-parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any disagreement regarding contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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.

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 11.5 "Intellectual Property" and Section 22.2 "In-License Agreements" of this Registration Document for a description of our license agreements. If we fail to comply with our obligations under these agreements, or we 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 for infringing 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 products 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 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.

We may not be successful in obtaining or maintaining necessary rights to gene therapy components and processes for our development pipeline.

Because our development pipeline may require the use of proprietary rights held by third-parties, the growth of our business likely will depend, in part, on our ability to acquire, in-license or use proprietary rights from third-parties in the future. We may be unable to acquire or in-license compositions, methods of use, processes or other intellectual property rights from third-parties necessary to advance our research or allow commercialization of our product candidates at a reasonable cost or on reasonable terms, or that we may otherwise identify as necessary or desirable for our product candidates. In that event, we may be required to expend significant time and resources to redesign our product candidates or the methods for manufacturing them or to develop or license from third-parties replacement technology, some or all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our product candidates or future products or methods for manufacturing the same, resulting in either an injunction prohibiting our manufacture or sale of such products, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third-parties. The in-licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to in-license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We may be unable to in-license or acquire third-party intellectual property rights on terms acceptable to us or at all.

For example, we sometimes collaborate with non-profit or academic institutions to further our preclinical research or development activities under written agreements with these institutions. Typically, these institutions may provide us with an option to negotiate a license to, or co-ownership of, any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license or ownership rights within the specified timeframe or under terms that are acceptable to us or at all. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate and our business, financial condition, results of operations and prospects could be adversely affected.

Our patent protection could be reduced or eliminated for non-compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to the USPTO, the European Patent Office, or the EPO, and to various government patent agencies outside of the United States and the European Union, over the lifetime of our patent applications or in-licensed patents or applications and any patent rights we may own in the future. For the patent applications that we own, we employ reputable outside counsel to help us timely pay these fees due to the USPTO, the EPO and other government patent agencies and, for our in-licensed patents, we rely on our licensing partners to timely pay these fees. The USPTO and various other government patent agencies, including the EPO, require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are dependent on our licensors to take the necessary actions to comply with these requirements with respect to our in-licensed intellectual property and rely on advice from our outside counsel to comply with these requirements with respect to our patent applications and any other patent rights we may own in the future. In certain cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States and the European Union could be less extensive than those in the United States or the European Union. Our patent applications and in-licensed patent rights may not have corresponding other countries patents or patent applications. In addition, the laws of some other countries do not protect intellectual property rights to the same extent as U.S. federal and state laws in the United States or European patent laws. 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.

Many companies have encountered significant problems in protecting, defending and enforcing intellectual property rights in other jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our in-licensed patents or any patents that issue from our applications or the marketing of competing products in violation of our proprietary rights. 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 in the future, 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.

Issued patents that we in-license and that cover our product candidates could be found invalid or unenforceable, and we may not be able to protect our trade secrets in court.

If we or one of our licensing partners initiate legal proceedings against a third-party to enforce a patent covering one of our

product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In all patent litigation, counterclaims by defendants alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include, without limitation, an alleged failure to meet any of several statutory requirements, such as lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion in the United States include, without limitation, an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO or made a misleading statement, during prosecution. Third parties also may raise similar claims before administrative bodies in the United States, the European Union or elsewhere, even outside the context of litigation. Such proceedings could result in the revocation or cancellation of or amendment to our patents or licensed patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing partners were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect our proprietary information, including know-how, processes, techniques and data, and technology that is not patentable or that we elect not to patent or which patents are difficult to enforce. However, trade secrets and other proprietary information can be difficult to protect and some courts inside and outside the United States and the European Union are less willing or unwilling to protect trade secrets and other proprietary information. If any of our trade secrets or other proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that information to compete with us. We seek to protect our trade secrets and other proprietary information, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or other proprietary information. We also seek to preserve the integrity and confidentiality of our trade secrets and other proprietary information by maintaining the physical security of our premises and the physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any such breach and we cannot guarantee that our trade secrets and other proprietary know-how will not be publicly disclosed.

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 burden is a high one requiring us 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 apply equally 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.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may infringe our intellectual property or the intellectual property of our licensors, or we may be required to defend against claims of infringement. To counter infringement or unauthorized use claims or to defend against claims of infringement can be expensive and time consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants or advisors are currently, or were previously, employed, consulted or advised at universities or other biotechnology or pharmaceutical companies, including some of our competitors or potential competitors. We may be subject to claims that such individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to obtain patent protection for our product candidates.

In the United States, the European Union and elsewhere, patent law and its interpretation is constantly in a state of development and flux always vulnerable to modification or repeal by legislators and changes in policy or interpretation and application by courts or patent offices. This also applies particularly to the biotechnological and pharmaceutical areas.

Recent patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy-Smith Act includes several significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack

the validity of a patent by the USPTO administered post-grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications of those of our licensors and the enforcement or defense of any patents issuing from these applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. For example, the Leahy-Smith Act provides a new administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, that provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own licensed patents and any future patents owned by us will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Moreover, if such challenges occur, as indicated above, we have no right to control the defense. Instead, we would essentially rely on our licensor to consider our suggestions and to defend such challenges, with the possibility that it may not do so in a way that best protects our interests.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and "gene patents" have recently been decided by the Supreme Court of the United States, or the Supreme Court. On March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative* Services *v. Prometheus Laboratories, Inc.*, or *Prometheus*, a case involving patent claims directed to a process of measuring a metabolic product in a patient to optimize a drug dosage for the patient. According to the Supreme Court, the addition of well-understood, routine or conventional activity such as "administering" or "determining" steps was not enough to transform an otherwise patent-ineligible natural phenomenon into patent-eligible subject matter. On July 3, 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to not patent-eligible subject matter. On June 13, 2013, the Supreme Court issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, or *Myriad*, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that an isolated segment of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent eligible.

On March 4, 2014, the USPTO issued a guidance memorandum to patent examiners entitled "2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena And/Or Natural Products." These guidelines instruct USPTO examiners on the ramifications of the *Prometheus* and *Myriad* rulings and apply the *Myriad* ruling to natural products and principles including all naturally occurring nucleic acids. Patents for certain of our product candidates may contain claims related to specific DNA sequences that are naturally occurring and, therefore, could be the subject of future challenges made by third-parties. In addition, the recent USPTO guidance could make it impossible for us to pursue similar claims in U.S. patent applications we may prosecute in the future.

We cannot assure investors that our efforts to seek patent protection for our technology and products in the United States will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the Supreme Court's decisions in *Prometheus* and *Myriad* may have on the ability of life science companies to obtain or enforce patents relating to their products and technologies in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. In December 2014, the USPTO issued its Interim Guidance on Patent Subject Matter Eligibility, in which it extended Myriad's "marked difference" standard for patent subject matter eligibility to all potential natural products. This standard applies to patent claims that recite not only nucleic acids (such as DNA in

Myriad), but also other subject matter that could be considered a natural product, such as peptides, proteins, extracts, organisms, antibodies, chemicals, and minerals. As a consequence of the *Myriad* decision and the USPTO's Interim Guidance, if any of our future product candidates utilize isolated DNA, peptides, proteins or the like, we will not be able to obtain patents in the U.S. claiming such novel gene targets that we discover, which could limit our ability to prevent third-parties from developing drugs directed against such targets.

Moreover, although the Supreme Court has held in *Myriad* that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third-parties could allege that activities that we may undertake infringe other gene-related patent claims, and we may deem it necessary to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or paying to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter. Such outcomes could harm our business, financial condition, results of operations or prospects.

The laws and regulations governing patents in the United States, the European Union and elsewhere could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce our existing in-licensed patents and any patents that we might obtain in the future. In particular, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Europe's planned Unified Patent Court, scheduled to begin in 2017, may particularly present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. While that new court is being implemented to provide more certainty and efficiency to patent enforcement throughout Europe, it will also provide our competitors with a new forum to use to centrally revoke our European patents. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by that court. We will have the right to opt our patents out of that system over the first seven years of the court, but doing so may preclude us from realizing the benefits of the new unified court.

Upon the expiration of any of our in-licensed U.S. and European patents, or any patents issuing from our patent applications, we may not receive the benefit of patent term extension or data exclusivity for our product candidates in the United States and the European Union.

Depending upon the timing, duration and specifics of any marketing approval by the FDA of our product candidates, one or more of our U.S. or European patents that we in-license or that may issue from our patent applications may be eligible for limited patent term extension.

In the U.S., one or more of the in-licensed U.S. patents, or any patent that issues from our U.S. patent application, may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

In the European Union, one or more of the in-licensed European Union patents, or any patents that issue from our European Union patent applications, may be eligible for limited patent term extension if a Supplementary Protection Certificate, or SPC, is available under Regulation (EC) No 469/2009. Further protection may also be available by means of a Paediatric Extension to such an SPC. Alternatively, our licensors we may be able to extend their *de facto* exclusive rights by means of trial data exclusivity protection. In any case, failure to obtain, or lack of eligibility for, such protection may allow our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially to the extent that we, and/or our licensors have no effective period of market exclusivity.

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.

The validity of our registered trademark for "GenSight" in France could be challenged by third-parties. Likewise, our

pending Community Trade Mark application for "GenSight," and any subsequent trademark applications we make, are not guaranteed to become registered. For example, a trademark application may be subject to an opposition proceeding in the USPTO, the Office for Harmonization in the Internal Market or corresponding other trademark offices, which could result in the total or partial refusal of the trademark application. Our Community Trademark application for "GenSight" is currently the subject of opposition proceedings. See Section 20.5, "Legal and Arbitration Proceedings" of this Registration Document. Even if we are successful in registering "GenSight" or other trademarks or trade names, such trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing other marks. We may not be able to protect our rights to our trademark and trade name, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names or copyrights may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks alleging that the use of a corporate name or logo, product names or other signs by which we distinguish our products and services are infringing their trade mark or allied rights. The outcome of such claims is uncertain and may adversely affect our business and/or our freedom to use our corporate name or other relevant signs as well as all the risks identified in the above paragraph. If litigation arises in this area it may lead to significant costs and diversion of management and employee attention.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we in-license or may own in the future;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we in-license or that we own or may own in the future;
- we, or our current or future licensors or collaborators, might not have been, or might not be, the first to file the patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that the pending licensed patent applications of our licensors or those that we own or may own in the future will not lead to issued patents;
- issued patents that our licensors hold rights to, or that our licensors or we may hold rights to in the future, may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- other may conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- we may choose not to file a patent application for certain trade secrets or other proprietary information, and a third-party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations or prospects.

4.9 MARKET RISKS

Interest Rate Risk

We have no credit facilities. The repayment flows of the conditional advances from Bpifrance Financement are not subject to interest rate risk.

We believe we have very low exposure to interest rate risk. Such exposure primarily involves money market funds and time deposit accounts. Changes in interest rates have a direct impact on the rate of return on these investments and the cash flows generated.

Foreign Currency Exchange Risk

We are exposed to foreign exchange risk inherent in certain services provided in the United States, which have been invoiced in U.S. dollars. We do not currently have revenues in euros, dollars nor in any other currency. Currently, we incur a small portion of our expenses, and may in the future derive revenues, in currencies other than the euro, in particular, the U.S. dollar. As a result, we

are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Due to the relatively low level of these expenditures, the exposure to foreign exchange risk is unlikely to have a material adverse impact on our results of operations or financial position.

Our exposure to currencies other than the U.S. dollar is negligible. For the fiscal years ended December 31, 2015 and 2016, less than 8% and 22%, respectively, of our purchases and other external expenses were made in U.S. dollars, generating foreign exchange losses of €22,391 and €59,181. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. For example, an increase in the value of the euro against the U.S. dollar could have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, which in the future may adversely affect our financial condition, results of operations and cash flows. As we further increase our business activity, particularly in the United States, we expect to face greater exposure to exchange rate risk and would then consider adopting an appropriate policy for hedging against these risks.

Liquidity Risk

Since inception, we have financed our activities primarily through private placements, funding received from Bpifrance Financement and receipt of the CIR. However, we have never had recourse to bank loans.

We have incurred significant research and development efforts and expenses relating to clinical studies since our incorporation, which has generated negative operating cash flows to date. Cash flows relating to our operations amounted to €(19,609,446) and €(12,094,554) respectively for the fiscal years ended December 31, 2016 and 2015.

We do not currently believe that we are exposed to short-term (12 months) liquidity risk, considering the cash, cash equivalents and short-term investments that we had available as of December 31, 2016 amounting to €53,982,211, which was primarily cash and money market funds and time deposits that are convertible into cash immediately without penalty. In addition, we have undertaken a specific risk review regarding liquidity risk and we consider that we are able to meet our future repayments of conditional advances from Bpifrance Financement.

We expect to have significant ongoing financing needs 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. See Section 4.1, "Risks Related to our Financial Condition and Capital Requirements—We may need to raise additional capital in the future, which may not be available on acceptable terms, or at all" of this Registration Document.

Credit Risk

We aim to engage in prudent management of our level of cash and cash equivalents. Cash and cash equivalents include cash on hand and common financial instruments held by us, which mostly include securities and fixed-term structured monetary products). As of December 31, 2016, given the current low interest rates, our cash is exclusively held on current accounts.

We believe that the credit risk related to our cash, cash equivalents and short-term investments is not significant in light of the quality of the co-contracting financial institutions, which include BNP Paribas and Crédit Industriel et Commercial.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

4.10 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 paid for all of our insurance policies for the fiscal year ended December 31, 2016 amounted to €86,166.

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°AP438391)**		
Property and contents insurance, including:		Premises: Unlimited Contents: €772,438 (2016 values)	
• Fire and similar events		€772,438 per occ/agg	
• Natural disasters		€772,438 per occ/agg	€250
• Climate events		€772,438 per occ/agg	
• Water damage		€386,219 per occ/agg	
• Theft-vandalism: damage to property		Unlimited	
• Theft-vandalism: damage to contents		€193,110	
• Glass breakage		€5,000	€80
All Electronical Damage	**AXA (N°7457910104)**		
Electronical Property Insurance			
• Electronical property damage		€50,000 Electronical property value	€200
• Electronical non physical damage		€5,000	€760
Directors & Officers civil liability insurance: claims made or pursued world-wide	**CHUBB (N° RD0082467967)**	Capped at €5,000,000 except for : (per "insured year")	€10,000 for reimbursement of the company following a complaint made or pursued in whole or part in the United States
Cover for management staff :			
• Defense costs		€5,000,000	
• Employee spouse		€5,000,000	
• Founder		€5,000,000	
• Psychological support		€30,000	
• Civil fines		€250,000	
• Bail		€5,000,000	
• All risks excluding harmful events attributable to the manager and arising exclusively as a result of his function		€5,000,000	
• Personal tax		€5,000,000	
Company cover			
• Claim for "non-separable" fault		€5,000,000	
• Claim against a legal entity director		€5,000,000	
• Crisis management costs		€45,000	

Risks covered	Insurer	Amount	Excess per claim
Civil Liability	**CHUBB (N° RC0099500275)**		
Civil operating liability:			
All damage taken together including bodily harm:		€7,500,000 per "claim"	
• Inexcusable fault		€1,000,000 per victim capped at €3,000,000 per "insured year"	
• All "material" and "non-material" damage including:		€1,500,000 per "claim"	
– "non-consecutive non-material damage"		€200,000 per "claim"	€1,500
– "property damage"		€50,000 "per claim"	€1,500
– "any damage resulting from accidental pollution"		€300,000 per "insured year"	€1,500
Criminal defense-Appeal		€30,000 per dispute	€1,500
Civil product liability:			
All damage taken together including bodily harm:		€3,000,000	
• "Non-consecutive non-material damage"		€200,000 except for professional civil liability €100,000	€10,000
Comprehensive IT risks	**AXA (N°5887372304)**		
• Computer and office equipment, fixed and other telecommunication equipment, laptops		€40,000	€200
• Data		€5,037	€765
Employee Travel Insurance	**AXA (N°STAM1000533)**		
Assistance (for individuals and legal assistance abroad, business assistance, travel incident assistance)		€500	
Medical insurance and luggage and professional equipment insurance		€150,000 for medical insurance and €5,000 for luggage and professional equipment	
Research sponsor's civil liability insurance			
Study GS-LHON-CLIN-03A in mainland France and its overseas departments and territories (excluding Monaco):	HDI Gerling		
• Victim		€1,000,000	€1,500 per victim capped at €16,000 per protocol
• Research protocol		€6,000,000	
• Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000,000	

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

Risks covered	Insurer	Amount	Excess per claim
GS-LHON-CLIN-01	**HDI Gerling**		
In mainland France and overseas departments and territories (excluding Monaco):			
• Per victim		€1,000,000	€1,500 per victim capped at €16,000 per protocol
• Per Research protocol		€6,000,000	
• Claims made during an insurance year by one and the same sponsor for several research protocol		€10,000,000	

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.

5

INFORMATION ABOUT THE ISSUER

5.1 HISTORY AND DEVELOPMENT

5.1.1 COMPANY NAME

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

5.1.2 PLACE OF REGISTRATION AND REGISTRATION NUMBER

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

5.1.3 DATE OF INCORPORATION AND DURATION

5.1.3.1 Date of incorporation of the Company

We were incorporated on April 17, 2012.

5.1.3.2 Duration

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

5.1.4 REGISTERED OFFICE, LEGAL FORM AND APPLICABLE LEGISLATION

5.1.4.1 Registered office

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

5.1.4.2 Legal form and applicable legislation

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.

5.1.5 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.á 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 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

5.2 INVESTMENTS

5.2.1 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 for the relevant periods:

	As of December 31,	
	2015 €	2016 €
Cash flows from investment activities		
Acquisitions of property, plant and equipment	(699,427)	(188,177)
Acquisitions of intangible assets	(7,517)	(1,047)
Acquisitions of non-current financial assets	(79,545)	7,770
Sales of property, plant and equipment	–	11,000
Purchase of short-term investments	1,403,938	–
Net cash flows from investment activities	**617,449**	**(170,454)**

Over the course of the period presented, our investments primarily consisted of investments in short-term investments as a result of managing our cash surplus, as well as investments in our offices, equipment, installations and furniture.

5.2.2 ONGOING INVESTMENTS

We currently expect that the amount of our cash expenditures for investment in 2017 will be generally consistent with the level of investment during the 2015 to 2016 period. We expect that the types of investments that we make and our investments objectives will be similar in nature to investments made during the 2015 to 2016 period. However, investment expenditures can be uneven and unpredictable, particularly when they are associated with external growth transactions.

5.2.3 FUTURE PLANNED INVESTMENTS

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

6

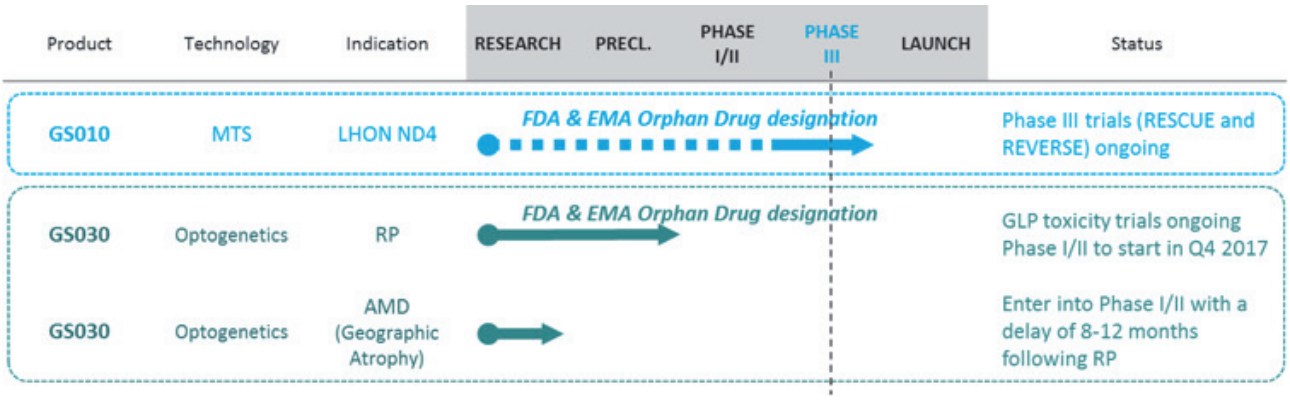
BUSINESS OVERVIEW

6.1 OVERVIEW

We are a biotechnology company discovering and developing novel therapies for neurodegenerative retinal diseases and diseases of the central nervous system. To address these therapeutic areas, we leverage our integrated development platform by combining a gene therapy-based approach with our core technology platforms of mitochondrial targeting sequence, or MTS, and optogenetics. Our management and scientific teams have extensive experience in gene therapy and drug development, in particular in the field of ophthalmology, and have served in leadership roles at several innovative ophthalmology companies.

Our initial focus has been on developing therapies for severe retinal diseases, with the goal of preserving or restoring vision in patients suffering from such diseases. Using our gene therapy based approach, our two lead product candidates, GS010 and GS030 are designed to be administered in a single treatment to each eye by intravitreal, or IVT, or subretinal injection in order to provide patients with a long-lasting functional cure, potentially for the rest of their lives.

Our pipeline currently comprises two lead product candidates for the treatment of sight-threatening retinal degenerative diseases, together with products in preclinical development targeting ophthalmic and neurodegenerative diseases. See Section 6.8, "Product & Development Pipeline" of this Registration Document. Set forth below is a table summarizing the development programs for our two lead product candidates:



GS010 continues to progress globally in line with our initial timelines. We were initially expecting the topline data of both RESCUE and REVERSE to be available in December 2017, based on enrollment ending in December 2016. We completed enrollment of REVERSE in February 2017, and now expect to release topline data by the end of the first quarter 2018. Because we are recruiting patients in the very early stages of the disease, enrollment of RESCUE is expected to be completed by the end of the second quarter of 2017, hence topline data is expected by the end of the second quarter of 2018.

As we had prioritized our resources for GS010 in the first half of 2016 prior to successfully completing our initial public offering on Euronext Paris, we are now conducting a GLP toxicity study in non-human primates, expecting to initiate a first-in-man Phase I/II clinical trial in RP patients in the fourth quarter of 2017. We had initially expected to start this trial in the second quarter of 2017.

The technologies that we utilize in our product candidates have been the subject of publications in leading scientific journals. However, given our stage of development, our two lead product candidates have not yet been mentioned in such publications.

Our two lead product candidates have obtained orphan drug designation in the United States and the European Union which mainly grant a period of seven and ten years, respectively, of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. See Section 6.10, "Government Regulation" of this Registration Document for more information.

GS010 for the Treatment of LHON

Our first core technology platform, based on our MTS is, to our knowledge, the only existing technology that permits missing mitochondrial proteins to be shuttled into the mitochondrion, enabling the restoration of mitochondrial function. Using our proprietary MTS technology platform, we are developing product candidates for the treatment of Leber Hereditary Optic Neuropathy, or LHON, an orphan mitochondrial disease leading to irreversible and sudden sight loss in teens and young adults and for which no treatment approved by the FDA is currently available. Our lead product candidate, GS010, targets LHON due to a mutation in the NADH dehydrogenase 4 mitochondrial gene, or ND4. NADH dehydrogenase is an enzyme that acts on NADH, the reduced form of nicotinamide adenine dinucleotide,

and is an important enzyme in cellular metabolism. Based on data from regional studies, we estimate the incidence of LHON, all mutations included, to be approximately 1,400 to 1,500 new patients who lose their sight every year in the United States and Europe. Our GS010 product candidate is intended to address new cases of LHON of less than one year.

GS010 has received orphan drug designation for the treatment of LHON in the United States and the European Union. We have completed a Phase I/II trial for GS010 in France in 15 patients with advanced LHON with an ND4 gene mutation and GS010 was shown to be safe and well tolerated. Although the Phase I/II trial was designed specifically as a safety and tolerability trial and was conducted in patients with advanced disease who were not expected to recover significant vision, improvement of some electrophysiological parameters was observed, suggesting that GS010 may be active in restoring a level of functionality in ganglion cells. The FDA cleared our Investigational New Drug, or IND, application, in the United States on August 19, 2015 and our Clinical Trial Applications, or CTAs, have been cleared in all European countries in which submissions were made, allowing for the initiation of our Phase III trials at clinical centers. We initiated Phase III clinical trials of GS010 in the fourth quarter of 2015 at seven sites, one each in France, Germany, Italy and the United Kingdom and three in the United States. We expect that the benefits of GS010 treatment will be prevention of further vision loss and/or vision restoration, leading to increased autonomy and overall quality of life. We believe that, given its stage of clinical development, GS010 has the potential to be the first therapy approved by the FDA, for the treatment of LHON. We have also initiated a research program to target other LHON mutations using our MTS technology platform. Our GS011 product candidate is designed to treat LHON due to mutation in the NADH dehydrogenase 1 mitochondrial gene, or ND1. Given the unmet medical need and the orphan status of the disease, we believe that the market for LHON treatment is very attractive.

Given the current stage of development of GS010, the observed treatment outcome after 78 weeks of follow-up in our Phase I/II clinical study indicates that the mean change in visual acuity in the treated eye compared to baseline for the fourteen treated patients who had lost sight due to LHON was an improvement of thirty letters, equivalent to six lines on the ETDRS chart. For more information, please see Section 6.6, "Our Lead Product Candidate: GS010 for the Treatment of LHON—Clinical Development Program for GS010" of this Registration Document. We believe that our MTS technology platform is unique and can be used to address indications outside of ophthalmology involving defects of the mitochondrion, such as Kearns-Sayre syndrome, mitochondrial encephalopathy and other disorders of the central nervous system. The technology is protected by patents over which we have acquired exclusive licenses for ophthalmic disease indications and non-exclusive licenses in other mitochondrial diseases.

For information on competition for GS010 in the treatment of LHON, see Section 6.9, "Competition" of this Registration Document.

GS030 for the Treatment of RP

Our second core technology platform is optogenetics, a novel approach that restores vision to patients by using gene therapy to introduce a gene encoding for light-sensitive protein into specific target cells in the retina by injection in order to make them responsive to light. An external wearable medical device to specifically stimulate the transduced cells is currently being developed to amplify the light signal and enable vision restoration. Patients will need to wear the external wearable device in order to enable restoration of visual function. Using our optogenetics technology platform we are developing our product candidate, GS030, to restore vision in patients suffering from Retinitis Pigmentosa, or RP. RP is an orphan disease caused by multiple mutations in several genes involved in the visual cycle. Our optogenetics technology platform is independent of the specific genetic mutations that lead to the disease. On average, RP patients begin experiencing vision loss in their young adult years, eventually turning blind around the age of 40 to 45. There is currently no existing treatment for RP. RP has an estimated prevalence of 1.5 million people throughout the world. We believe that our GS030 product candidate would benefit patients in the early stages of RP.

GS030 has received orphan drug designation for the treatment of RP in the United States and the European Union and 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. In other studies we have also restored the functioning of the visual cortex and visual behaviors *in vivo* in blind rats using GS030. In September 2016, we initiated a GLP regulatory toxicity study in non-human primates. We intend to start clinical trials of GS030 in the fourth quarter of 2017, upon regulatory and ethics committee approval, with the expectation of receiving interim data within one year from onset of the study.

We believe that our optogenetics technology platform could also be used to treat patients suffering from geographic atrophy, or GA, which is a late-stage form of age-related macular degeneration, or AMD, a well-known disease affecting the elderly that results in blindness. We plan to move GS030 into a clinical trial in patients suffering from GA once clinical proof-of-concept studies have been successfully completed for RP. We have compiled a portfolio of exclusive licenses for specific light-sensitive proteins to be used in developing products that restore vision in RP and GA patients.

GS030 is currently completing preclinical development, and a first-in-man is expected by the end of 2017 with a Phase I/II clinical study in RP patients, hence the Company cannot comment on any expected clinical outcome at this stage.

For information on competition for GS030 in the treatment of RP and GA, see Section 6.9, "Competition" of this Registration Document.

Reliance on third-parties' intellectual property rights

Although in 2016 we filed one patent application in the United States and two patent applications in the European Union, we do not currently own any issued patents, and we are heavily reliant upon licenses to certain patent rights and other intellectual property from third-parties that are important or necessary to the development and commercialization of our technology and products.

Experienced 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. Dr. Gilly was Chief Executive Officer of Transgene S.A., or Transgene, heading Transgene's public listing and financing. Dr. Gilly was also founder and Chief Executive Officer of Fovea Pharmaceuticals S.A., or Fovea, and later became the Executive Vice President of the Ophthalmology Division of Sanofi S.A., or Sanofi, after Fovea was acquired by Sanofi. Following the acquisition of Fovea, Dr. Gilly started and founded Pixium Vision and acted as Chairman and Executive Officer until January 2015. Dr. Gilly is currently non-executive Chairman of the Board of Directors of Pixium Vision. 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 Director of Institut de la Vision and Chairman of the Department of Ophthalmology at the *Centre Hospitalier National d'Ophtalmologie des XV-XX* in Paris, France. Since July 2016, Dr. Sahel has also been the Chairman of the Department of Ophthalmology at the Brain Institute at the University of Pittsburgh (PA). Dr. Sahel has conducted pioneering research into the understanding of the pathological mechanisms involved in RP and was recently recognized by the U.S. Foundation Fighting Blindness. Our co-founder, Botond Roska M.D. Ph.D., Professor at University of Basel and senior group leader at the Friedrich Miescher Institute, or FMI, in Switzerland focuses on the structure and function of the retina and optogenetic vision restoration. For more information on our management and directors see Section 14.1.2, "Biographical Information About the Members of the Board of Directors and Officers of the Company."

Commercialization Strategy

We intend to commercialize our product candidates by ourselves in the United States and in certain countries in the European Union. In other geographies and indications outside of ophthalmology, our strategy is to explore selective partnerships with parties who have relevant clinical and commercial expertise. However, on an ongoing basis, we examine opportunities for partnerships and collaborations across all jurisdictions as they arise. We may choose in the future to enter into collaborations with these parties for the development and commercialization of our product candidates.

6.2 OUR KEY ADDRESSABLE MARKETS IN OPHTHALMOLOGY

Inherited diseases of the eye can cause severe vision loss leading to blindness. These conditions can have significant, multidimensional effects on patients' quality of life, including their physical and emotional well-being. In high-income countries, health-related quality of life in severely visually impaired persons has been shown to be similar or even lower, and emotional distress higher, as compared to other serious chronic health conditions such as stroke or metastasized solid tumors.

Treatment for blindness represents a major unfulfilled medical need throughout the world, including Europe and the United States. In 2014, there were approximately 285 million visually impaired people worldwide and 39 million were totally blind (Source: World Health Organization, Fact Sheet No. 282, updated August 2014.) Blindness and visual impairment impact not only the individual but also the family, caregivers, and the community, leading to significant societal costs. The societal costs of blindness are a major economic and social issue related to direct healthcare costs and indirect costs, including lost productivity and costs of care by non-professionals. A study sponsored by Prevent Blindness in the United States and conducted by the University of Chicago in 2013 estimated that the total annual cost of vision disorders and blindness in the United States was $140 billion with direct costs representing approximately 48% of the total annual cost (estimated at $66.8 billion) (Source: NORC, Cost of Vision Problems: The Economic Burden of Vision Loss and Eye Disorders in the United States, June 11, 2013.) Direct costs included the medical costs of treating the disorders diagnosed, those incurred as a result of impaired vision, the cost of medical visual prostheses, adaptations and assistance devices, as well as direct services including special training and assistance programs. Indirect costs represented approximately 52% of the total annual cost of vision disorders and blindness (estimated at $72.2 billion) resulting from impaired vision, in particular the loss of productivity and the need for supportive care, long-term care and the costs of social programs (Source: NORC, Cost of Vision Problems: The Economic Burden of Vision Loss and Eye Disorders in the United States, June 11, 2013.) In Europe, the total cost of blindness is estimated at €32 billion (Source: European Forum Against Blindness, The Cost of Blindness, Press release dated October 9, 2014.) The disparity between European and U.S. estimates result

from (i) different methods used in the European Union and the United States for calculating costs and (ii) an extrapolation from different evaluation processes used in studies conducted in the European Union based on data from a limited sample of countries.

We believe that the multi-billion dollar global ophthalmic drug market is witnessing significant growth. Some of the key factors driving the growth of the ophthalmic drug market are thought to be aging populations, the development of innovative therapeutic approaches, technological changes in drug delivery techniques, and increasing government initiatives for healthcare infrastructure in developing countries.

There is currently no FDA-approved treatment for many monogenic, or single gene, mutation conditions such as LHON. We believe the use of gene therapy in ophthalmology has great potential to address these conditions, where other approaches have proven inadequate. Moreover, gene therapy tends to be technically feasible in rare diseases with very high unmet needs and defined outcomes. We believe that our ability to commercialize our gene therapy approaches in ophthalmology will benefit from the potential to target a select number of treatment centers in key countries, involving specialists such as retinal surgeons, neuro-ophthalmologists and orthoptists. As a result, we believe that our future commercial operations will employ a limited number of highly skilled sales people, both in North America and Europe.

We expect the approval of new gene therapies in ophthalmology and other fields over the next five years to provide some benchmarks for pricing strategies and lead to evolutions in pricing and reimbursement systems to accommodate the high value of such therapies. Current pricing in other therapeutic areas include Eleprase (for Hunter Disease) at approximately $400,000/year/life-long, Soliris (for Hemoglobinuria) at approximately $410,000/year/life-long, Naglazyme (for Maroteaux-Lory) at approximately $365,000/year/life-long, Glybera (for gene therapy) at approximately €250,000/year/five years and Strimvelis at €665,000/treatment. (Source: LifeSci Capital, Analysis of the Orphan Drug Market, February 4, 2016.)

6.3 OUR FOCUS

We believe that the characteristics of our core technology platforms combined with our extensive expertise allow us to address areas of significant unmet medical need through novel gene therapy approaches. Our focus includes:

Product Candidates Addressing Significant Unmet Medical Need

The initial focus of our integrated development platform is the ophthalmic market, specifically with products in development for the treatment of LHON and RP.

Our lead product candidate GS010 has entered a Phase III trial for the treatment of LHON, which has no approved therapy available in the United States. In the European Union, the EMA granted marketing authorization under exceptional circumstances for Raxone/Idebenone as a treatment for LHON in September 2015. Our novel approach potentially represents a therapeutic solution for patients for whom there is no existing treatment. Based on data from regional studies, 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 designated as a rare and orphan disease in the United States and Europe.

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, about 350,000 to 400,000 patients suffer from RP (Source: Oxford University Press, Human Molecular Genetics, 1996, Vol. 5, No. 8 1193–1197: A ninth locus (RP18) for autosomal dominant retinitis pigmentosa maps in the pericentromeric region of chromosome 1.) and every year between 15,000 and 20,000 patients with RP lose their sight. RP is a rare and orphan disease that has no current treatment. (Source: RP Fighting Blindness.org, About RP.)

A Gene Therapy Approach that is Well-Placed to Address Ophthalmic Disorders and Disorders of the Broader Central Nervous System

Gene therapy involves the insertion of genes into cells either to replace defective genes that cause disease because they fail to produce a functional protein or to produce therapeutic proteins locally. Gene therapy offers the possibility to administer the treatment once, or a limited number of times, to achieve a long-term, durable benefit and potentially a cure.

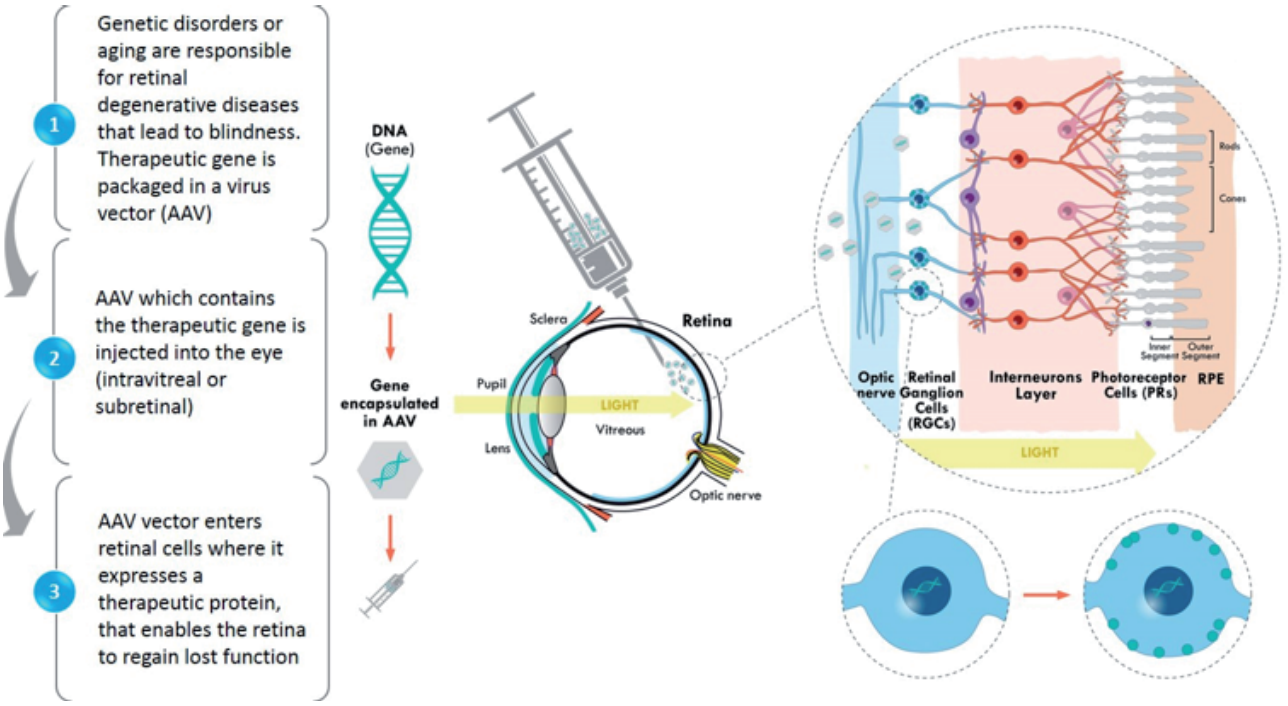
In the last two decades, gene therapy has become a powerful, viable and safe treatment modality to address diseases in a targeted and efficient way. The following recent events have reinforced the likelihood that gene therapy will be an effective therapeutic approach to address unmet medical needs:

- **Clinical data**. Positive data from gene therapy have been reported in a variety of indications including several ophthalmic diseases such as Leber congenital amaurosis, or LCA, and the wet form of AMD.
- **Product approval.** In 2012, the EMA granted approval under exceptional circumstances in the European Union for Glybera, a product developed by uniQure for the treatment of lipoprotein lipase deficiency. In 2016, the EMA issued market authorization in the European Union for Strimvelis, a drug developed by GlaxoSmithKline Trading Services Limited, or GlaxoSmithKline, for the treatment of severe combined immunodeficiency due to deaminase deficiency. As a result, Glybera and Strimvelis have become the first gene therapy products approved in the European Union.

- **Guidance from regulatory agencies.** The FDA has provided guidance for the development of gene therapy products, establishing the Office of Cellular, Tissue and Gene Therapies within the CBER to consolidate the review of gene therapy products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. The EMA has provided guidance for the development of gene and cell therapy products through the CHMP with support from the CAT, which plays a central role in the scientific assessment of advanced-therapy medicines.
- **Pharmaceutical industry investment in gene therapy.** Large, global biotechnology and pharmaceutical companies have recently increased their investments and strategic partnering activity in the gene therapy field, including partnerships between Spark Therapeutics Inc. and Pfizer Inc., Sangamo BioSciences Inc. and Shire plc, Adverum and Regeneron Pharmaceuticals, Inc., Applied Genetic Technologies Corporation and Biogen Inc., Dimension Therapeutics Inc. and Bayer HealthCare AG, Voyager Therapeutics, Inc. and Sanofi/Genzyme, Bristol-Meyers Squibb Company and uniQure N.V. and Baxalta Incorporated (which was acquired by Shire plc) and Regenxbio Inc.

Our technologies use AAV vectors for the treatment of retinal diseases. AAV vectors are the safest, most studied, and most widely used vectors in the field of gene therapy. The use of AAV vectors in the retina has proven to be an efficient way to transfer genes into cells and the resulting protein expression appears sustainable over the long term.

Applications of Gene Therapy in Ophthalmology



We believe that gene therapy, combined with our key technology platforms described below, is the right approach for the treatment of sight-threatening ophthalmic diseases for the following reasons:

- The genetics of the retina are well understood and genetic mutations have been clearly and unequivocally associated with the presence of disease symptoms and disease progression;
- The anatomy of the eye makes it a closed system, which facilitates the administration of biological products and reduces the risk of leakage or shedding in the rest of the body, thus limiting undesired systemic effects of treatment;
- The eye benefits from some level of immune privilege that lowers the risk of harmful inflammation and immune response against foreign antigens;
- Retinal cells are subject to limited or no renewal, allowing the sustained expression of a therapeutic gene over several years;
- Access and visualization inside the eye are facilitated by the availability of various non-invasive devices and imaging techniques to monitor the condition of the retina;
- The potential of optogenetics to expand to mutation-independent strategies prevent vision loss or restore vision without the need to identify specific genetic defects causing disease; and

- Gene therapy has the potential to address significant unmet medical needs in a number of sight-threatening diseases, creating an attractive market opportunity.

We believe that the potential pricing of gene therapy products will reflect the long-term benefits of a one-time, single injection treatment with the potential to be curative. We believe that prices for gene therapy treatment of sight-threatening diseases may exceed the current prices of many orphan drugs. Gene therapies may require new pricing and reimbursement approaches to achieve a fair recognition of value for developers while providing broad access to patients and an acceptable budget impact on health systems. Since gene therapies provide long-term or definitive benefits, pricing based on multiples of the yearly cost of expensive drugs, such as protein replacement therapies, could be justified. Pricing for organ transplant procedures may also provide a basis for pricing of gene therapy as both treatments are intended to be one-off procedures that require a significant upfront investment. Both treatments are considered to be challenging surgical procedures, with a high importance attributed to patient selection. Although there is some level of uncertainty about their long-term benefits, gene therapy and organ transplants provide comparable patient value as they have the potential to be life-changing; transplants replace a non-functional or diseased organ, whereas gene therapies restore function to a diseased organ. However, the key benefit of gene therapy compared to organ transplants, resides in its unlimited level of supply. In the United States, the total cost of a heart transplant, including pre- and post-surgery treatments is approximately $1.2 million, whereas the most expensive procedures, such as intestinal transplants, reach in excess of $1.5 million. (Source: Nature Biotechnology, Volume 33, Number 9, September 2015: The payers' perspective on gene therapy.) Less complex and more frequent transplants, such as kidney or pancreas transplants are estimated to cost $300,000. (Source: Nature Biotechnology, Volume 33, Number 9, September 2015: The payers' perspective on gene therapy.)

We believe that gene therapy could also be used for the treatment of neurodegenerative diseases. For example, local and targeted administration is possible in the brain, which features a certain level of immune privilege, while the limited turn-over of neurons would allow achieving sustained expression over several years. We believe that gene therapy could also be used for the treatment of other diseases affecting different organs. Several companies are developing gene therapy approaches to treat neurodegenerative diseases such as Parkinson's disease. Other approaches target treatment of diseases such as hemophilia A and B, Alpha-1 Antitrypsin deficiency or Thalassemia by targeting liver cells.

Leveraging Our Leading Technology Platforms to Address Ophthalmic and Central Nervous System Disorders: MTS and Optogenetics Technology Platforms

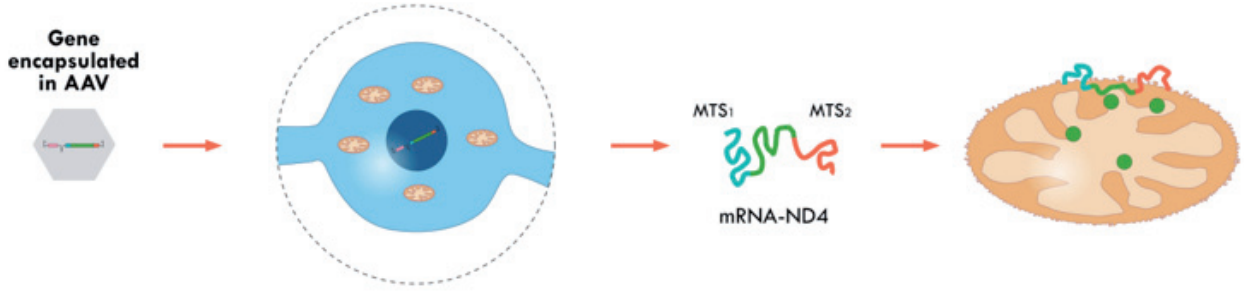
We have developed an integrated development platform to replace or restore the function of retinal cells that have degenerated in order to regain quality of sight for patients, thereby transforming their lives. Our integrated platform combines gene therapy with our core MTS and optogenetics technology platforms, reflecting substantial cross-disciplinary know-how in early research and development, process development, assay development and validation, product design, clinical trial design and execution and regulatory affairs. 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.

Mitochondrial Targeting Sequence (MTS)

MTS, our first core technology platform is, to our knowledge, the only existing technology that permits missing mitochondrial proteins to be shuttled into the mitochondrion, thereby enabling restoration of mitochondrial function.

Our MTS technology platform enables efficient expression of a mitochondrial gene by DNA and delivery of messenger ribonucleic acid, or mRNA, to polysomes located at the mitochondrial surface. This allows for the synthesis, internalization and proper localization of the mitochondrial protein.

Illustration of MTS Mechanism



Mitochondrial DNA mutations, whether inherited or acquired, lead to impairment of the electron transport chain functioning. Impaired electron transport, in turn, leads to decreased adenosine triphosphate, or ATP, production, overall reduced energy supply to the cells, formation of damaging free-radicals and altered calcium metabolism. These toxic consequences lead to further mitochondrial damage including oxidation of mitochondrial DNA, proteins and lipids, and opening of the mitochondrial permeability transition pore, an event linked to cell death. This cycle of increasing oxidative damage insidiously damages neurons, including those in the retina, over a period of years, eventually leading to neuronal cell death.

LHON originates mainly from mutations in three NADH dehydrogenase mitochondrial genes: ND1, ND4 and ND6. Because ND4 mutations account for more than 75% of the LHON population in North America and Europe, we chose to first focus on this specific mutation. (Source: Puomila, A et al., Epidemiology and penetrance of Leber hereditary optic neuropathy in Finland, European Journal of Human Genetics (2007).) We have demonstrated the feasibility of using our MTS technology platform for the treatment of LHON due to the ND4 gene mutation in animal studies. We plan to use our MTS technology platform to address other LHON mutations and have already initiated a research program for our next potential product candidate, GS011, which targets the ND1 gene mutation.

Optogenetics

A number of sight-threatening diseases are caused by the inability of the retina to detect light due to damaged photoreceptor cells. Optogenetics uses gene therapy to introduce a gene encoding for a light-sensitive protein into specific target cells in the retina enabling them to respond to light stimulation in place of damaged photoreceptor cells.

Optogenetics is a biotechnology that has triggered an increasing level of interest in the past decade. In addition to vision loss, other potential indications include hearing loss, diabetes, heart failure, epilepsy, neuropathic pain and drug addictions. Several approaches are currently in development ranging from stem cell engineering to genome editing (Crisp-Cas9). The increasing interest in optogenetics is demonstrated by the number of peer reviewed papers that has grown from as little as five in 2005, to over 700 in 2016.

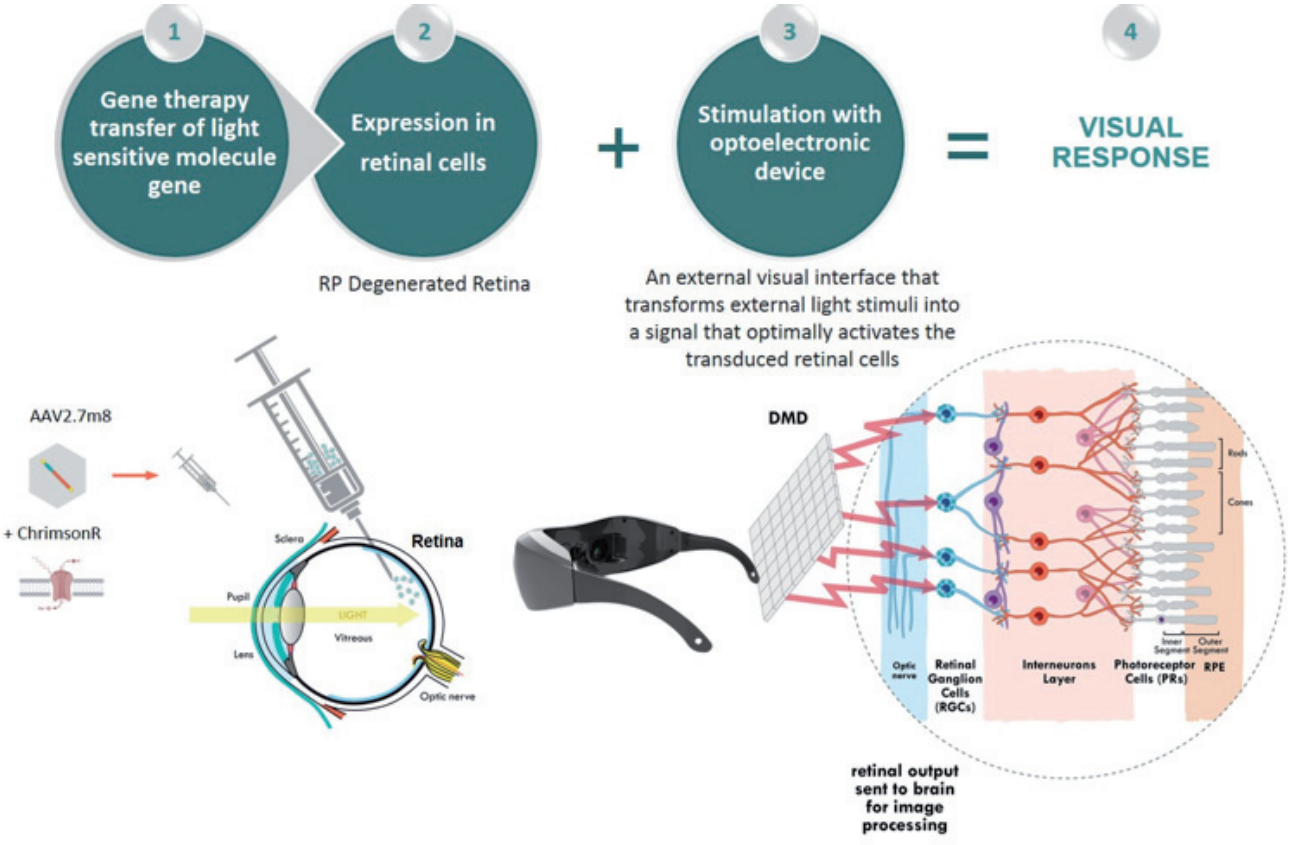
We believe optogenetics offers a unique opportunity to enable the stimulation of individual retinal neurons. To our knowledge the only existing alternative technology to stimulate the retina to induce visual perception involves the use of electrical stimulation. This technology is being deployed by medical technology companies, such as Second Sight Medical Products, Inc., or Second Sight, and Pixium Vision, using retinal implants that place electrode arrays on the surface of the retina. However, this approach has several limitations due to the number and size of electrodes that can be implanted in the retina. We believe that our technology has the potential to overcome the current limitations of electrode-based neuronal stimulation.

Retinal optogenetics involves (i) the insertion of a gene encoding a protein that confers light responsiveness into target cells and (ii) the use of an external wearable medical device to deliver light at the desired intensity and wavelength in order to stimulate the transduced retinal cells to transmit a signal to the brain. We believe that optogenetics can be applied effectively to stimulate the retinas of blind patients and obtain a meaningful sensory response in their visual cortex.

Our preclinical studies using photoreceptor deficient mice that are blind have shown that light triggers electrical signals in the visual cortex after the transduction of retinal cells with channelrhodopsin. These studies demonstrated that the retina of the test subjects regained photosensitivity, which is transmitted *via* the optic nerve to the brain. Visual behavior of the previously blind mice was restored at a level similar to that of mice with normal vision. We achieved similar results in experiments involving the retinas of non-human primates.

We have chosen to target RP as the first indication using our optogenetics technology. Our GS030 product candidate uses optogenetics with an external wearable medical device in the form of biomimetic goggles to provide light source and stimulation algorithms.

The Optogenetics Concept



We are developing our optogenetics technology in collaboration with several of the most well-respected international academic teams in the field, including the FMI in Switzerland, the Max Planck Institute in Germany, the M.I.T., in the United States, and the *Institut de la Vision* in France.

GS030 uses optogenetics and can address diseases of photoreceptor degeneration regardless of the type of mutation. Therefore, we believe that GS030 could be used for the treatment of other retinal degenerative diseases such as GA in the future.

In addition, we believe that we could leverage our optogenetics platform into indications outside ophthalmology that are receptive to electrical stimulation, such as congenital deafness and pain treatment.

6.4 OUR STRATEGY

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

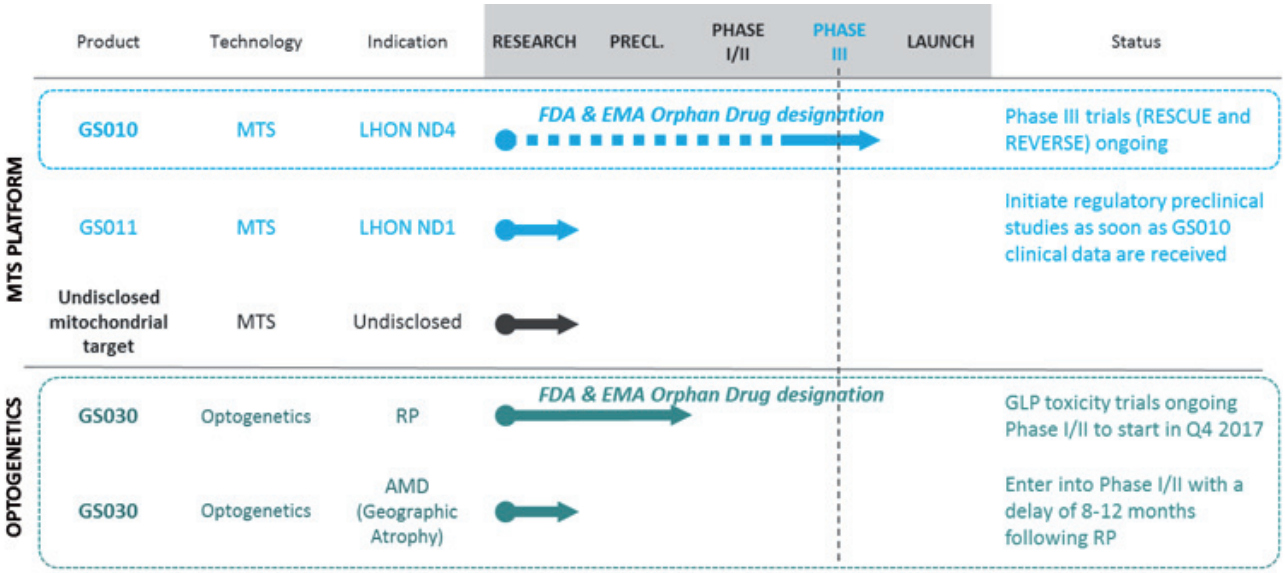
- **Complete clinical development and commercial launch of our lead product candidate, GS010, for the treatment of LHON.** We initiated Phase III clinical trials of GS010 in the fourth quarter of 2015 and expect to report results of these studies during the first half of 2018. Upon completion of the Phase III trials, if successful, we intend to apply for regulatory approval in the United States and Europe in the second half of 2018. GS010 has received orphan drug designation for the treatment of LHON in the United States and the European Union. We believe that, given its stage of clinical development, GS010 has the potential to be the first FDA-approved therapy for LHON, addressing a significant unmet medical need.
- **Advance clinical development of our second lead product candidate, GS030, using our optogenetics technology for the treatment of RP.** Our second lead product candidate, GS030 entered preclinical GLP toxicology studies in September 2016. GS030 has received orphan drug designation for the treatment of RP in the United

States and the European Union. We intend to initiate clinical development in RP patients in the fourth quarter of 2017, upon regulatory and ethics committee approval, with the expectation of receiving interim data in 2018. 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 the sight of patients who are blind due to RP.

- **Expand our pipeline by leveraging our proprietary MTS technology platform.** Our initial focus for our MTS technology platform is ophthalmology and, in particular, the treatment of LHON using GS010. Several degenerative diseases of the optic nerve, such as LHON, have long been associated with defects of the mitochondria. There is increasing evidence for mitochondrial involvement in other neurodegenerative diseases, including rare diseases such as Kearns-Sayre syndrome or Alpers disease and more frequent disorders such as Parkinson's disease or amyotrophic lateral sclerosis. We believe our capabilities, clinical experience and know-how 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, we have initiated a research program for GS011 using our MTS technology platform to treat LHON due to mutation in the ND1 gene.
- **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 since 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 GA.
- **Directly commercialize our lead products, GS010 and GS030, in key geographies.** We currently possess all commercial rights to our platform technologies, product candidates and development programs. If approved, we intend to commercialize GS010 and GS030, initially in the United States and the European Union. Because of the orphan nature of LHON and RP, we believe a targeted sales and marketing organization would be able to reach specialized ophthalmology centers and their patients. For example, we believe that this sales force approach would be sufficient to manage commercialization of GS010 in North America and in Europe, since we anticipate that a large majority of patients suffering from these diseases will be referred to a limited number of large, well-equipped and renowned eye hospitals in each country. We plan to deploy a similar commercialization strategy in Europe. We intend to find partners for Asia and the rest of the world.
- **Leverage our management's expertise to acquire or in-license complementary 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. We believe that our management team's expertise in the gene therapy market provides our company with a competitive advantage in evaluating product opportunities.

6.5 PRODUCT & DEVELOPMENT PIPELINE

Our pipeline currently comprises two lead product candidates for the treatment of sight-threatening retinal degenerative diseases, together with products in preclinical development targeting ophthalmic and neurodegenerative diseases. Set forth below is a table summarizing our development programs:



GS010 continues to progress globally in line with our initial timelines. We were initially expecting the topline data of both RESCUE and REVERSE to be available in December 2017, based on enrollment ending in December 2016. We completed enrollment of REVERSE in February 2017, and now expect to release topline data by the end of the first quarter 2018. Because we are recruiting patients in the very early stages of the disease, enrollment of RESCUE is expected to be completed by the end of the second quarter of 2017, hence topline data is expected by the end of the second quarter of 2018.

As we had prioritized our resources for GS010 in the first half of 2016 prior to successfully completing our initial public offering on Euronext Paris, we are now conducting a GLP toxicity study in non-human primates, expecting to initiate a first-in-man Phase I/II clinical trial in RP patients in the fourth quarter of 2017. We had initially expected to start this trial in the second quarter of 2017.

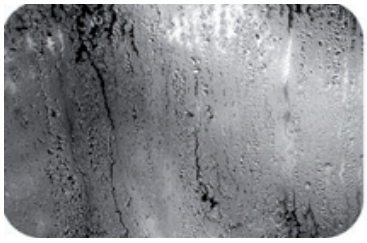
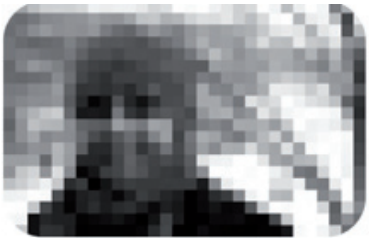
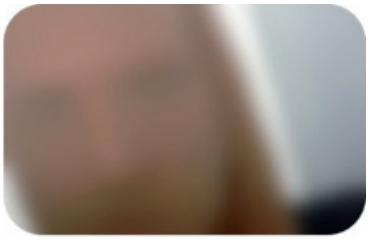
6.6 OUR LEAD PRODUCT CANDIDATE: GS010 FOR THE TREATMENT OF LHON

We are developing GS010 as a treatment for LHON due to the ND4 gene mutation, a rare mitochondrial genetic disease. GS010 is based on our MTS technology platform, which permits missing mitochondrial proteins to be shuttled into the mitochondrion, enabling the restoration of mitochondrial function. There is currently no FDA-approved treatment to prevent loss of sight or restore vision in LHON patients.

LHON Overview

LHON is a rare, maternally-inherited mitochondrial genetic disease that causes the onset of irreversible and severe loss of sight leading to blindness and disability in teens and young adults. LHON causes patients to suffer from sudden and rapid vision loss resulting in disability that affects patients and their families socially, emotionally and financially. LHON greatly alters the patient's ability to perform daily life activities, reduces their autonomy and, in particular, affects their ability to read, drive and recognize facial features and expressions. The quality of life of patients with LHON is generally poor.

LHON: neuro-degenerative mitochondrial disease characterized by sudden loss of sight

Patients with LHON typically suffer vision loss over a period of weeks. Approximately half of patients with LHON experience vision loss in both eyes two months after onset. Over the first nine months after onset, the sudden loss of vision in LHON is generally associated with a significant thinning of the retinal ganglion cell layer, a period during which patients typically lose 45 to 55% of their RGCs (Source: "Natural History of Leber's Hereditary Optic Neuropathy: Longitudinal Analysis of the Retinal Nerve Fiber Layer by Optical Coherence Tomography", Ophthalmology Volume 117, Number 3, March 2010). After this first phase, the speed of degeneration appears to slow down significantly and the number of remaining RGCs stabilizes. At six months after onset examination reveals atrophic changes of the optic nerve in most patients. In the majority of patients vision loss is sequential, although some patients have simultaneous bilateral onset. Vision loss reaches a nadir several weeks after onset and patients suffer severe loss of central acuity. Although maintaining peripheral vision to a variable extent, the majority of patients with the ND4 mutation qualify for legal blindness. For the vast majority of patients with the ND4 mutation vision loss is not recovered.

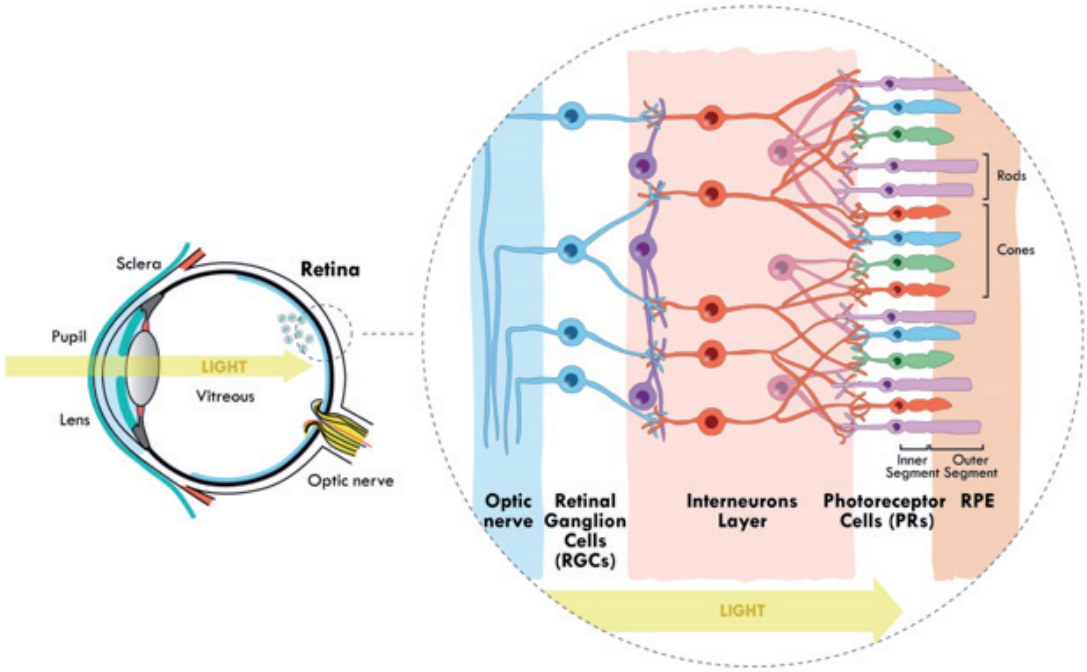
For ND4 patients the delay between the first affected and second affected eye averages 1.8 months and the duration of progression of vision loss averages 3.2 months. The mean Early Treatment Diabetic Retinopathy Study, or ETDRS, score at 12 months is 23.3 letters in patients within the first year of vision loss onset. The normal visual acuity score is 20/20 or 20/25 equivalent to an ETDRS score of 100 and 95 letters respectively. This indicates a mean potential loss of approximately 75 letters.

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

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 oxidative phosphorylation. Within mitochondria enzyme complexes carry out chemical reactions that drive the production of ATP. ATP is the main energy source within the cell. Complex I is responsible for the first step in the process that leads to the generation of ATP. Three different genes encoding for four NADH dehydrogenases have been linked to LHON and are considered to be the primary mutations for the disease to manifest.

Although the genetic mutation is present throughout the body, LHON symptoms are almost uniquely limited to retinal ganglion cells, or RGCs, leading to their dysfunction and to optic nerve atrophy. RGCs are located near the inner surface of the retina. They receive visual information from photoreceptors. RGCs collectively transmit image-forming and non-image forming visual information from the retina to several regions in the brain. Once the RGCs degenerate, signals can no longer be transmitted to the brain resulting in loss of vision.

Schematic Cross-Section of the Human Retina



The onset of vision loss due to LHON typically occurs between 15 and 35 years of age.

Existing Therapies for the Treatment of LHON

No treatments for vision loss due to LHON have been approved in the United States. In the European Union, the EMA granted marketing authorization for Raxone/Idebenone under exceptional circumstances as a treatment for LHON in September 2015. People known to be carriers of one of the primary genetic mutations that cause LHON are advised to avoid environmental triggers for the disease, such as cigarette smoking and alcohol consumption. There are a number of alternatives offered to patients, although to our knowledge their efficacy for halting or reversing vision loss has not been clinically proven. These alternatives include enzyme supplements and antioxidants, such as Coenzyme Q10 and Idebenone.

Market Opportunity for LHON

LHON is the most common illness caused by mitochondrial DNA, or mtDNA, mutations. Limited data exists for LHON incidence and prevalence. 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. Based on the limited data available, we estimate prevalence for LHON to be between

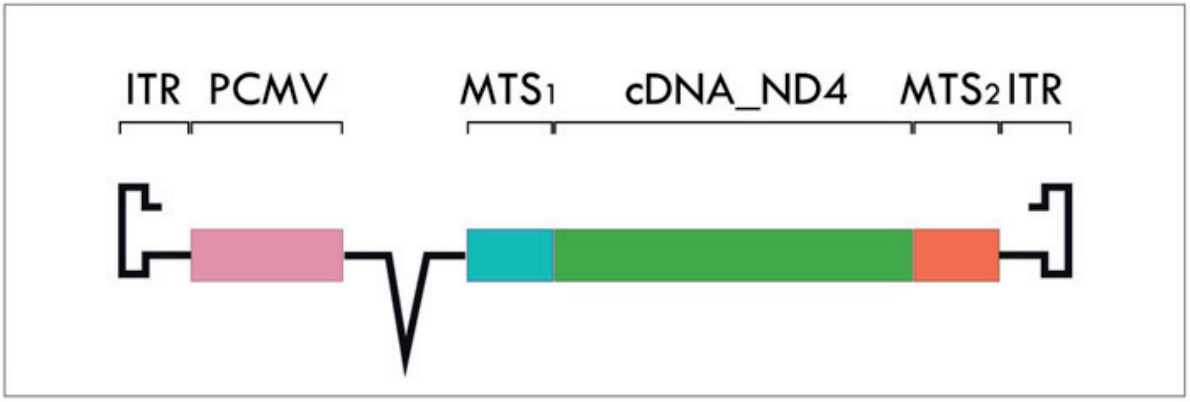
one in 31,000 and one in 40,000. Our GS010 product candidate is intended to address new cases of LHON of less than one year.

European and North American studies of LHON patients indicate that the ND4 mutation accounts for up to 75% of LHON cases. In Asian countries, the proportion of ND4 mutation is higher, ranging from 80% to 85%.

Our LHON Product Candidate: GS010

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.

Schematic Design of GS010



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. For such purpose, the ND4 transgene is flanked by our MTS, the cox10 MTS, which is referred to as MTS1 in the above diagram, coupled to cox10 3' untranslated region, or UTR, which is referred to as MTS2 in the above diagram, allowing ND4 mRNA to be addressed to polysomes that are attached to the outer mitochondrial membrane. This results in synthesis of ND4 protein within the mitochondrial membrane. ND4 protein is then further shuttled into the mitochondria and integrated into complex I of the respiratory chain in order to restore normal function.

Preclinical Development of GS010

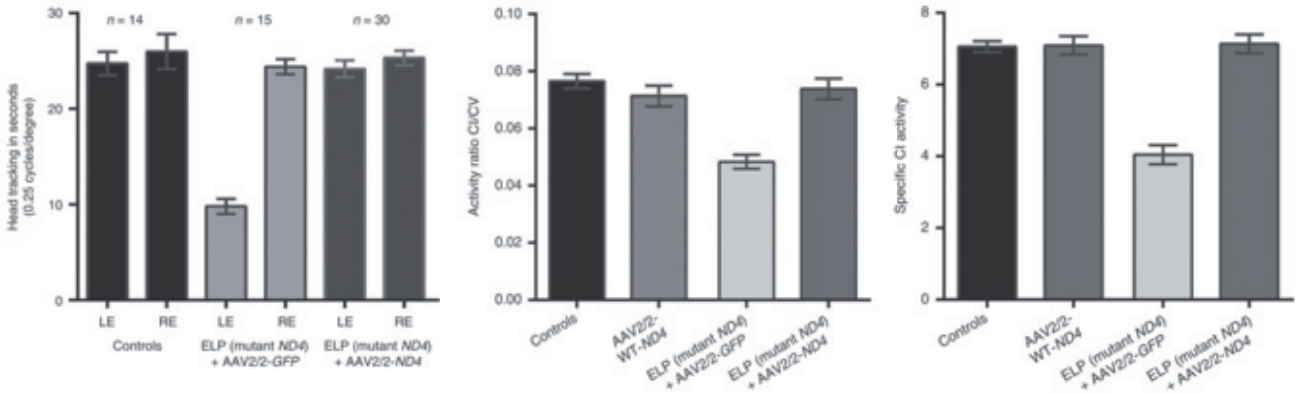
Our preclinical studies demonstrated that, *in vitro*, GS010 restored mitochondrial respiratory chain function in ND4-mutated patient fibroblasts and, *in vivo*, protected RGCs and restored vision in a rat model of LHON.

In a cellular assay with cells derived from LHON patients with the ND4 mutation, GS010 was able to restore mitochondrial function and ATP production. We isolated and cultured fibroblasts from LHON-ND4 patients. In these fibroblasts, we demonstrated that GS010 restores mitochondrial function, including complex I activity and ATP production, to the level of normal fibroblasts.

We also determined that, *in vivo*, IVT injection of GS010 leads to the expression of the human, wild-type ND4 in rat RGCs. The human protein was also found within the mitochondria.

We also tested GS010 in a rat model of LHON that reproduces the main features of the human disease, including a progressive loss of RGCs, optic nerve atrophy, alteration of mitochondrial function in the optic nerve and impairment of vision. We observed the preservation of RGC and optic fiber integrity after injection of GS010 10 days after induction of LHON. Normal vision was also maintained for up to six months. We detected human ND4 mRNA at 12 months in GS010-treated retinas of LHON rats. In addition, in the LHON rat model, GS010 was also shown to preserve mitochondrial function of the optic nerve as measured by the complex I/V activity ratio. The figure set forth below presents some of the results.

Assessment of Visual Function and Respiratory Chain complex I Activity in LHON Rats



(A) The visual performance of the animals is evaluated using the optomotor test. This test measures the number of times the rats turn their heads in the same direction as the drum rotations. Here, LHON rats treated with GS010 retrieve similar visual behavior as control (healthy) rats.
(B) The mitochondrial activity (energy production) is measured using specific enzymatic markers. Histograms representing complex I / complex V activity ratios in the left panel or specific complex I enzymatic activity are displayed. Error bars are standard error mean.
(Source: Molecular Therapy: Efficiency of gene therapy with the mitochondrial ND4 gene for optic atrophy, H Cwerman-Thibault *et al*, 2015.)

These data demonstrate that GS010 delivers human ND4 protein to RGC mitochondria and that ND4 integrates complex I of the respiratory chain.

We completed a GLP toxicology study in 24 monkeys over a period of six months. IVT injection of GS010 at different dose-levels was safe and well tolerated. Evaluation classically included ophthalmology examinations and histology such as biodistribution, shedding and immuno-monitoring. After six months follow-up of systemic histological effects, GS010 was demonstrated to be locally well tolerated with some anterior uveitis at two doses, and no functional alteration of the retina. Vector DNA was found in the retina as well as in the anterior segment of the eye, with significant detection of ND4 mRNA in the retinas of all non-human primates at three months post injection.

Bilateral Injections

LHON is a bilateral disease typically involving sequential, but occasionally simultaneous, vision loss in both eyes. In December 2016, we initiated a preclinical program to test the safety of bilateral injections of GS010, within a maximum of three months in each eye, in non-human primates to support future clinical activity with regards to local tolerance and immune response.

The preclinical follow-up study will be six months after GS010 is administered to the second eye. We believe that this study period is appropriate to assess safety and tolerability for persistence of AAV2, duration of expression and immunogenicity. As agreed with the EMA, reproductive toxicology studies are not required.

Clinical Development Program for GS010

The clinical development program for GS010 was designed as a two-phase approach of proof of safety and tolerability followed by proof of efficacy. The proposed clinical plan takes into account the severity of visual outcomes for patients suffering LHON, the rarity of the disease, the lack of existing treatment options and the likelihood of a therapeutic window.

Phase I/II dose-escalation safety study for GS010 (CLIN-01)

The clinical development of GS010 was initiated in 2014 with the CLIN-01 trial, which is the first-in-man safety and tolerability study of GS010, and recruitment was completed at the end of April 2015 and a follow-up study is currently ongoing. CLIN-01 was conducted at the *Centre Hospitalier National d'Ophtalmologie des XV-XX* in Paris.

CLIN-01 was designed to test the safety and tolerability profile of GS010 with ascending doses in patients with LHON due to the ND4 mutation, including four ascending dose cohorts each comprised of three patients: 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.

According to the protocol, we included three additional patients in the study, who were administered the maximum tolerated dose level to increase the reliability of our observations. Several secondary endpoints were included in CLIN-01: immuno-monitoring and vector bio-dissemination, visual acuity, color and contrast vision as well as structural tests such as optical coherence tomography, or OCT, and electrophysiological tests related to the functioning of the RGCs and the optic nerve. The dose to be used in the efficacy study will be based on the accruing data from CLIN-01.

Patients enrolled in CLIN-01 were required to have severe vision loss, which is measured by visual acuities of less than 20/200 in cohorts. Given the neurodegenerative nature of LHON, these patients had developed an optic neuropathy prior to entering the

study. GS010 was administered in the more severely affected eye of the patients. In patients with relatively chronic optic neuropathy, visual response to GS010, as assessed by the visual testing noted above, was expected to be limited, especially in regards to recovery of central visual acuity and visual field.

15 patients were included in CLIN-01 and each patient received a single IVT injection of GS010.

The members of the data safety monitoring board, or DSMB, recommended dose escalation in accordance with the protocol and without restriction after data review of each of the first three dose-escalation cohorts. A fourth cohort was then injected with the maximal feasible dose of 1.8E11 vg/eye. After subsequent review of the safety and tolerability data of this cohort, the DSMB recommended an extension cohort with a dose of 9E10 vg/eye. Three patients were included in an extension cohort and injected with 9E10 vg/eye. A review of the cumulative safety data up to eight weeks post-IVT injection of the last patient of this cohort took place on June 22, 2015. The DSMB recommended no further exposure of patients to GS010 within CLIN-01 as the safety and tolerability profile of GS010 is satisfactory based on current accrued data. They further recommended pursuing close, structured monitoring of patients in subsequent studies of GS010.

Our interim clinical study report dated August 4, 2015 analyzed the accrued data from all 15 subjects of all cohorts in CLIN-01. Within the reporting periods four subjects completed 48 weeks of follow-up, three subjects completed 36 weeks, two subjects completed 24 weeks, three subjects completed 12 weeks and three subjects completed eight weeks of follow-up. Overall, GS010 appears to be well tolerated with a good safety profile. Systemic tolerance was noted to be very good. Local, ocular, side effects occurred, were mostly mild, well tolerated and when required, treatment responsive to standard therapies. The most common ocular side effects were elevated intraocular pressure, or IOP, and ocular inflammation. These were well tolerated without reported sequelae and treatment responsive to standard therapies. Overall IVT injection of GS010 was well tolerated and when side effects did occur and required treatment they were well managed with non-invasive standard therapies.

The clinical investigation center conducting the CLIN-01 trial performed an exploratory analysis of the vision test results of all 15 subjects and published a report on June 30, 2016 documenting its findings and confirming the trends observed in the preliminary report that included the nine first treated patients. All 15 subjects completed 48 weeks of follow-up. Consistent with the protocol requiring treatment of the worst functioning eye, baseline mean Log of the Minimal Angle of Resolution, or LogMAR, visual acuity was worse in the treated eyes than fellow non-treated fellow eyes. We observed that 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. In addition, the magnitude of treatment effect was greater when the baseline vision status was relatively better. Although the study was not designed to demonstrate efficacy of the treatment, due to the diversity of doses and the heterogeneity of patients, these preliminary results are encouraging. After talks with experts, the Company has designed its ongoing Phase III trials to target a more homogeneous patient population, very recently diagnosed (less than 12 months), which could maximize the benefits and efficacy of treatment. These findings support the clinical development strategy for the Phase III RESCUE and REVERSE trials currently ongoing and that have been designed on the basis of this approach. RESCUE and REVERSE will collectively assess the effect of GS010 within the first year of disease by analyzing the very recently affected subjects in RESCUE (zero to six months disease duration) and the recently affected subjects in REVERSE (seven months to one year disease duration). Both RESCUE and REVERSE assess for the better-seeing eye at baseline taking into account the baseline status when assessing the magnitude of treatment effect at 48 weeks.

The evaluation of color vision at 48 weeks using the Farnsworth D15HUE color test indicated that the magnitude of difference in the treated eye versus the untreated eye was related to baseline color vision status and a shorter duration of symptoms (< two years) with a signal in favor of the treated eyes.

Visual Function Evolution: Trends of Improved Acuity at Week 78

In December 2016, we reported results in 14 patients after 78 weeks of follow-up (one patient withdrew its consent after 48 weeks of follow-up).

As described in the following table, we continue 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 to week 78	Treated Eye (TE) mean change (LogMAR)	Untreated Eye (UTE) mean change (LogMAR)	Outcomes in Visual Acuity **TE vs UTE**
All patients (n=14)	+30 letters (-0.61)	+15 letters (-0.31)	+15 letters (-0.30 LogMAR)
Patients with ≤ 2y disease duration (n=5)*	+32 letters (-0.63)	+12 letters (-0.23)	**+20 letters (-0.40 LogMAR)**

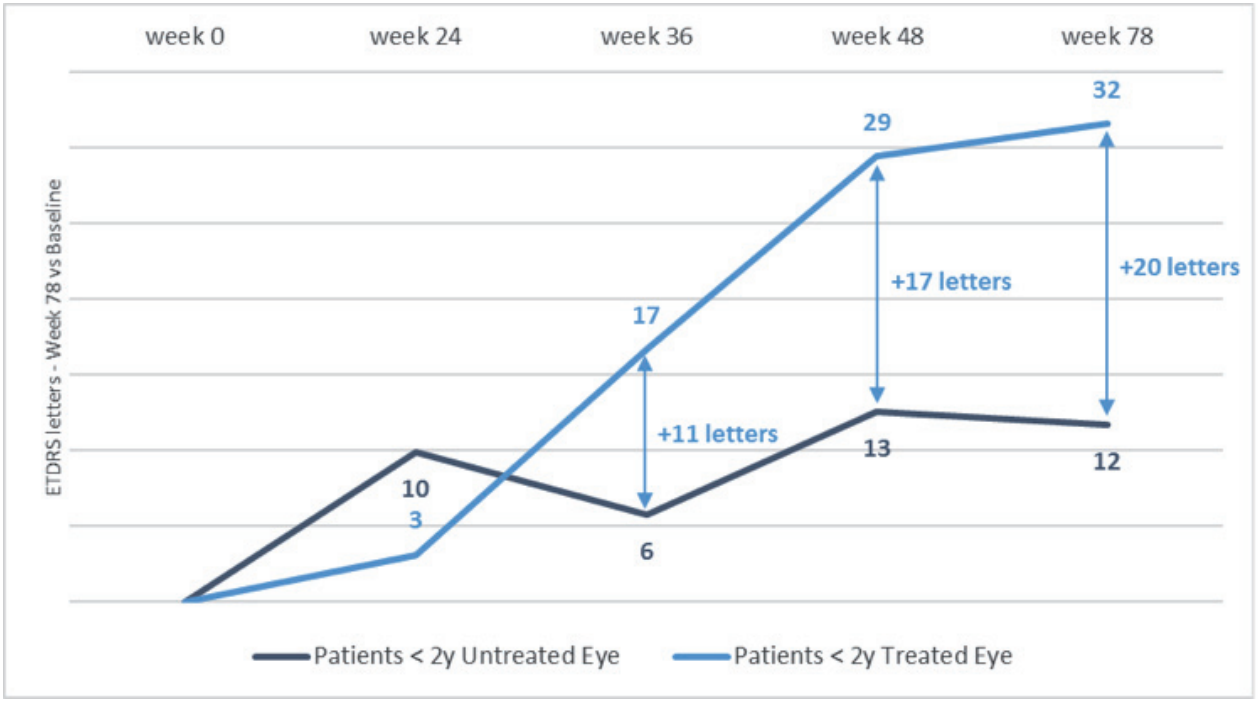
Note (*) Excludes "hand motion" patients, in accordance with the Phase III protocol.

-0.1 LogMar = + 5 ETDRS Letters

5 letters correspond to one line on the ETDRS chart. Therefore a difference of 20 letters is equivalent to 4 lines on the ETDRS chart.

Evolution of visual acuity in the treated eye vs. untreated eye at week 78 of follow-up in patients with less than 2 years of vision loss symptoms

(in equivalent number of letters read; n=5)*



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

Phase III clinical study for GS010 (RESCUE and REVERSE)

The second part of the clinical development of GS010 is designed to demonstrate efficacy in patients with the ND4 mutation. The FDA cleared our IND in the United States on August 19, 2015 and our CTAs have been cleared in all European Union countries in which submissions were made, allowing all centers of our Phase III trials to commence on March 16, 2016. The first patient, first visit, or FPFV, at a trial site occurred in January 2016 and recruitment began at all centers after study initiation visits which were carried out between December 2015 and April 2016. As of the date of this Registration Document, all 36 patients have been enrolled in REVERSE, completing the enrollment, and 27 patients have been randomized and treated in RESCUE, and more patients are undergoing screening. We expect to complete enrollment of RESCUE in the first half of 2017.

Given that time since onset of vision loss is considered to be a major factor in the ability to intervene therapeutically due to the neuro-degenerative nature of LHON and the cell death of the RGCs, the proposed plan divides patients with the onset of vision loss of less than one year into two separate groups. This will allow us to define the efficacy of GS010 in early affected populations of patients at different stages of the disease and to compare homogeneous patient populations.

The studies focus first on patients who have manifested visual decline for up to one year. The two studies, which are being conducted in parallel, are:

- RESCUE (CLIN-03A), the full title of which is "A Randomized, DoubIE-Masked, Sham-Controlled, Clinical Trial to Evaluate the Efficacy of a Single Intravitreal Injection of GS010 (rAAV2/2-ND4) in Subjects Affected for 6 Months or Less by Leber's Hereditary Optic NeUropathy Due to the G11778A Mutation in the Mitochondrial NADH Dehydrogenase 4 Gene," to evaluate the efficacy of GS010 in patients with an onset of vision loss up to six months in duration (≤ 180 days); and
- REVERSE (CLIN-03B), the full title of which is "A Randomized, DoubIE-Masked, Sham-Controlled, Clinical Trial to Evaluate the Efficacy of a Single Intravitreal Injection of GS010 (rAAV2/2-ND4) in Subjects Affected for More Than 6 Months To 12 Months by Leber's Hereditary Optic NeuRopathy Due to the G11778A Mutation in the Mitochondrial NADH DehydrogenaSe 4 Gene," to evaluate the efficacy of GS010 in patients with an onset of vision loss for seven to 12 months in duration (181 to ≤ 365 days).

The 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 or as prophylaxis for vision loss in an eye not yet affected. The trials will also seek to identify the therapeutic window of opportunity for treatment after onset of disease. 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.

An additional trial of GS010, CLIN-04, is planned in patients with vision loss due to the ND4 mutation for more than one year and less than three years. Vision loss in those patients may be recent enough to allow for vision recovery using our GS010 product candidate. We plan to use data from CLIN-01, RESCUE and REVERSE to guide the extent of investigation in this more chronic population so that only patients with potential benefit will be exposed to GS010.

RESCUE – Patients Affected for Up to Six Months

RESCUE is designed as a randomized, double-masked, sham-controlled, multi-center, multi-country clinical trial in Europe and the United States, of LHON patients with the ND4 mutation with vision loss of less than six months in duration. We plan to enroll 36 LHON patients. The study design compares treated eyes versus eyes receiving sham treatment.

- **Primary efficacy endpoint.** Efficacy of GS010 in treated eyes relative to sham treated eyes will be based on Best Corrected Visual Acuity, or BCVA, as measured with the ETDRS at 48 weeks post dose. The patients' LogMAR, scores, which are derived from the number of letters they read on the ETDRS chart, will be used for statistical purposes.
- **Secondary efficacy endpoints.** The secondary efficacy endpoints will involve the application of the primary analysis to best seeing eyes that received GS010 compared to those receiving sham and to worse seeing eyes that received GS010 compared to those that received sham. Additionally, a categorical evaluation with a responder analysis will be evaluated, for example, the proportion of patients who maintain vision (< ETDRS 15L loss), the proportion of patients who gain 15 ETDRS letters from baseline and the proportion of patients with Snellen acuity of > 20/200. Complementary vision metrics will include automated visual fields, OCT, and color and contrast sensitivity, in addition to quality of life scales, bio-dissemination and the time course of immune response.

REVERSE – Patients Affected for 7-12 Months

REVERSE is designed as a randomized, double-masked, sham-controlled, multi-center, multi-country clinical trial in Europe and the United States, of LHON patients with the ND4 mutation with vision loss of 181 to ≤ 365 days in duration. We plan to enroll 36 patients. The study design compares treated eyes versus eyes receiving sham treatment.

- **Primary efficacy endpoint.** Efficacy of GS010 with respect to sham will be based on BCVA, as measured with the ETDRS at 48 weeks post dose. The patients' LogMAR, scores, which are derived from the number of letters they read on the ETDRS chart, will be used for statistical purposes.

- **Secondary efficacy endpoints.** The secondary efficacy endpoints will involve the application of the primary analysis to best seeing eyes that received GS010 compared to those receiving sham and to worse seeing eyes that received GS010 compared to those that received sham. Additionally, an evaluation with a responder analysis will be evaluated, for example, the proportion of patients who maintain vision (< ETDRS 15L loss), the proportion of patients who gain 15 ETDRS letters from baseline and the proportion of patients with Snellen acuity of > 20/200. Complementary vision metrics will include automated visual fields, OCT and color and contrast sensitivity, in addition to quality of life scales, bio-dissemination and the time course of the immune response.

Study Conduct for RESCUE and REVERSE

In these efficacy trials for GS010, treatment will be administered to a single eye of each subject once by IVT injection. The dose level of GS010 in the efficacy RESCUE and REVERSE trials will be determined based on outcomes of the safety and tolerability CLIN-01 study. We plan to administer a dose of 9E10 vg/eye *via* IVT injection, as defined by CLIN-01 to be the maximum tolerated dose, in a volume of 90 µL.

RESCUE and REVERSE, 12 study visits are planned during the first half of 2018 for each patient, including a selection visit, an inclusion visit, a treatment visit, and nine follow-up visits post-IVT injection over a 96 to 100 week period. Data for REVERSE will be available at 48 weeks by the end of the first quarter of 2018, and we expect data for RESCUE to be available by the end of the second quarter of 2018 based on recruitment ending in the second quarter of 2017.

At the end of the initial study period, a long-term follow-up period will commence for a duration of three years, to ensure the durability of safety and efficacy outcomes.

Pediatric Investigational Plan for GS010

The visual prognosis in LHON is dependent on two major factors: gene mutation, of which ND4 has the worst prognosis, and age of onset of vision loss. An earlier age of onset is consistent with a better visual prognosis and, in general, the pediatric population has better visual outcomes relative to the adult LHON population. This is especially true in patients younger than approximately 15 years of age. Upon the EMA's advice, we submitted an amendment to the two current Phase III protocols in all countries to allow inclusion of patients between 15-18 years. Such amendment was submitted in May 2016 and approved in September 2016 in France, the United Kingdom, the United States and Italy. A Pediatric Investigational Plan, or PIP, has been submitted and is currently being discussed with the EMA.

Currently, patients less than 15 years of age are expected to be included in a national history registry study in order to further delineate vision outcomes in the pediatric population. Based on data from RESCUE and REVERSE studies, we will investigate and expect to agree with the EMA on the strategy to adopt during the first half of 2018.

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 last meetings with the FDA in April and December 2016, the FDA made a number of recommendations with respect to our RESCUE and REVERSE studies, as well as the bilateral treatment of LHON patients. Based on these recommendations, we intend to advance the timing of our planned submission of a Special Protocol Assessment, or SPA, to test the safety and efficacy of bilateral injections of GS010 prior to submitting our application for marketing authorization for bilateral treatment. This clinical study could be initiated as early as the second half of 2017 once the feasibility of the SPA has been agreed with stakeholders, such as key opinion holders and patients, and approved by the FDA and ethics committees.

If the results of our RESCUE and REVERSE studies are successful, we intend to submit an application for marketing authorization in the United States in late 2018, with the goal of obtaining approval or accelerated approval from the FDA based on final study results to commercialize GS010 for the treatment of LHON, and then based on the completion of our bilateral clinical study for the treatment of both eyes. We would expect to obtain full approval for the treatment of both eyes from the FDA within 12 to 24 months following the initial approval or accelerated approval.

In parallel, we have had several interactions with the Committee for Medicinal Products for Human Use and the Scientific Advice Working Party of the EMA, or SAWP, since October 2014. SAWP has endorsed our proposal to study the treatment effect of GS010 in a randomized trial setting including sham control, as well as the measurement of efficacy. All of our CTAs have been approved in the European Union countries in which submissions were made and by all ethics committees in such countries.

We approached the Paediatric Committee, or PDCO, of the EMA in August 2016 and applied for agreement on a PIP with the EMA.

In September 2016, we received approval from regulatory agencies and ethics committees in the United States, France and the United Kingdom to include teenage patients (between 15 and 18 years of age) in RESCUE and REVERSE Phase III trials with GS010 for the treatment of LHON. Available epidemiologic data suggest that teenage patients may represent between 14 and 22% of all LHON patients (all mutations included).

6.7 OUR SECOND PRODUCT CANDIDATE: GS030 FOR THE TREATMENT OF RP

Our second product candidate, GS030, is based on optogenetics, a technology that makes cells responsive to light. We are using a modified AAV2, to which we have exclusive rights in optogenetics, to introduce a DNA sequence that encodes a photosensitive protein, ChrimsonR, into the nucleus of the target cells. Once this protein is expressed, it confers a photoreceptor-like function to the target cell, enabling the restoration of vision in patients with extremely reduced vision or who are blind due to RP. We have secured exclusive rights to several specific light-sensitive proteins known as opsins, including ChrimsonR, in ophthalmology from M.I.T. and, through our license with Novartis(1), from the Friederich Miescher Institute. Once transfected, the opsins expressed by the targeted retinal cells will be stimulated by a specific wavelength transmitted by an external wearable medical device in the form of biomimetic goggles, which we are developing. Patients will need to wear the external wearable device in order to enable restoration of visual function.

We believe the application of this novel technology to treat RP will improve patients' ability to see, and therefore increase their autonomy, independence and overall quality of life.

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 both non-syndromic forms involving isolated visual disability as well as syndromic forms involving other organs or tissues, such as Usher disease or Bardet-Biedl syndrome, which manifests both in the retina and in the cochlea of the ear. The mutations that cause RP are heterogeneous and include recessive, dominant and X-linked forms of more than 60 genes and affect a variety of cell functions. Syndromic forms of RP are equally heterogeneous.

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

Illustration of Progressive Vision Loss in RP Patients

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 the 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 ultimately leads to blindness. Some patients become blind as early as age 30, and the majority of patients become legally blind before the age of 60.

Existing Therapies for the Treatment of RP

To date, no therapeutic treatments have been approved for RP by the FDA or the EMA. Vitamin A has been discussed as potentially having a progression slowing effect, but we are not aware of any clinical studies demonstrating such effects in RP. No therapy is currently available that has shown to halt vision loss or to restore vision. Therefore, treatment of RP is considered a significant unmet medical need.

Other approaches to treat vision loss due to RP are under development, including gene replacement therapy and small molecule therapeutics. Given that RP is a group of genetic diseases involving more than 60 different genes, specific gene replacement therapies will be limited to a tiny fraction of the patient population at one time. We believe such technologies would not be as efficient as our optogenetic approach, which has the potential to treat RP independent of the specific genetic

(1) In the context of this license, the Company initially developed a first optoenetics product using an halorhodopsin protein (eNpHR) associated with the specific promoter hCAR, packaged in an AAV2 vector. Preclinical work has been conducted in 2014 in mice and primates. Preliminary results have concluded that the construct used as GS020 was not active enough to provide sufficient expression and functional responses in primates, the most relevant animal model for photoreceptor degeneration. Additional research works are currently being conducted by the Company's academic partners to foster the expression by optimizing the genetic construct.
In parallel, the Company has worked on a different AAV construct based on a different photoswitch, a channelrhododpsin called ChrimsonR and this became the GS030 program. The AAV vector and the stimulation device that the Company uses have remained the same. In addition to advancing GS030, the Company remains committed to improving an halorhodopsin approach with the objective to build up a complete and integrated optogenetics platform.
As a result of not actively using the in-licensed protein in a clinical stage product candidate, the Company has no financial obligation towards Novartis. Should the Company do so in the future, the financial terms of the agreement would apply.

mutation and could potentially treat all RP patients. As a result, we believe our optogenetic approach is a breakthrough technology that can provide significant competitive advantages as compared to existing modalities.

Another alternative to treat vision loss from RP involves medical devices in the form of retinal implants, such as those being developed by Pixium Vision or Second Sight which has received marketing approval for its product in Europe and the United States. Retinal implants have proven to restore some visual perception in patients. Retinal implants are intended for patients with advanced RP who have lost their photoreceptors. Retinal implants generate external electrical impulses, whereas our optogenetics product, GS030, creates an intrinsic and physiological electrical activity at the cell level.

By giving the ability to sense light to other neuronal cells of the retina, such as RGCs, our strategy is applicable even at advanced stages of rod and cone degeneration.

Market Opportunity in RP

RP is the leading cause of hereditary blindness in developed countries, with a prevalence of about 1.5 million people (Source: *Institut de la Vision*, Retinitis pigmentosa, May 12, 2015) throughout the world. In Europe and the United States, about 350,000 to 400,000 patients (Source: RP Fighting Blindness. org, About RP and Oxford University Press, Human Molecular Genetics, 1996, Vol. 5, No. 8 1193–1197: A ninth locus (RP18) for autosomal dominant retinitis pigmentosa maps in the pericentromeric region of chromosome 1) suffer from RP and every year between 15,000 and 20,000 patients with RP suffer vision loss. (Source: RP Fighting Blindness.org, About RP and Oxford University Press, Human Molecular Genetics, 1996, Vol. 5, No. 8 1193–1197: A ninth locus (RP18) for autosomal dominant retinitis pigmentosa maps in the pericentromeric region of chromosome 1). There is currently no curative treatment for RP, which is designated as a rare and orphan disease in the United States and Europe. We believe that our GS030 product candidate would benefit patients in the early stages of RP.

The threshold for loss of function is usually defined as 20/200. The main impacts at this stage are the inability to read despite visual aids, difficulties with facial recognition, and difficulties navigating unassisted outside the home. Once patients become legally blind, they may continue to experience declining vision. Most RP patients have already lost the ability to work and function independently outside the home before reaching this stage.

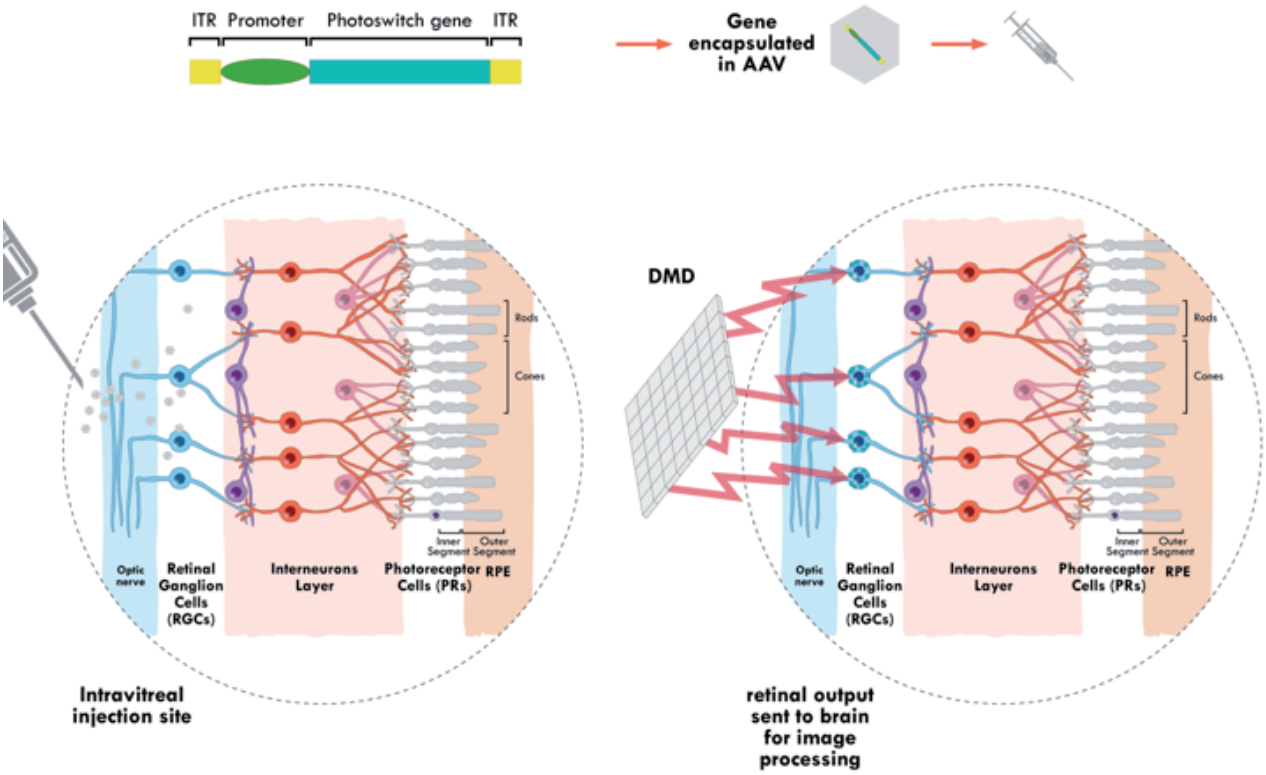
Certain key opinion leaders have stated that these studies may underreport the number of severely visually impaired patients with RP since they were based on patients with active follow-up at major centers. We believe that many patients stop seeing ophthalmologists within a few years after reaching legal blindness because of a perceived lack of treatment and difficulty in traveling to medical centers.

Optogenetics for the Treatment of RP

The optogenetics strategy in the retina of a patient suffering from RP aims at conferring light sensitivity to normally light insensitive retinal neurons, such as RGCs, in order to restore a light response. While there is significant loss of photoreceptor cells, other retinal cell types are usually preserved.

Our primary optogenetics strategy consists of introducing ChrimsonR, a light-sensitive protein belonging to the channelrhodopsin 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.

Gene Therapy Applied to Optogenetics



Because cells expressing optogenetic protein are less light sensitive than normal photoreceptors, vision under regular daylight conditions is unlikely to be possible. Our biomimetic goggles, which mimic 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.

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 470 nm 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. 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.

No adverse effects associated with GS030 in non-human primates at two and six months

Preliminary results obtained from non-GLP experiments in non-human primates have demonstrated that GS030 is very well tolerated after bilateral intravitreal administration. Subjects were monitored at two and six months and all parameters were observed to be normal: normal ophthalmology examinations, no histological findings in retina tissues, no apparent inflammation or modification of the structure of the retina. Although a very mild

increase in serum antibodies was detected, such response was not detected in the aqueous humor of injected eyes.

Proof-of-concept study showing restoration of retinal electrical activity by ChrimsonR in a mouse model of RP

An rd1 mouse, which is a relevant model of RP, 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.

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

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. This study confirmed the initial data and supports the sustainability of expression of GS030 in the retina of monkeys.

Optoelectronic external wearable medical device: the Biomimetic goggles

The natural range of light sensitivity of human photoreceptor cells is larger 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.

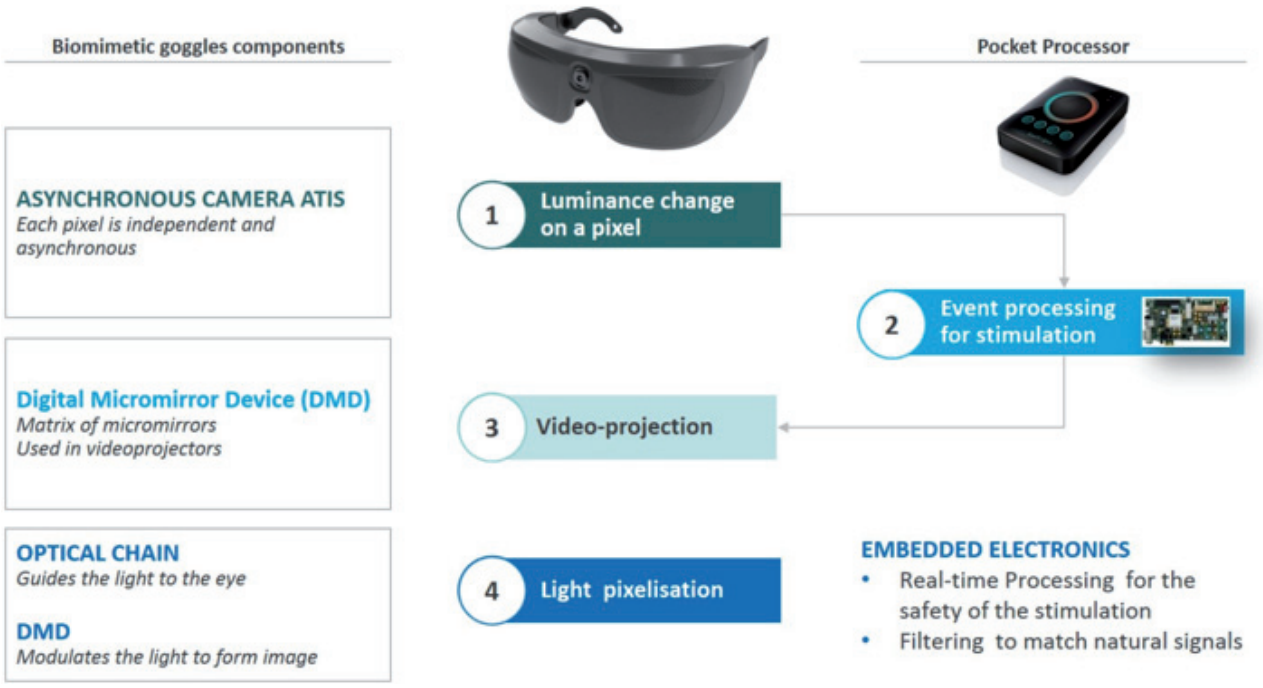
We are developing an external wearable medical device composed of:

- 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 wavelength of 550-640 nm.

Software will be provided to medical centers that will allow 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 clinical trials and commercialization.

Preclinical Development of GS030 for RP

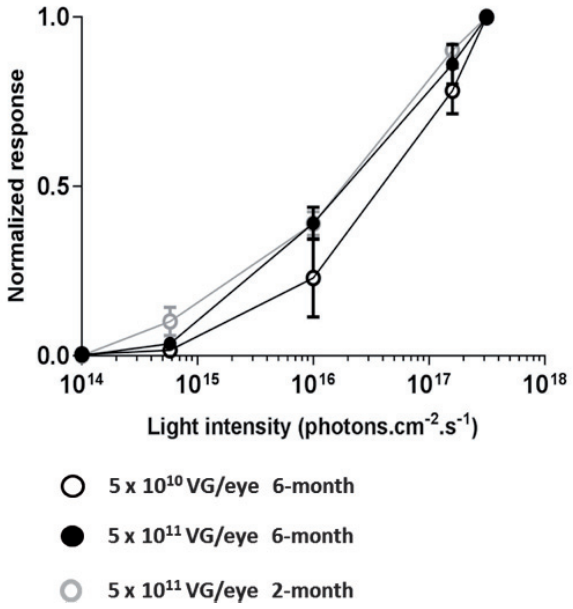
We are planning to conduct the following three main studies in order to support the clinical Phase I/II CTA submission:

Preliminary toxicity study showing safety of GS030 in non-human primates

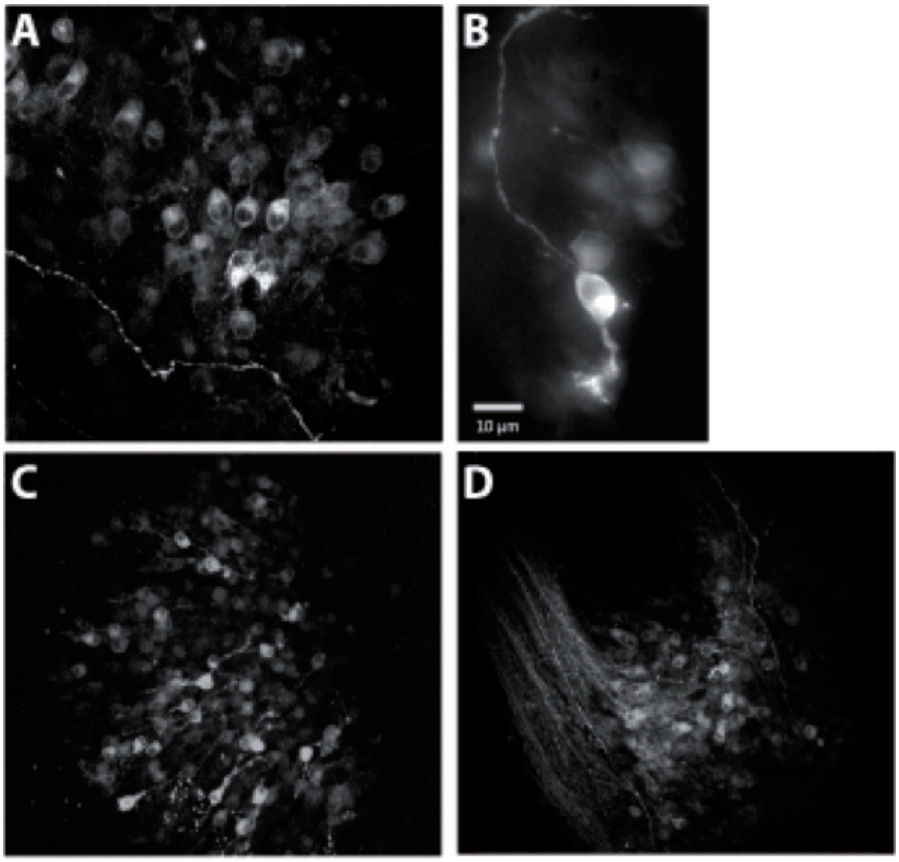
We conducted an exploratory ocular histopathology study in non-human primates to investigate potential ocular toxicity following single bilateral IVT administration of GS030. No ophthalmological signs of intolerance or toxicity, structural modifications or inflammation of the retina were observed up 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 6 months.

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

Irradiance-firing relationship



Expression of ChrR-tdT in midget cells of the perifovea



We are preparing the following studies in order to support the clinical Phase I/II CTA submission:

- A local tolerance study evaluating GS030 in combination with 600 nm light exposure in a mouse model of RP; and
- A long-term toxicity and biodistribution of GS030 GLP study in monkeys.

The first study will assess the phototoxicity of three levels of light intensities in rd1 mice injected with GS030. One dose level of GS030, which is the highest dose, will be combined to a single two-hour exposure to 600 nm light at three levels of intensity in order to cover the intended use in Phase I/II clinical setting. The purpose of the study is 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.

The second study will evaluate 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 will be injected bilaterally. The study will allow us to evaluate 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. This study will be conducted according to GLP regulations.

We submitted a request for a non-clinical scientific advice recommendation from the EMA in April 2016, as well as 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 are currently planning a Phase I/II, open-label, single-center trial to evaluate the safety and tolerability of GS030 and the external wearable medical device in RP patients. This study may be conducted at the *Centre Hospitalier National d'Ophtalmologie des XV-XX* in Paris, France and eventually in other countries upon final advice from our clinical advisory board. The trial will include secondary endpoints that could serve to demonstrate proof of concept of the efficacy of our optogenics 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.

Conceptually, four patient cohorts will be studied. The initial three cohorts will undergo dose escalation to determine the maximal tolerated or feasible dose of GS030. In the fourth cohort, either the maximal tolerated or maximal feasible dose will be administered for safety analysis and proof of concept data collection.

The study is planned to encompass the testing of traditional ophthalmic parameters, such as visual acuity tests and electrophysiology, and also functional vision tests, such as avoiding obstacles or moving in unfamiliar or changing environments. We plan to carry out patient 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.

The study is planned to include adult patients with documented diagnosis of RP. The initial cohorts will enroll RP patients with virtually no light perception. Pending safety outcomes, RP patients 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 patients 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.

Patients may be screened for inclusion with structural and electrophysiology-based assessments for the ability of this visual apparatus to relay signals from photo-activated RGCs to the primary visual cortex utilizing various clinical tools. These include, but are not limited to, electroretinography, or ERG, visual evoked potentials, or VEPs, OCT, fundus autofluorescence and magnetic resonance imaging. Although currently not widely available for clinical use, adaptive optics imaging of the cellular mosaic of the retina is also intended to be included.

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 patients 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 patients. As a result, the time point of gain of efficacy may vary among patients. Improvement will be assessed by whether a patient 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 September 2015, we held an innovation meeting with the French National Regulatory Authority, or ANSM with the objective of obtaining input and guidance on our innovative

GS030 therapeutic approach. We plan, if necessary, to request a follow-up meeting in the form of a scientific advice request to ensure that the future regulatory submission of GS030 will comply with ANSM's expectations for the CTA of the first in human study Phase I/II clinical trial.

In February 2016, we submitted a scientific advice request to the EMA focusing on the non-clinical program with an emphasis on the planned toxicology and tolerance studies. Our objective in seeking this scientific advice was to validate the adequacy of our non-clinical toxicology and safety program designed to support the first-in-man study.

In April 2016, we requested the 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.

The Office of Combination Product of the FDA has informed us that GS030 will be classified as a combination product and determined that the CBER would be the jurisdiction in charge.

In September 2016, GS030 received orphan drug designation and ATMP classification from the EMA for the treatment of RP in the European Union. In January 2017, we received FDA orphan drug designation for GS030 in RP.

We submitted a request for a non-clinical scientific advice recommendation from the EMA in April 2016, as well as a Type-C meeting with the FDA in December 2016, to validate the non-clinical program and future requirements for the device. Both 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 therefore initiated the studies during the fourth quarter of 2016.

We plan to continue this early dialogue to ensure that our development plan, both non-clinical and clinical, will meet the expectation of both the FDA and the EMA for the future development and clinical phase to be conducted in the United States.

Market Opportunity for GS030 in GA

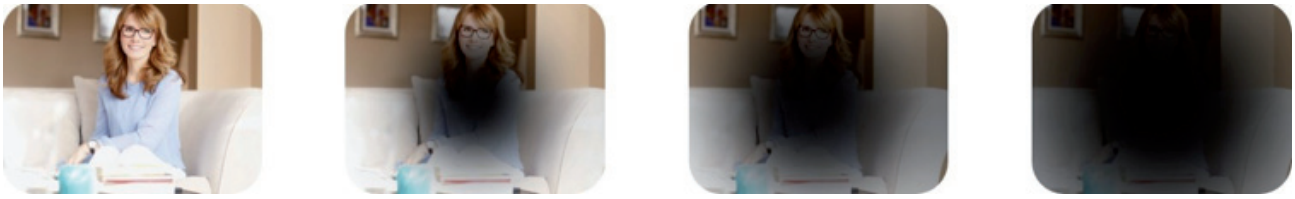
AMD is a degenerative disorder driven by genetic and environmental factors. As its name implies, the disease specifically affects the macula, which is the central retina, while the peripheral retina is spared. Peripheral visual field is usually preserved even in the late stages of the disease. Central vision is essential to read, to perform precise tasks and recognize faces. Retention of peripheral vision allows the patient to maintain some degree of autonomy.

Macular degeneration typically occurs in patients over the age of 55. We estimate that about 15 million patients suffer from AMD in the United States. (Source: Foundation Fighting Blindness, What is macular degeneration?" and American Optometric Association, "Care of the Patient with Age-Related Macular Degeneration.) The early form of AMD is called dry-AMD and evolves over time to late AMD. Late AMD can take two forms, either wet-AMD or GA. However, late-stage AMD patients represent only a fraction of this population, of which about one third are patients suffering from GA. The effect of age on GA is significant, as its prevalence increases significantly in those older than 75, reaching 22% in the population over 90. We believe that there are more than 250,000 patients who are blind from GA in Europe and North America. (Source: AMD Book.org, Geographic Atrophy.)

We believe that GS030 could be used for the treatment of dry-AMD, or GA. Although RP and GA have very different origins, both diseases are characterized by the degeneration of the photoreceptor cells in the patient's retina. Currently, there is no cure for GA.

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

Illustration of Progressive Vision Loss in GA



Once the proof of concept in humans has been demonstrated from the results of our clinical trial in RP patients, we will start developing GS030 for GA patients. Our plan is to demonstrate that GS030 can be used to restore visual perception within the atrophic zone of the central retina. Our pivotal trial will recruit patients with well documented GA and a functional optic nerve. The patients taking part in this trial will receive a single IVT injection and the progression of their central visual acuity will be monitored at six and 12 months.

6.8 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 and all regulatory submission and (iv) oversee, review and control all the methods and protocols used to ensure that the final product meets the quality specifications that we set.

We partner with leading CMOs in gene therapy manufacturing, including Novasep, Lonza and Genethon, 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 either produced using transient triple transfection process or using the baculovirus process. Production is carried out in compliance with cGMP by CMOs that have been certified by national regulatory authorities.

Manufacturing Process Using Transient Triple Transfection

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.

Drug substance is filtered and filled in individual vials. Batches are currently produced at the Genethon Bioprod facility in France in compliance with cGMPs. In anticipation of our commercial needs and process validation, we began implementing the transfer of the manufacturing process to the Henogen S.A., or Henogen facility in Belgium in June, 2015, to ensure both clinical and commercial supply for the European Union and the United States. Henogen is a subsidiary of the Novasep group. 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 GMP.

Manufacturing Process Using Baculovirus Production

The AAV is produced in SF9 insect cells using two recombinant baculovirus vectors. One vector carries the viral genome, 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 rAAV 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 sterile filtered before being placed into individual vials and stored.

We are currently conducting a process development program with Lonza in the United States on a scale that will support non-clinical 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 provides high-quality products and is FDA inspected. Lonza has broad experience in submitting BLAs for biologic products in the United States and regulatory dossiers to other national regulatory authorities in Europe, Canada and Australia among others.

6.9 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.

Most gene and cell therapy products are still in the early stages of development. Except for Glybera, the product being marketed by uniQure and Chiesi Farmaceutici SpA, no other AAV-based gene therapy has been approved. We are aware of several companies focused on developing gene therapies in various other indications, including bluebird bio, Inc., Applied Genetic Technologies Corporation, Asklepios BioPharmaceutical, Inc., Audentes Therapeutics, Inc., Adverum, Dimension Therapeutics, Inc., NightstaRx Ltd, Spark Therapeutics, Inc., uniQure, Voyager Therapeutics, Inc and GlaxoSmithKline.

Competition for GS010 in the Treatment of LHON

While no treatment has received market authorization for the treatment of LHON from the FDA, the Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine in the United States is developing a similar gene therapy approach to GS010 to treat LHON patients. This approach includes the ND4 gene and a mitochondrial targeting sequence but unlike

GS010, does not include the sequence that allows the binding to the surface of the mitochondria as part of their construct, the lack of which we believe is a major drawback. We believe that the ground-breaking nature of our MTS technology platform and our freedom to operate give us an advantage over competitors. The Bascom Palmer Eye Institute recently published data indicating that no serious safety problems had been observed and that some trends in vision acuity improvement had been observed in the first five participants enrolled in the Phase I trial of virus-based gene transfer for this mitochondrial disorder. Additional follow-up studies of these and additional participants planned for the next four years is needed to confirm these preliminary observations. (Source: W Feuer et al. Ophthalmology 2015.)

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. In the study, nine patients were administered rAAV2-ND4by IVT injection to one eye and then followed for nine months. According to the data, the visual acuity of the injected eyes of six patients improved by at least 0.3 LogMAR after nine months of follow-up. In these six patients, the visual field was enlarged but the retinal nerve fiber layer remained relatively stable. None of the nine patients had local or systemic adverse events related to the vector during the nine-month follow-up period. The findings suggest that a single-dose IVT I rAAV2-ND4 injection can be safe and effective. One limitation of this study was the small sample size and the preliminary nature of the findings resulting thereof. A long-term, multicenter, and large-sample size study is necessary to confirm the potential of LHON gene therapy. (Source: Wan, X. et al. Efficacy and Safety of rAAV2-ND4 Treatment for Leber's Hereditary Optic Neuropathy. Sci. Rep. 6, 21587; doi: 10.1038/srep21587 (2016)).

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, or Santhera, in Switzerland using a chemical entity, Idebenone. In September 2015, Santhera announced that the EMA had granted marketing authorization under exceptional circumstances for Raxone/Idebenone as a treatment for LHON with significant post marketing obligations; and
- Stealth Biotherapeutics Inc. using an antioxidant agent known as Ocuvia, which is currently in clinical trials.

Competition for GS030 in the Treatment of RP

Our main competitor in optogenetics for RP is RetroSense Therapeutics, LLC, or RetroSense, which is developing a ChR2-based optogenetic product that will have to utilize blue light to stimulate the ChR2. Retrosense announced the initiation of Phase I studies in March 2016 in the United States. To our knowledge, we are the only company developing a technology to light at near-red wavelength that we believe will offer improved safety features. Retrosense was acquired by Allergan plc in September 2016.

In January 2017, Applied Genetic Technologies Corporation announced the initiation of a strategic collaboration with Bionic Sight LLC to develop an optogenetic therapy using a neuro-prosthetic device to treat retinal diseases causing blindness.

We are aware of other companies and institutions focused on developing other technologies to treat vision loss due to RP, such as gene replacement therapy and small molecule therapeutics, including Genable Technologies Ltd in Ireland, Oxford BioMedica plc in the United Kingdom, Proretina Therapeutics S.L. in Spain, ReGenX Biosciences LLC, in United States and QLT Inc. in the United States.

We are also aware of technologies that stimulate the retina to induce visual perception using electrical stimulation. This technology is being deployed by medical technology companies, such as Second Sight and Pixium Vision, using retinal implants that place electrode arrays on the surface of the retina. However, this approach has several limitations due to the number and size of electrodes that can be implanted in the retina. We believe that our technology has the potential to overcome the current limitations of electrode-based neuronal stimulation.

Competition for GS030 in the Treatment of GA

In addition, no approved therapy currently exists for GA, the leading cause of visual impairment in an aging population in the United States and other developed countries. Most major clinical-stage therapeutic treatments for GA are in the field of cell therapy, except for the clinical development of lampalizumab, an anti-Factor D, which is being led by F. Hoffmann-La Roche Ltd. GlaxoSmithKline plc's anti-amyloid beta mAb for patients with GA is in Phase II clinical trials. Novartis' LFG-315 C5 mAb for patients with GA is in Phase II clinical trials.

6.10 GOVERNMENT REGULATION

We are subject to a variety of laws and regulations in France, the United States and the European Union. 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 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.** Clinical studies are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

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 studies 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 study by signing an informed consent form.

Government Regulation in the European Union

European Union Biological Products Development Process, Including France

In the European Union, 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 in the conduct of clinical trials on medicinal products for human use, or Clinical Trials Directive, as 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 European Union on May 27, 2014.

In France, the Clinical Trials Directive was 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. France adopted several changes to the laws and regulations on clinical trials in 2016.

The Clinical Trials Regulation entered into force on June 16, 2014 and it will take effect six months after the publication of the notice referred to in Article 82(3), but in any event no earlier than May 28, 2016. 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.

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

- 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. 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;

- 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. 2004-806 of August 9, 2004 on public health policy;
- Act No. 2004-801 of August 6, 2004 on data protection (and its implementing decrees);
- Act No. 2002-3003 of March 4, 2002 on rights of patients and on the quality of the healthcare system and its implementing decrees;
- Act No. 78-17 of January 6, 1978 on information, technology and civil liberties, as notably amended by Act No. 2004-801 of August 6, 2004 on data protection and its implementing decrees.

Regulatory authorization/approval required for the conduct of a clinical trial

Under European law, the sponsor may not start a clinical trial until the French ethics committee (*Comité de Protection des Personnes*, or CPP) has issued a favorable opinion and provided that the competent authority of the relevant Member State has not informed the sponsor of any grounds for non-acceptance. The authorization and oversight of clinical trials remains the responsibility of each Member State.

Under French law, a prior authorization issued by the ANSM and a favorable opinion of a competent research and ethics committee of the jurisdiction in which the investigator exercises its activity are required for the conduct of clinical trials, for medicinal products and medical devices.

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 pre-clinical 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 the terms of the abovementioned Decree of April 26, 2006, 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. Finally, under Article L.1123-11, 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, it may at any time request changes to procedures for the realization of research, and suspend or ban this research.

The decision of November 24, 2006 sets forth the rules for good clinical practice, or 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 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.

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.

Regulatory approval of biological products in the European Union

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit an MAA. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity.

If granted, 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 market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

Protection of personal data

Personal data collected during clinical trials should be declared in simplified form to the *Commission Nationale Informatique et Libertés*, or CNIL. Patients then have a right to access and correct this data pursuant to Act No. 78-17 of January 6, 1978, as amended by the abovementioned Act No. 2004-801 of August 6, 2004.

European Union Marketing Authorizations

In the EEA, medicinal products can only be commercialized after obtaining a MAA from the competent regulatory authorities. There are different types of marketing authorizations including:

Centralized Procedure

A centralized MAA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, and is valid in all EU Member States and throughout the entire territory of the EEA.

The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of acquired immune deficiency syndrome, or AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure.

When a medicinal product does not fall within the mandatory scope of the Centralized Procedure, the applicant may use the decentralized procedure or the mutual recognition procedure in order to obtain a marketing authorization in one or more countries in the European Union. In these cases, the competent authorities of the Member States will issue the MAA.

Decentralized Procedure

If the product has not received a national MAA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure.

Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MAA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMSs) for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MAA in all the Member States (*i.e.* in the RMS and the CMSs).

Under the above described procedures, before granting the MAA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Mutual Recognition Procedure

Where a product has already been authorized for marketing in a Member State of the EEA, the existing national MAA can be recognized in another Member States through the mutual recognition procedure.

Regulatory approval of medical devices in the European Union

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. 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.

French Pharmaceutical Company Status

To date, we do not have the status of pharmaceutical establishment, and therefore, cannot either manufacture the product candidates we develop or directly consider their commercialization. Obtaining the pharmaceutical establishment license directly, either as distributor *"exploitant"* or as manufacturer, requires 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.

We currently entrust CMOs with the manufacturing and release by a qualified person of clinical batches and intend to continue relying on CMOs for the production of our commercial batches.

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.

The FDA approval must be obtained before clinical testing of biological products commences, and each clinical study protocol for a gene therapy product is reviewed by the FDA and, in some instances, the NIH, through its RAC. FDA approval also 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.

Within the FDA, CBER regulates gene therapy products. The CBER works closely with the NIH and its 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. Although FDA has not yet approved any human gene therapy product for sale, it has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing subjects involved in gene therapy studies for delayed adverse events, potency testing and chemistry, manufacturing and control information in gene therapy INDs.

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 IND, which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies 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 studies;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with 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 study sites that generated the data in support of the 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; however, NIH recently announced that the RAC will soon only publicly review clinical trials if the trials cannot be evaluated by standard oversight bodies and pose unusual risks.

The clinical study 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 study 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 study can begin. The FDA may impose clinical holds on a biological product candidate at any time before or during clinical studies 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 studies 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 studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study

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 studies 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 study must be reviewed and approved by an IRB at or servicing each institution at which the clinical study 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 studies 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 study subject or his or her legal representative and must monitor the clinical study until completed. Clinical studies 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 studies, sometimes referred to as Phase IV clinical studies, may be conducted after initial marketing approval. These clinical studies 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 study investigators. Annual progress reports detailing the results of the clinical studies 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 studies 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 study 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 study at its institution if the clinical study 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 studies, 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 studies 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. According to the FDA's fee schedule, effective through September 30, 2016, the user fee for an application requiring clinical data, such as a BLA, is $2,374,200. PDUFA also imposes an annual product fee for biologics of $114,450 and an annual establishment fee of $585,200 on facilities used to manufacture 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 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 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 studies 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 studies 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 studies. 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 postmarketing clinical studies, sometimes referred to as Phase IV clinical studies, 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 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 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 studies 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 benfit. 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 postmarketing clinical studies. 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 studies 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 PPACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which 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 study or studies. 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 study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study 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 study. 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 study, 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

If we obtain regulatory approval for any of our product candidates, we may also be subject to healthcare regulation and enforcement by the federal government and the states and other governments in which we conduct our business. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- the Health Insurance Portability and Accountability Act, or HIPAA, as amended by The Health Information Technology for Economic and Clinical Health Act, or HITECH, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of certain protected health information used by or transmitted to certain covered entities or business associates; and
- state and other national law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers; state 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 otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances which may apply more broadly and be more complex, thus complicating compliance efforts.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States, the European Union and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payers. Third-party payers include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payer will pay for the drug product. Third-party payers may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary

or cost-effective. If third-party payers do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. 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. By way of example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, contains provisions that may reduce the profitability of drug products, including, for example, increased the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care plans, addressed a new method by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

Modifications to or repeal of all or certain provisions of the Affordable Care Act are expected as a result of the outcome of the recent presidential election and Republicans maintaining control of Congress, consistent with statements made by Donald Trump and members of Congress during the presidential campaign and following the election. We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.We expect that additional U.S. 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 drug candidates or additional pricing pressures. We expect that the pharmaceutical industry will experience pricing pressures due to the increasing influence of managed care (and related implementation of managed care strategies to control utilization), additional federal and state legislative and regulatory proposals to regulate pricing of drugs, limit coverage of drugs or reduce reimbursement for drugs, public scrutiny and the Trump administration's agenda to control the price of pharmaceuticals through government negotiations of drug prices in Medicare Part D and importation of cheaper products from abroad.

In addition, 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. For example, 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 is negotiated with the Economic Committee for Health Products, or CEPS.

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 studies, commercial sales and distribution of our products, and pricing and reimbursement. The requirements and process governing the conduct of clinical studies, 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.

7

ORGANIZATIONAL CHART

At the date of this Registration Document, we do not hold any subsidiary or have any significant interest in any company.

8

PROPERTY, PLANT AND EQUIPMENT

8.1 SIGNIFICANT EXISTING OR PLANNED PROPERTY, PLANT AND EQUIPMENT

We lease office space, consisting of 656 square meters located in Paris, France. The lease for this facility expires on December 31, 2024. We believe our current office space is sufficient to meet our needs in the immediate foreseeable future and we do not expect any additional needs before 2018.

8.2 ENVIRONMENT AND SUSTAINABLE DEVELOPMENT

Environmental constraints are unlikely to significantly affect our activities. However, sustainable development is a priority for us. We focus our efforts on cost reduction, energy savings and operations that increasingly comply with the principles of sustainable development.

8.2.1 CORPORATE SOCIAL RESPONSIBILITY

Please refer to Section 17.2, "Corporate Social Responsibility" of the Registration Document.

8.2.2 ENVIRONMENTAL RESPONSIBILITY

In order to evaluate and report its impact on the environment, GenSight Biologics has implemented a series of measurement tools.

General policy

Given the nature of its activities, GenSight Biologics is not subject to any environment-specific certification. The Company did not record any provision for risk related to an environmental matter.

Our activities do not include industrial production or distribution, and do not therefore use raw materials. We do not produce significant greenhouse gas emissions.

In this context, the only indicator that is relevant is "business travel."

Pollution and waste management

The activities of the Company do not produce any hazardous waste.

The Company has introduced a separate collection policy to encourage recycling.

Given the nature of its activities, GenSight Biologics does not generate any noise pollution.

Sustainable resources management

The Company's activities consume water and raw materials notably related to the use of printing paper and electricity in a very standard and limited way, generating an impact on the environment that is deemed very low.

These activities do not generate any significant risks for the environment.

Greenhouse gas emission

In 2016, GenSight Biologics implemented measurement tools to evaluate greenhouse gas emissions related to its business travel, which represent by far the greatest contribution to its emissions.

In teqCO_2	2016	2015
Airplane	58.18	63.26
Train	1.13	0.98

Although operating international activities, the Company encourages teleconferencing. When business travel is required, the Company favors, wherever possible, travel by train, which has lower carbon dioxide emissions than air travel. However, many partners of the Company are based in the United States (regulatory agencies, clinical investigators, investors, industrial partners and scientific meetings, etc.), which lowers the opportunities for reducing carbon dioxide emissions apart from teleconferencing.

8.2.3 CORPORATE SOCIETAL RESPONSIBILITY

Territorial, economic and social impact

Given the limited number of employees and the activities of the Company, it has no impact on employment, regional development or on local populations.

Compliance with humane experimental practices on animals

GenSight Biologics subcontracts its experimental research activities on animal models. The Company pays considerable attention to selecting renowned contractors that are certified by AAALAC International, a private non-profit organization that is an international reference in assessing the humane animal treatment in experimentation.

Supplier selection criteria and fairness of practices

The Contract Manufacturing Organisations, or CMOs, with which GenSight Biologics works are selected on the basis of their technological capacity and expertise in executing the requested production activity, as well as on their regulatory compliance with Good Clinical Practices and Good Manufacturing Practices, as described in European and U.S. regulations.

To this end, the Company performs audits of candidate CMOs with a view to assessing the compliance of their practices and systems; audits are also carried out of selected CMOs at a frequency determined during the lifetime of the partnership.

Actions taken to prevent corruption

The Company has carried out an inventory of the geographical location of its main suppliers in order to determine the percentage of its service providers located in countries for which the Corruption Perceptions Index, or CPI, score is above 60.

This inventory reviewed at 13 suppliers, representing 71% of the payments made by the Company in 2016. It indicated that all these suppliers (100%) are located in countries for which the CPI score is above 60.

Steps taken to ensure consumer health and safety

None of the Company's drug candidates is currently on the market or has been granted marketing authorization. Those that are furthest advanced are being tested in humans in the context of clinical trials that are governed by stringent states regulations.

Human rights

GenSight Biologics is developing drugs that may be able to treat diseases with a high medical need. The Company undertakes to respect patients participating in its clinical trials.

Our practices aiming to produce reliable, pertinent and traceable data are controlled through our quality system, which draws on everything from exploratory research to clinical development.

Product reliability is controlled throughout the development process for the drug candidate, and the Company undertakes to maintain the highest standards quality.

The corollary of these commitments is transparency, particularly with regard to patients. Publication of scientific and especially clinical data is a practice shared by all players in the industry, particularly through presentations during specialized conferences, publication on dedicated sites and articles in peer-reviewed journals.

8.2.4 NOTE ON METHODOLOGY

Specific points by indicator

Greenhouse gas: emissions due to energy consumption of buildings, employee travel and annual consumption/recharging of gas coolants used in refrigeration and climate-control groups.

Total personnel: all registered employees at the end of the fiscal year, regardless of type of employment contract (excluding interns, temporary employees and subcontractors).

Total entering/departing: total number of employees entering/departing the company during the year. The eligible population applies to the "total personnel" indicator.

Number of accidents: any accident occurring suddenly due to the fact or occasion of the work and giving rise to official justification is recorded as a work accident.

Rate of absenteeism: the number of days of absences over the theoretical number of days worked. Included are sick leave, absences due to occupational accidents, absences for personal projects.

Grenelle II Concordance Table

Information required by Article R. 225-105-1 of the French Commercial Code	Registration Document	Comment
Employment		
The total workforce and breakdown of employees by gender, age and geographic area	Section 17.2	
New hires and redundancies	Section 17.2	
Remuneration and changes in remuneration	Section 17.2	
Organization of work		
Organization of working hours	Section 17.2	
Absenteeism	Section 17.2	
Labor/management relations		
Organization of staff dialogue, specifically information, employee consultation and employee negotiation procedures	Section 17.2	
Analysis of collective labor agreements	Section 17.2	

Information required by Article R. 225-105-1 of the French Commercial Code	Registration Document	Comment
Health and safety		
Workplace health and safety conditions	Section 17.2	
Analysis of workplace health and safety agreements signed with trade union organizations or employee representatives	Section 17.2	
Workplace accidents, specifically their frequency and severity, and occupational illnesses	Section 17.2	
Training		
Training policies implemented	Section 17.2	
Total number of hours of training	Section 17.2	
Diversity and equal opportunities/equal treatment		
Policy implemented and steps taken to promote gender equality	Section 17.2	
Policy implemented and steps taken to promote hiring and integration of the disabled	Section 17.2	
Policy implemented and steps taken in the area of anti-discrimination	Section 17.2	
Promotion of and compliance with the provisions of basic ILO agreements regarding		
Freedom of association and the right to bargain collectively		The Company complies with the provisions of ILO insofar its part of our legal framework.
The elimination of discrimination in respect of employment and occupation		
The elimination of forced or obligatory labor		
The effective abolition of child labor		
General environmental policy		
Company organization to take environmental issues into account and, as necessary, environmental evaluation and certification processes		Given the Company's activities, GenSight Biologics do not face any environment-specific issue.
Employee environmental protection training and information		
Resources dedicated to preventing environmental and pollution risks		
The amount of provisions and insurance for environmental risks, except if the nature of this information would cause serious harm to the company in connection with on-going litigation	Section 8.2	
Pollution		
Measures to prevent, reduce or remedy discharges into the water, air and soil that have serious environmental effects	Section 8.2	
Consideration of noise and other forms of pollution specific to a particular activity	Section 8.2	
Waste management		
Measures to prevent, recycle and eliminate waste	Section 8.2	
Measures to reduce food wastage	Section 8.2	

Information required by Article R. 225-105-1 of the French Commercial Code	Registration Document	Comment
Sustainable use of resources		
Water consumption and water supplies based on local constraints	Section 8.2	
Consumption of raw materials and steps taken to improve efficiency of use	Section 8.2	
Energy consumption, steps taken to improve energy efficiency and use of renewable energy	Section 8.2	
Land use		Given the Company's activities, this information is not relevant.
Climate change		
Greenhouse gas emissions	Section 8.2	
Adaptation to climate change impacts		Given the Company's activities, this information is not relevant.
Protection of biodiversity		
Steps taken to develop biodiversity		Given the Company's activities, this information is not relevant.
Territorial, economic and social impact of the company's operations		
On employment and regional development	Section 8.2	
On neighboring and local populations	Section 8.2	
Relationships with individuals or organizations affected by the company's operations		
Conditions for dialogue with these individuals or organizations	Section 8.2	
Partnership and sponsorship activities	Section 8.2	
Sub-contracting and suppliers		
Consideration of social and environmental issues in the company's purchasing policy	Section 8.2	
Significance of sub-contracting and consideration, in relationships with sub-contractors and suppliers, of their social and environmental responsibility	Section 8.2	
Fair business practices		
Actions taken to prevent corruption	Section 8.2	
Steps taken to ensure consumer health and safety	Section 8.2	
Human Rights		
Steps taken to support human rights	Section 8.2	

8.2.5 THIRD PARTY'S REPORT ON THE REPORT ON THE COMPANY'S CSR REPORT

S.A. GENSIGHT BIOLOGICS
Head Office: 74, rue du Faubourg Saint-Antoine – 75012 PARIS

REPORT BY ONE OF THE STATUTORY AUDITORS, APPOINTED AS INDEPENDENT THIRD PARTY, ON THE HUMAN RESOURCES, ENVIRONMENTAL AND SOCIAL INFORMATION INCLUDED IN THE MANAGEMENT REPORT

FOR THE YEAR ENDED DECEMBER 31, 2016

This is a free English translation of one of the Statutory Auditors' report issued in French and is provided solely for the convenience of English-speaking readers. This report should be read in conjunction with, and construed in accordance with, French law and professional standards applicable in France.
Report by one of the Statutory Auditors, appointed as independent third-party, on the human resources, environmental and social information included in the management report

To the Shareholders,

In our capacity as Statutory Auditor of GENSIGHT BIOLOGICS, appointed as independent third-party and certified by COFRAC under number 3-1117[1], we hereby report to you on the human resources, environmental and social information for the year ended December 31, 2016 included in the management report (hereinafter named "CSR Information"), pursuant to article L.225-102-1 of the French Commercial Code *(Code de commerce)*.

Company's responsibility

The Board of Directors is responsible for preparing a company's management report including the CSR Information required by article R.225-105-1 of the French Commercial Code in accordance with the protocol used by the Company (hereinafter the "Guidelines"), summarised in the management report.

Independence and quality control

Our independence is defined by regulatory texts, the French Code of Ethics *(Code de déontologie)* of our profession and the requirements of article L.822-11 of the French Commercial Code. In addition, we have implemented a quality control process including documented policies and procedures regarding compliance with the ethical requirements, French professional standards and applicable legal and regulatory requirements.

Statutory Auditor's responsibility

On the basis of our work, our responsibility is to:

- Attest that the required CSR Information is included in the management report or, in the event of non-disclosure of a part or all of the CSR Information, that an explanation is provided in accordance with the third paragraph of article R. 225-105 of the French Commercial Code (attestation regarding the completeness of CSR Information),
- Express a limited assurance conclusion that the CSR Information taken as a whole is, in all material respects, fairly presented in accordance with the Guidelines (conclusion on the fairness of CSR Information).

Our work involved one person and was conducted between September 2016 and March 2017 during a 30 hours period of work.

We performed our work in accordance with the French professional standards and with the order dated May 13, 2013 defining the conditions under which the independent third-party performs its engagement and with the international standard ISAE 3000[2] concerning our conclusion on the fairness of CSR Information.

1 – Attestation regarding the completeness of CSR Information

Nature and scope of our work

On the basis of interviews with the individuals in charge of the relevant departments, we obtained an understanding of the Company's sustainability strategy regarding human resources and environmental impacts of its activities and its social commitments and, where applicable, any actions or programs arising from them.

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

(1) Whose scope is available at www.cofrac.fr.
(2) ISAE 3000 – Assurance engagements other than audits or reviews of historical financial information.

For any information that is not disclosed, we verified that explanations were provided in accordance with article R.225-105, paragraph 3 of the French Commercial Code.

Conclusion

On the basis of the work performed, we attest that the required CSR Information has been disclosed in the management report.

2 – Conclusion on the fairness of CSR Information

Nature and scope of our work

We conducted six interviews with the persons responsible for preparing the CSR Information in the departments in charge of collecting the information and, where appropriate, responsible for internal control and risk management procedures, in order to:

- Assess the suitability of the Guidelines in terms of their relevance, completeness, reliability, neutrality and understandability, taking into account industry best practices, where appropriate,
- Verify the implementation of data-collection, compilation, processing and control process to reach completeness and consistency of the CSR Information and to obtain an understanding of the internal control and risk management procedures used to prepare the CSR Information.

We determined the nature and scope of our tests and procedures according to the nature and importance of the CSR Information with respect to the characteristics of the Company, the human resources and environmental challenges of its activities, its sustainability strategy and industry best practices.

Regarding the CSR Information that we considered to be the most important(1) :

- At the level of the entity, we referred to documentary sources and conducted interviews to corroborate the qualitative information (organization, policies, actions), performed analytical procedures on the quantitative information and verified, using sampling techniques, the calculations and the consolidation of the data. We also verified that the information was consistent and in agreement with the other information in the management report,
- At the level of the single site, we conducted interviews to verify that procedures are properly applied and we performed tests of details, using sampling techniques, in order to verify the calculations and reconcile the data with the supporting documents. Our tests were performed on 100% of the headcounts and 100% of the quantitative environmental data published.

For the remaining consolidated CSR Information, we assessed its consistency with respect to our understanding of the company.

We also assessed the relevance of explanations provided, if needed, for any information that was not disclosed, either in whole or in part.

We believe that the sampling methods and sample sizes we have used, based on our professional judgement, are sufficient to provide a basis for our limited assurance conclusion; a higher level of assurance would have required us to carry out more extensive procedures. Due to the use of sampling techniques and other limitations inherent to information and internal control systems, the risk of not detecting a material misstatement in the CSR information cannot be totally eliminated.

Conclusion

On the basis of the work performed, no material misstatement has come to our attention that causes us to believe that the CSR Information, taken as a whole, is not presented fairly in accordance with the Guidelines.

PARIS, March 15, 2017

One of the Statutory Auditors
BECOUZE

S. BERTRAND
Partner, Sustainability Services

(1) **Social information:** headcount, distribution of employees by gender, age, geographic zone, degrees, type of contracts, net new hires by type of contracts, number of departures, absenteeism rate, number of workplace accidents with absence from work, distribution of working time, total number of hours of training, percentage of women in the staff and in the Board of Directors, percentage of people with disabled worker status in the workforce.
Environmental information: quantity of tons CO_2 equivalent related to travels of the employees.
Societal information: percentage of suppliers located in countries for which the Corruption Perception Index score is above 60.

9

OPERATING AND FINANCIAL REVIEW

The following information concerning our financial condition and results of operations is derived from our financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2016 and should be read in conjunction with our financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal years ended December 31, 2016 included in Section 20.1.1, "Company's Annual Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2016" to this Registration Document.

Our 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 financial statements as of and for the fiscal year ended December 31, 2016. The report of our Statutory Auditors for the financial statements included in this Registration Document is included in Section 20.1.2.

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, 2016:

	2016 (€)
Statutory net loss under French GAAP	***(17,397,676)***
Share-based payments	*(4,634,525)*
Intangible assets	*(18,329)*
Employee benefits	*(31,498)*
Unrealized gains on financial assets	*366*
Net loss under IFRS	***(22,081,663)***

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.

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.

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.

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, 2016 and 2015:

	Year ending December 31,	
	2015 €	2016 €
Statements of income (loss) data:		
Operating income	3,559,998	3,000,665
Operating expenses:		
Research and development	10,722,104	18,529,135
General and administrative	6,499,188	6,490,216
Total operating expenses	17,221,292	25,019,351
Operating income (loss)	(13,661,294)	(22,018,686)
Financial income (loss)	7,674	(62,977)
Net income (loss)	(13,653,620)	(22,081,663)
Basic and diluted earnings (loss) per share[(1)]	(1.21)	(1.36)
Number of shares used for computing basic and diluted earnings (loss) per share	11,239,666	16,252,765

(1) See Note 21 to our financial statements as of and for the fiscal year ended December 31, 2016 for further details on the calculation of basic and diluted earnings (loss) per share.

9.1 OVERVIEW

We are a biotechnology company discovering and developing novel therapies for neurodegenerative retinal diseases and diseases of the central nervous system. To address these therapeutic areas, we leverage our integrated development platform by combining a gene therapy-based approach with our core technology platforms of MTS and optogenetics. Our management and scientific teams have extensive experience in gene therapy and drug development, in particular in the field of ophthalmology, and have served in leadership roles at several innovative ophthalmology companies.

We have never generated any revenues from 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 we expect will take a number of years and is subject to significant uncertainty. To date, we have financed our operations primarily through private placements of ordinary shares and preferred shares, 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 our initial public offering in 2016.

We have incurred operating losses in each year since our inception in April 2012. Substantially 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 4.1, "Risks Related to Our Financial Condition and Capital Requirements." 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 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 others 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 financial statements for the period ended December 31, 2016, such 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, or IFRIC, or the former Standing Interpretations Committee, or SIC.

9.2 FINANCIAL OPERATIONS OVERVIEW

9.2.1 OPERATING INCOME

Our operating income consists of revenues and other income.

9.2.2 REVENUES

To date, we have not generated any revenue from the sale of our products.

Our ability to generate 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 trials. Our lead product candidate, GS010, entered into Phase III trials in the fourth quarter of 2015 and full results are expected by the first half of 2018. Even if the results from such Phase III trials are successful, we do not expect to file for regulatory approval until the second half of 2018. Even if we are able to manage 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.

9.2.3 OTHER INCOME

Subsidies and Conditional Advances

Due to the innovative nature of our product candidate development programs, we have benefited from certain sources of financial assistance from Bpifrance Financement. Bpifrance Financement's mission is to provide assistance and support to emerging French enterprises 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 one non-refundable subsidy from Bpifrance Financement in connection with our development of product candidates using our optogenetics technology platform. Of the €865,000 received in December 2014, we recognized €642,960 and €31,029 for the years ended December 31, 2015 and 2016, respectively, in other income based on research and development expenses incurred as of December 31, 2015 and 2016, as applicable, with the balance recorded in deferred revenue in our statement of financial position.

Funds received from Bpifrance Financement in the form of conditional advances are recognized as financial liabilities, as we are obligated to reimburse Bpifrance Financement for such conditional advances in cash based on a repayment schedule.

For more information with respect to the subsidies and conditional advances, see Section 10.3, "Funding Sources" of this Registration Document.

Research Tax Credits

The CIR is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. 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 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.

The main characteristics of the CIR are the following:

- the CIR results in a cash inflow to us from the tax authorities, *i.e.*, 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 received a reimbursement of the CIR for 2014 during 2015. We requested the reimbursement of the 2015 CIR under the Community tax rules for small and medium-sized companies in compliance with the regulatory texts in effect and we received the reimbursement in December 2016. We have requested the reimbursement of the 2016 CIR in the amount of €2,929,874, which had not yet been received at the date of this Registration Document.

9.2.4 OPERATING EXPENSES

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

9.2.4.1 Research and Development

We engage in substantial research and development efforts to develop innovative pharmaceutical product candidates. Research and development expense consists 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, 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 36 patients for REVERSE in February 2017, and expect to complete enrollment of 36 patients for RESCUE in the second quarter of 2017.
- **GS030:** In 2014 and 2015, we conducted preclinical, proof-of-concept studies with different molecules that led to the definition of GS030. We have initiated GLP, toxicology studies on non-human primates and expect to move GS030 to a Phase I safety and tolerability trial in humans in the third quarter of 2017, subject to regulatory review.

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.

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 4.2, "Risks Related to the Discovery and Development and Regulatory Approval of Our Product Candidates."

9.2.4.2 General and Administrative

General and administrative expenses consist primarily of personnel costs and share-based compensation for personnel other than research and development 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 postal and 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 continued increases 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 investor relations costs.

9.2.4.3 Finance Income (Expense)

Our cash and cash equivalents have been deposited primarily in savings and time deposit accounts with original maturities of six months or less. Given the current level of interest rates,

our savings and deposit accounts generate a modest amount of interest income. We expect to continue this investment philosophy.

Our financial expenses exclusively relate to foreign currency losses related to the purchase of services denominated in U.S. dollars.

9.2.4.4 Sales and Marketing

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, especially as it relates to the sales and marketing of our product candidates.

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

9.2.5 CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our 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 financial statements for the period ended December 31, 2016 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. We issued 268,235 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 *Share-based Payment*, or IFRS 2, 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 was 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 is 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 amount of the conditional advances granted was €5,685,975, of which €678,000 was received in December 2014 and €2,278,914 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 €6,490,000. Following the repayment of the conditional advances, we may be required to make additional payments over a period of two years of up to €2.72 million, depending on whether we reach cumulative revenues, excluding taxes, of €80 million by 2029. See also Note 10.1 to our audited financial statements for the year ended December 31, 2016. 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 financial statements for the conditional advances may be reduced. The current and non-current portions of the financial liability recognized in our financial statements associated with these conditional advances are determined based on the applicable reimbursement schedules at the end of each reporting period. 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. In addition, in the case of conditional advances, we treat the benefit resulting from the low interest nature of the award as a subsidy and recognize this amount as other income over the applicable repayment period. We determine the amount of this deemed subsidy amount by applying a discount rate equal to the rate of fungible treasury bonds over the time period that corresponds to the time period of the repayment of the advances.

Share-Based Compensation

We have granted share-based warrants in the form of BCE and BSA, and performance shares in the form of AGA, since July 8, 2013 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

Grant date	Number of shares granted	Ordinary share fair market value per share at grant date
July 26, 2016	766,000	€8.000

We account for share-based compensation in accordance with the authoritative guidance on share-based compensation. 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.

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 trading history for our ordinary shares, 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 French 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 granted during the periods presented:

	As of December 31,	
	2015	2016
Volatility	76.49%	62.46%
Risk-free interest rate	1.09%	-0.5%
Expected life (in years)	10 years	3.73 years
Dividend yield	— %	— %

Fair Value of Our Ordinary Shares. Prior to the listing of our ordinary shares on Euronext Paris, we were required to estimate the fair value of our ordinary shares. Therefore, our Board of Directors estimated the fair value of our ordinary shares contemporaneously, with input from management, considering our most recently available independent third-party valuations and the board's assessment of additional objective and highly subjective factors that it believed were relevant.

The method used to determine the fair value of the ordinary shares at each grant date on July 8, 2013, April 9, 2014, December 3, 2014, and July 8, 2015 was an income approach based on discounted cash flows. This method involves estimating future cash flows, based on the expected stage of development for our products candidates, the related amount of research and development expenditures to be incurred as well as the degree of completion of significant development milestones. These assumptions, along with the discount rate used and the estimated market size for our product candidates and the population of patients, are highly complex and subjective variables. For the grants dated as of December 3, 2014 and July 8, 2015, the determination of the fair value of our ordinary shares was performed using a hybrid method, in accordance with the Accounting and Valuation Guide *Valuation of Privately-Held Company Securities Issued as Compensation* of the American Institute of Certified Public Accountants. The hybrid method is a hybrid of the probability-weighted expected return method, or PWERM, and the Option-Pricing Method, or OPM. Specifically, the value of the ordinary shares is estimated based upon an analysis of values assuming various future outcomes (low or high probability of the occurrence of an initial public offering or delayed exit), using specific estimated total equity values for the low and high probability initial public offering scenarios, and a lower equity value based on the income approach with the OPM to allocate this value across the various securities. The share value is based upon the probability-weighted present value of values allocated to each security.

On July 7, 2015, we sold 4,624,871 Series B preferred shares for an aggregate purchase price of €32,142,855 in a private placement. The fair value of a Series B preferred share has been estimated to be €6.95 per share based on agreed-upon terms between us and potential investors, the negotiation of which was finalized early May 2015.

As of July 8, 2015, based on an independent third-party valuation expert, the fair value of our ordinary shares was €7.80 per ordinary share, an increase of €5.65 per ordinary share, from €2.15 as of December 31, 2014. The increase was driven primarily by our consideration of the pre-money valuation of our Series B share financing and was also impacted by assumptions regarding the increased probability that we would complete an initial public offering in the near-term in addition to certain other assumptions regarding the timing, value and probability of other scenarios.

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

9.3 RESULTS OF OPERATIONS

Comparisons for the Years Ended December 31, 2015 and 2016

Operating Income

We generated operating income of €3,559,998 in 2015 and €3,000,665 in 2016, a decrease of 16%. Income was exclusively generated by our CIR and by subsidies received from Bpifrance Financement for research projects conducted by us.

	As of December 31,	
	2015 €	2016 €
Revenues	—	—
Other income	3,559,998	3,000,665
CIR	2,874,069	2,929,874
Subsidies	685,929	70,791
Total operating income	**3,559,998**	**3,000,665**

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 the year ended December 31, 2015, we recorded other income related to CIR of €2,874,069, which was reimbursed in cash in December 2016. The €911,682 of CIR recorded in 2014 was received in cash in 2015. We requested the reimbursement of the 2016 CIR in the amount of €2,929,874, which has not been received at the date of this Registration Document.

The decrease in Other income recorded in 2016 was mainly due to the subsidy received in December 2014 from Bpifrance Financement, and recognized *prorata* in 2014, 2015 and 2016.

Research and Development Expenditures

From 2015 to 2016, the total amount spent by us for research and development activity increased from €10,722,104 to €18,529,135, or an increase of 73%.

Our research and development expenses in the periods presented, 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 36 patients for REVERSE in February 2017, and expect to complete enrollment of 36 patients for RESCUE in the second quarter of 2017.
- **GS030:** In 2014 and 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 prior to moving GS030 to a Phase I safety and tolerability trial in humans in the third quarter of 2017, subject to regulatory review.

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.

	As of December 31,	
	2015 €	2016 €
Personnel expenses(1)	3,066,853	4,375,276
Sub-contracting, collaboration and consultants	6,449,199	11,357,583
Licensing and intellectual property	173,340	1,075,087
Real estate property rental	628,442	615,111
Conferences and travel expenses	245,289	814,610
Allowance for amortization and depreciation	111,597	173,172
Others	47,383	118,296
Total R&D expenses	**10,722,104**	**18,529,135**

(1) Includes €579,687 and €1,846,464 related to share-based compensation expense for 2015 and 2016, respectively.

The increased expenditures from year to year resulted from:

- a 43% increase of total payroll dedicated to research and development, resulting in both an increase in staff from 17 employees at the end of 2015 to 20 employees at the end of 2016, and in share-based compensation expense related to granting warrants to employees. Excluding these non-cash share-based compensation expenses, total payroll dedicated to research and development increased by 2%;
- a 76% increase in subcontracting and collaborations that includes the costs of service providers in connection with conducing manufacturing, non-clinical and clinical studies in 2016, and in particular, conducting our two Phase III trials for GS010;
- a 520% increase in licensing and intellectual property that primarily relates to milestone payment in 2016 in connection with one of our license agreements; and
- a 232% increase in travel expenses, exclusively due to providing travel arrangements and accommodation for patients enrolled in RESCUE and REVERSE Phase III trials of GS010.

Excluding non-cash share-based compensation expense, research and development expenditures increased from €10,142,417 to €16,682,671, or an increase of 64%.

General and Administrative Expenses

During the period presented, our general and administrative expenses remained stable at €6,490,216 in 2016, compared to €6,499,188 in 2015.

In 2015, general and administrative expenses included approximately €2.9 million of non-recurring legal, audit and professional services related to the proposed initial public offering on the NASDAQ in 2015, that were not deducted from shareholders' equity as the operation was cancelled, and therefore recognized as expenses.

Excluding these non-recurring expenses in 2015 and non-cash share-based compensation expenses, general and administrative expenditures increased from €2,622,361 to €3,702,155, or an increase of 41%. This increase primarily related to costs 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 corporate communications and investor relations costs.

Our general and administrative expenses are broken down as follows:

	As of December 31,	
	2015 €	2016 €
Personnel expenses[1]	2,047,893	4,532,907
Fees[2]	3,273,420	698,830
Communication and travel expenses	744,546	683,579
Real estate property rental	202,192	198,350
Office furniture and small equipment	43,516	64,439
Postal and telecommunication expenses	59,387	84,168
Allowance for amortization and depreciation	27,072	29,396
Directors attendance fees and expenses	34,713	85,900
Insurance and banking fees	26,394	79,309
Equipment rental	19,296	20,671
Others	20,760	12,667
Total G&A expenses	**6,499,188**	**6,490,216**

(1) Includes €952,189 and €2,788,061 related to share-based compensation expense as of December 31, 2015 and 2016, respectively.
(2) Includes €2.9 millions of legal, audit and professional services related to the proposed initial public offering on the NASDAQ in 2015.

Our general and administrative expenses consist primarily of salaries and related costs for personnel and travel expenses for our employees in executive, operational, finance, legal and human resources functions, facility-related costs, as well as audit, legal, regulatory and tax-related services associated with maintaining compliance with Euronext Paris listing and AMF requirements, director and officer insurance premiums, and corporate communications and investor relations costs.

Financial Income (Loss)

Our net financial profit (loss) decreased to €(62,977) in 2016 from €7,674 in 2015. Our financial income decreased to €26,491 in 2016 from €41,308 in 2015, primarily due to the current low interest rates despite an increase of cash and cash equivalents, and we generated foreign exchange losses of €58,225 in 2016 related to the purchase of services denominated in foreign currencies, primarily in U.S. dollars.

10

CAPITAL RESOURCES

10.1 OVERVIEW

We have financed our operations since inception primarily through private placements of equity securities raising a total of €91.7 million net of transaction-related costs as of December 31, 2016 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, and 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.

10.2 ANALYSIS OF CASH FLOW

The table below summarizes our sources and uses of cash for the years ended December 31, 2015 and 2016:

	As of December 31,	
	2015 €	2016 €
Net cash flows from operating activities	(12,094,553)	(19,641,790)
Net cash flows from investment activities	617,449	(170,454)
Net cash flows from financing activities	30,867,543	43,734,547
Net (decrease)/increase in cash and cash equivalents	**19,390,439**	**23,922,303**

Our net cash flows from operating activities were (€19,641,790) and (€12,094,553) for 2016 and 2015, respectively.

During 2016, our net cash flows from operating activities increased due to our growing efforts in advancing our research and development programs, mainly GS010, that progressed through two Phase III trials in the fourth quarter of 2015. Our net cash from operating activities in 2016 consisted primarily of a net loss of €(22,081,663) adjusted for non-cash items, including share-based payments of €4,634,525, retirement pension obligations of €31,498 and amortization and depreciation of €202,712.

Changes in working capital amounted to €(2,428,718) and €(128,877) for 2016 and 2015, respectively. The significant items in the change in working capital in 2016 include a decrease in accounts payable of €(3,458,603) primarily due to accrued expenses in 2015 of €2.1 million related to our proposed initial public offering on NASDAQ. This item was partially offset by a decrease in other receivables of €(972,759) mainly related to CIR and VAT claimed reimbursements, as well as prepaid expenses.

Our net cash flows from investment activities were €(170,454) and €617,449 in 2016 and 2015, respectively. This increase mainly reflects the sale of short-term investments, as a result of managing our cash surplus, in 2015 partially offset by the cost of refurbishing our new premises in 2015.

Our net cash flows from financing activities increased to €43,734,547 in 2016 from €30,867,543 in 2015, due to net proceeds received in our initial public offering on Euronext Paris in July 2016.

10.3 FUNDING SOURCES

During 2015 and 2016, we obtained new financing by issuance of securities and receipt of conditional advances and a non-refundable subsidy from Bpifrance Financement.

	Equity capital	Conditional advances	Subsidies	Total
2014 (including financing and advances received prior to 2014)	€19,442,555	€678,000	€865,000	€20,985,555
2015	€30,867,543	–	–	€30,867,543
2016	€41,434,289	€2,278,914	–	€43,713,203
Total	**€91,744,387**	**€2,956,914**	**€865,000**	**€95,566,301**

On July 7, 2015, we sold Series B preferred shares for which we received net proceeds of €30,837,294 in a private placement.

On July 8, 2015, we issued warrants for which we received proceeds of €30,250.

On July 13, 2016, we sold ordinary shares for which we received net proceeds of €36,428,635 in our initial public offering on Euronext Paris.

On August 10, 2016, we sold ordinary shares for which we received net proceeds of €5,010,763 after exercising the overallotment option in connection with our initial public offering on Euronext Paris.

On September 3, 2016, we sold ordinary shares for which we received net proceeds of €2,800 in connection with the exercise of share warrants.

On October 6, 2016, we sold ordinary shares for which we received net proceeds of €4,068 in connection with the exercise of share warrants.

On October 31, 2016, we issued warrants for which we received proceeds of €133,250.

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 amount of the conditional advances granted was €5,685,975, of which €678,000 was received in December 2014 and €2,278,914 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 payment schedule for conditional advances under the program is summarized below:

- €678,000 received in December 2014;
- €2,278,914 received in July 2016[(1)];
- €494,000 to be received in November 2017;
- €852,975 to be received in November 2018; and
- €986,000 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 €6,490,000, including interest at an annual rate of 1.44%, is as follows:

- €550,000 on or before June 30, 2022;
- €1,000,000 on or before June 30, 2023;
- €1,500,000 on or before June 30, 2024;
- €1,700,000 on or before June 30, 2025; and
- €1,740,000 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 €2.72 million, depending on whether we reach cumulative revenue, excluding taxes, of €80 million by 2029. 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 will meet with us to assess the impact on the repayments and the repayment schedule.

Bpifrance Financement non-refundable subsidy

We have been granted a total of €1,147,471 in non-refundable subsidies as follows:

- €865,000 received in December 2014;
- €172,471 to be received in November 2018; and
- €110,000 to be received in November 2019.

The table below summarizes the subsidies and conditional advances as of December 31, 2016:

In euros	Entitled	Granted	Repayed	To be granted
Conditional advances	5,685,975	2,956,914	–	2,729,061
Subsidies	1,147,471	865,000	–	282,471
Total	**6,833,446**	**3,821,914**	**–**	**3,011,532**

(1) The estimated amount from the initial payment schedule was €2,675,000. The costs occurred by Company amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.

10.4
PRINCIPAL USES OF CASH

10.4.1 CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table discloses aggregate information about our material contractual obligations as of December 31, 2016 and the amount of future payments under these agreements:

	Total €	Less than one year	One to three years	Four to five years	More than five years
Conditional advances	2,956,914	–	–	–	2,956,914
Pension and employee benefits	72,967	–	–	–	72,967
Rental agreements	5,170,962	751,825	2,216,546	1,468,394	734,197
Collaborations and licensing arrangements	1,105,932	1,014,387	91,545	–	–
Total	**9,306,775**	**1,766,212**	**2,308,091**	**1,468,394**	**3,764,078**

On January 1, 2015, we entered into a lease agreement for our new premises with SAS Passage de l'Innovation, which was amended on January 1, 2016. Pursuant to this agreement, we will pay €734,197, excluding taxes, on an annual basis for rent, rental charges and other services provided by the lessor through the end of 2023.

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.

10.4.2 OPERATING CAPITAL REQUIREMENTS

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until the end of 2018. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. In any event, we have to raise additional capital to pursue preclinical and clinical activities, obtain regulatory approval for, and to commercialize our product candidates.

Until we can generate a sufficient amount of revenue from our product candidates, if ever, we expect to finance our operating activities through our existing liquidity.

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 Registration Document entitled Section 4 "Risk Factors."

10.4.3 CAPITAL EXPENDITURES

Our main capital expenditures in 2015 and 2016 were related primarily 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,	
	2015 €	2016 €
Licenses, software	7,517	1,047
Property, plant and equipment	704,961	188,177
Non-current financial assets	79,545	(7,770)
Total	**792,023**	**181,454**

In 2015, our capital expenditures primarily related to equipping and refurbishing our headquarters. We also paid a deposit to the lessor for its registered office, which has been recognized as Non-current financial assets as of December 31, 2015.

In 2016, our capital expenditures primarily related to equipping our headquarters and providing office and IT equipment.

As of December 31, 2016, we have no material contractual commitments to acquire property, plant or equipment.

11

RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

11.1 OVERVIEW

We engage in substantial research and development efforts to develop innovative product candidates. Research and development expense consists 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 36 patients for REVERSE in February 2017, and expect to complete enrollment of 36 patients for RESCUE in the second quarter of 2017.
- **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 and expect to move GS030 to a Phase I safety and tolerability trial in humans in the fourth quarter of 2017, subject to regulatory review.

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 4.2, "Risks Related to the Discovery and Development and Regulatory Approval of Our Product Candidates" of this Registration Document.

11.2 RESEARCH AND DEVELOPMENT EXPENDITURES

From 2015 to 2016, the total amount spent by us for research and development activity increased from €10,722,104 to €18,529,135, or an increase of 73%.

Our research and development expenses for the periods presented, and for the current period to date, mainly relate to GS010 and GS030, see Section 9, "Operating and Financial Review – Research and Development" of this 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, 2015 and 2016:

	As of December 31,	
	2015 (€)	2016 (€)
Personnel expenses[1]	3,066,583	4,375,276
Sub-contracting, collaboration and consultants	6,449,199	11,357,583
Licensing and intellectual property	173,340	1,075,087
Real estate property rental, net	628,442	615,111
Conferences and travel expenses	245,289	814,610
Allowance for amortization and depreciation	111,597	173,172
Others	47,383	118,296
Total R&D expenses	**10,722,104**	**18,529,135**

(1) Includes €579,687 and €1,846,464 related to share-based compensation expense for 2015 and 2016, respectively.

11.3 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 specialities 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)** is 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,** PhD, 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,** PhD, 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 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.

11.4 COLLABORATION, PARTNERSHIP AND RELATED AGREEMENTS

To our knowledge, as of the date of this 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:

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 to research, develop and commercialize selected research and development projects for gene therapy products within specific ocular indications using technology licensed by us under a license agreement with Inserm Transfert dated October 12, 2012. Under the terms of the partnership agreement, we and Genethon agree not to collaborate with any third-party or to develop internally any product(s) the subject of the agreement, without the prior written consent of the other party.

  The partnership agreement establishes a strategic committee comprising two duly authorized representatives of each of Genethon and us, whose purpose is, *inter alia*, to identify and determine whether to pursue a given research and development project. Once the strategic committee has determined to pursue a research and development project, the parties negotiate and enter into a corresponding project addendum, which will set forth the specific conditions applicable to the specific research and development project. As of the date hereof, we have entered into two addenda with Genethon with respect to the LHON research program.

- 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.

Agreements Relating to GS030

Friedrich Miescher Institute

Research Collaboration Agreement Relating to the Development and Testing of Optogenetic Tools (GS030)

- Object:

  On March 1, 2014, we entered into a research collaboration agreement with the FMI, under which the parties agreed to collaborate in research comprising the design, planning and carrying out of experiments on different animal models with the aim of testing new therapeutic approaches, including the development and testing of optogenetic tools.

- Financial obligations:

  Under the terms of this research collaboration agreement, we agreed to pay €111,240 to FMI in each of 2014, 2015, 2016 and 2017 as a contribution to the cost of the research work.

- Proprietary rights:

  Under the agreement, research materials developed using our research materials or developed jointly by us and FMI in the course of the research project will be jointly owned. Under certain circumstances, when the research materials are owned and developed solely by FMI, we will have an option to obtain a worldwide exclusive or non-exclusive license, with the right to create sub-licenses to affiliates, including the right to use the materials in research and to make, to make use of or to sell such materials.

- Term and termination:

  Either party may terminate the research collaboration agreement in the event that the other party materially breaches the agreement where such breach remains uncured for 15 days after written notice from the non-breaching party. The provisions relating to our rights to use the inventions created by the agreement shall survive termination of the agreement. Pursuant to an amendment signed in March 2017, the agreement shall now remain in force until February 28, 2018, subject to prior termination.

Sight Again Program

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

- Object:

  In July 2014, we entered into a consortium agreement with Pixium Vision, a company based in France that develops vision restoration systems and 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 *pro rata* 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 €50,000 per company, and shall expire when the cumulated amount of royalties paid reaches a total of €500,000.

- 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 agreement, reach cumulated revenues of €80 million (excluding taxes) we shall be required to make an additional payment to Bpifrance Financement of a maximum aggregate amount of €2.72 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. The parties have supplemented the agreements to include provisions relating to the development of GS030.

Agreements Relating to GS010 and GS030

Institut de la Vision

Framework Agreement Relating to Research and Development in Ophthalmic Diseases (GS010 and GS030)

- Object:

  In December 2013, we entered into a framework agreement with Université Pierre et Marie Curie, *Institut National de la Santé et de la Recherche Médicale*, *Centre National de la Recherche Scientifique* and *Centre de Recherche Institut de la Vision* under which the parties agree to create a partnership in the field of research and development in ophthalmic diseases.

  The framework agreement covers research activities, such as research on small molecules, proteins and expression of therapeutic genes, the study of therapeutic candidates on which we hold rights, cooperation in the field of sight restoring strategy by means of an optogenetic approach for persons suffering from RP or GA, in the field of mitochondria and therapeutic genetic remedies of LHON and by a transfer of biological equipment.

- Financial obligations:

Under the terms of this framework agreement, as amended, we agree to pay €2,275,920, excluding taxes, through March 14, 2018, in consideration for the specific research and development activities undertaken by the laboratory and the exclusive right of use in the field granted to us by our partners on joint results.

- Term and termination:

Either party may terminate this cooperation agreement in the event that the other party materially breaches or defaults in the performance of any of its material obligations, where such breach continues for one month after written notice of the non-breaching party. Either party is entitled to terminate this framework agreement in the event that we cease business operations or become the subject of a voluntary or involuntary petition in bankruptcy.

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.

11.5 INTELLECTUAL PROPERTY

11.5.1 IN-LICENSE AGREEMENTS

To our knowledge, as of the date of this 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 Relating to Patents Used in Connection with 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 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 the right to practice and use the know-how for any purposes as well as the patent rights and biological material for any purposes outside the treatment of ocular diseases in humans (including mitochondrial diseases of the ocular area). 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; (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; or (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.

Association Française contre les Myopathies

License Agreement Relating to Scientific Data Used in Connection with 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.

Under the agreement, AFM, Inserm, Genethon and UPMC, or 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 €10,000. We also are obliged to make milestone payments ranging from €12,500 to €375,000 upon the achievement of certain development, regulatory and commercial milestone events. We have paid the licensors €187,500 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; or (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.

Agreements Relating to GS030

Adverum Biotechnologies (formerly Avalanche Biotechnologies)

License Agreement Relating to Patents Used in Connection with 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 $50,000 to Adverum for each such extension.

- Financial obligations:

  We paid Adverum a one-time license fee of $30,000 in addition to $145,000 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 $30,000 per year, together with an annual license maintenance fee of $30,000 (minus the patent expenses paid in the prior year). Further milestone payments on a product-by-product basis are expected, upon the achievement of certain late milestone events.

  Further, upon the sale of any products or services licensed under the Adverum agreement, we are required to pay to Adverum our 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 our agreement with the Regents had it not been terminated.

Massachusetts Institute of Technology

License Agreement Relating to Patents Used in Connection with GS030

- Object:

  On January 4, 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. 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 in the retina, of the ChrimsonR and photoactivatable halorhodopsin protein (known as Jaws) gene expression sequences, 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 $45,000, license maintenance fees up to $100,000 per year and variable payments up to $7,300,000 depending on the achievement of milestone events. We also agreed to pay running mid-single-digit royalties on future net sales.

11.5.2 OWNED AND IN-LICENSED INTELLECTUAL PROPERTY

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 6.10, "Government Regulation" of this 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.

We have in-licensed numerous patents and patent applications. We also possess significant know-how and trade secrets relating to our product candidates. Our rights to intellectual property, whether in-licensed or 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.

Patents and Patent Application Families Relating to Our Two Lead Product Candidates

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 (US'740: accelerated examination ongoing)
RP (GS030)	University of California (Adverum)	Adeno-associated virus virions with variant capsid and methods of use thereof	2032	Australia, Canada Singapore, Israel, China, European Union, Korea, Japan, United States (2x), Russia, Mexico	Examinations pending worldwide Allowed in Europe
RP (GS030)	M.I.T.	Channelrhodopsins for optical control of cells	2032	Korea, United States, European Union, Hong Kong	United-States: pending European Union: pending

At least 25 patent applications that we in-license have been filed in the United States and other jurisdictions by or on behalf of our licensors. To date, four patents from these applications have been issued.

The patent application family we in-license from Adverum relates to AAV virions with altered capsid protein 7m8 AAV. One U.S. patent issued in 2015 and one application in this family is pending in the United States, and corresponding patent applications are pending in Australia, Canada, Europe, Israel, Japan, South Korea, China, Mexico, Singapore, Russia and Hong Kong. The European Patent Office issued notice of allowance in early 2017. Patents that grant from this patent family are generally expected to expire in 2032, subject to possible patent term extensions.

The patent application family we in-license under our license agreement with Inserm Transfert relates to allotropic expression of mitochondrial genes and products and methods relating to mitochondrial trafficking. Within this patent family, one U.S. patent issued in 2015, one divisional application is pending with the USPTO and one European patent issued in 2015. Patents that grant from this patent family are generally expected to expire in 2025, subject to possible patent term extensions.

The patent applications we in-license under our license agreement with M.I.T. are pending in the United States, Europe, Hong Kong and South Korea. The U.S. patent covering the Jaws gene expression sequences to which we have a license under the agreement issued in 2015. Patents that grant from this patent family are generally expected to expire in 2032, subject to possible patent term extensions.

We filed three priority patent applications in 2016 which will be filed worldwide in 2017:

Product candidate	Owner	Title	Patent Application Number	Filing date	Current status
RP (GS030)	GenSight Biologics	Optogenetic visual restoration using chrimson r	US62/329692	29/04/2016	Priority year
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	Priority year
RP (GS030)	GenSight Biologics UPMC CNRS INSERM	Medical device intended to be worn in front of the eyes	EP16306005.6	02/08/2016	Priority year

The "GenSight" trademark is registered in France in connection with our business and we have filed an application for a Community Trade Mark covering all 28 member states of the European Union. We may, in the future, file additional applications to register this trademark in other territories and/or file applications for other trademarks in certain markets of interest. See Section 4.8, "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 20.5, "Legal and Arbitration Proceedings" of this Registration Document.

In addition to the above, we have capabilities focused in the areas of preclinical research and development, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation. We believe that such capabilities, together with our expertise, will help us develop products based on our proprietary intellectual property.

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TREND INFORMATION

12.1
MOST SIGNIFICANT RECENT TRENDS SINCE THE END OF THE LAST FINANCIAL YEAR

Please refer to Section 20.6, "Significant Change in Financial or Trading position" of the Registration Document.

12.2
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.

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PROFIT FORECASTS OR ESTIMATES

We have elected not to include a profit forecast or a profit estimate in this Registration Document.

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ADMINISTRATIVE, MANAGEMENT AND SUPERVISORY BODIES AND SENIOR MANAGEMENT

14.1 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 16, "Board Practices" and in Section 21, "Additional Information" of this Registration Document.

14.1.1 DIRECTORS AND OFFICERS

Since the listing of our shares on Euronext Paris, Mr. Florent Gros and Mr. Earl Collier have resigned from their director positions and Bpifrance Participations, represented by Ms. Maïlys Ferrère, and Ms. Simone Seiter, 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 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	2018	Chief Executive Officer Director Co-Founder	Position and offices held as of the date of this Registration Document: • Chairman of the Board of Directors of Pixium Vision S.A., BrainEver SAS, Gecko Biomedical S.A., Chronocam 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. • Senior Vice President of the Ophthalmology Division of Sanofi 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 and Kutexis
Michael Wyzga	2018	Chairman of the Board of Directors Independent Director	Position and offices held as of the date of this Registration Document: • 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 and member of the audit and compensation committees of Exact Sciences Corporation • Member of the Board of Directors and chair of the audit committee of OncoMed Pharmaceuticals, Inc. Position and offices held during the last 5 years that are no longer held: • President and Chief Executive Officer and member of the Board of Directors of Radius Health, Inc. • Executive vice president, Finance and chief financial officer at Genzyme Corporation • Served as a member of the supervisory board of Prosensa Holding B.V.
Thomas Gidoin	–	Chief Financial Officer	Position and offices held as of the date of this Registration Document: Position and offices held during the last 5 years that are no longer held: • Vice president Finance at DBV Technologies S.A. • Ipsen S.A. (UK Operations Controller in London and Senior Financial Analyst in the Global Operations Division in Paris)

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
Nitza Thomasson	–	Chief Pre-Clinical Officer	Position and offices held as of the date of this Registration Document: • Head of Development at Gecko Biomedical • President of NTZ Consulting SAS Position and offices held during the last 5 years that are no longer held: • Director of the Preclinical Department at Sanofi S.A. Ophthalmology Business Division
Didier Pruneau	–	Chief Scientific Officer	Position and offices held as of the date of this Registration Document: Position and offices held during the last 5 years that are no longer held: • Head of the Scientific Evaluation and Drug Discovery Ophthalmology Division at Sanofi S.A.
Peter Goodfellow	2017	Independent Director	Position and offices held as of the date of this 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. Position and offices held during the last 5 years that are no longer held: • Director of the Muscular Dystrophy Group
Genghis Lloyd-Harris	2019	Director	Position and offices held as of the date of this Registration Document: • Partner at Abingworth • Serves on the Board of Directors of Avillion LLP, Wilson Therapeutics AB and Abingworth Position and offices held during the last 5 years that are no longer held: • Served on the Board of Directors of Syntaxin Ltd.
Simone Seiter	2020	Independent Director	Position and offices held as of the date of this Registration Document: • Vice President at QuintilesIMS Position and offices held during the last 5 years that are no longer held:
Guido Magni	2019	Director	Position and offices held as of the date of this Registration Document: • Partner with Versant Ventures • Serves on the Board of Directors of Nouscom GmbH, Aprea AB, Piqur Therapeutics AG, Tardeva and AM Pharma B.V. Position and offices held during the last 5 years that are no longer held: • Managing Director of EuroVentures, a Versant incubator • Member of the Board of Directors of Adolor, US, Mosaic Biomedicals and Biotie
Maïlys Ferrère	2019	Director	Position and offices held as of the date of this Registration Document: • Serves on the Board of Directors of DBV Technologies S.A., Valneva SE, Pixium Vision S.A. and Euronext Paris Position and offices held during the last 5 years that are no longer held: • Member of the Board of Directors of Novasep and Groupe Limagrain Holding S.A.

(*) 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 *(mandataire social)* of the Company.

14.1.2 BIOGRAPHICAL INFORMATION ABOUT THE MEMBERS OF THE BOARD OF DIRECTORS AND OFFICERS OF THE COMPANY

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 from which date he has served as non-executive Chairman of the Board of Directors. 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 S.A. 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 is our Chief Financial Officer. 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 at 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.

Nitza Thomasson, Ph.D. After 6 years of academic research (PhD in cognitive neurosciences, La Salpêtrière - Paris and Rush Hospital - Chicago), Nitza joined the pharmaceutical industry in 2001 and spent 7 years at Servier Pharmaceuticals as Head of Biological Studies in Neurospychiatry Department. Early 2009, she joined Fovea Pharmaceuticals, that became Sanofi Ophthalmology Business Division, as Director of Preclinical Department to lead CMC, DMPK, toxicity regulatory program and First into man study. In 2013, she started GenSight Biologics, a gene therapy company dedicated to rare ophthalmic diseases. As Chief Preclinical and CMC Officer, she leads development programs up to first clinical studies (including manufacturing, tox & biodistribution, clinical and regulatory activities).

Didier Pruneau, Ph.D., is our Chief Scientific Officer. From 1983 to 2005, Dr. Pruneau was Head of the Department of Pharmacology at Fournier Pharma, then, from 2006 to 2009, he was Head of Scientific Operations at Fovea, and then from 2009 to 2013, Head of the Scientific Evaluation and Drug Discovery Ophthalmology Division at Sanofi. Dr. Pruneau has expertise in pharmacology of G-protein coupled receptors, nuclear receptors and ion channels. Dr. Pruneau set up and led drug discovery programs in cardiovascular diseases, traumatic brain injury, skin diseases (wound healing), pain and metabolic diseases. Since 2006, he has been leading and coordinating gene therapy and optogenetic research projects in retinal diseases. Dr. Pruneau received a Ph.D. in biochemistry from Dijon University and a master's degree in pharmacology from Paris V University, followed by a fellowship in cardiovascular pharmacology in Melbourne, Australia. He is author or co-author of 80 peer-reviewed publications.

Directors

Michael Wyzga, has served as a member of our Board of Directors since October 2013. Mr. Wyzga is currently the President of MSW Consulting, Inc., a private company focused on strategic biotechnology consulting. Prior to that, 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, from December 2011 until November 2013. 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. Since February 2014, Mr. Wyzga has served as a member of the Board of Directors of Akebia Therapeutics, Inc., or Arkebia, a publicly traded biopharmaceutical company, where he is also a member of the compensation committee and chair of the audit committee. Since February 2013, Mr. Wyzga has also served as a member of the Board of Directors and chair of the audit committee of OncoMed Pharmaceuticals, Inc., or OncoMed, a publicly traded biopharmaceutical company. 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. Mr. Wyzga also previously served as a member of the Board of Directors of Idenix Pharmaceuticals, Inc., or Idenix, 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 Altus Pharmaceuticals, Inc., a publicly traded biopharmaceutical company that ceased operations in November 2009, 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 M.B.A. from Providence College and a B.S. from Suffolk University.

Mr. Wyzga has been chosen to serve on our Board of Directors due to his senior management experience at biopharmaceutical and biotechnology companies, his current and past experience on boards of directors of public companies, including his experience as chair of the audit committee at Idenix, OncoMed and Akebia, and his financial expertise.

Peter Goodfellow, Ph.D., is a science advisor and 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 GSK) as head of research. He has founded several biotechnology companies and has sat on the Boards of Prosensa Holdings N.V., deCode and several medical charities. Dr. Goodfellow holds doctorates from Oxford and Bristol Universities.

Genghis Lloyd-Harris, M.D., Ph.D., is Partner at Abingworth. Prior to joining Abingworth in 2004, Dr. Lloyd-Harris was Managing Director in the European equity research group at Credit Suisse First Boston (CSFB) where he was responsible for coverage of the European biotechnology industry and was ranked first for Pan-European Biotechnology in the Institutional Investor surveys each year from 2001 to 2003. Before joining equity research at CSFB, he worked for CSFB's health care group in the investment banking division in New York. Dr. Lloyd-Harris was previously a pediatrician in Melbourne, Australia. Dr. Lloyd-Harris holds a medical degree from the University of Liverpool, UK, a Ph.D. in clinical pharmacology from the University of Melbourne, Australia, and an MBA from Harvard Business School. Dr. Lloyd-Harris currently serves on the board of Avillion LLP, Wilson Therapeutics AB and Abingworth, and has previously served on the board of several companies, including Solexa Inc., Novexel S.A., HBI Ltd., Syntaxin Ltd., In Pharmatica Ltd. and Synosia AG.

Simone Seiter, M.D., Ph.D., is Vice President with QuintilesIMS based in Frankfurt, Germany for 10 years. She supports biotech companies, midsize and Top 10 pharma companies in developing commercialization strategies and launching new products. Prior to joining QuintilesIMS she worked at Capgemini as a consultant for six years and served as a postdoctoral Fellow at the National Institute of Health (United States) for two years. Dr. Seiter worked at the Universities of Heidelberg and Homburg, Germany as board certified dermatologist. Dr. Seiter holds an M.D. PhD degree from the University of Heidelberg and an MBA degree from the University of Applied Sciences in Neu-Ulm Germany.

Guido Magni, M.D., Ph.D., is a Partner with Versant Ventures, based in Basel, Switzerland. Dr. Magni previously served as a Managing Director of EuroVentures, a Versant incubator, where he was involved with several biotech investments including Synosia Therapeutics AG, which was sold to Biotie Therapeutics AG, or Biotie, Flexion Therapeutics AG and Okairos AG, which was sold to GSK. Dr. Magni was previously Global Head of Medical Sciences in Roche, in the Global Drug Development department. During his twelve years in this position, Dr. Magni oversaw the development and the registration of a large number of new chemical and biological entities including Pegasys, Mabthera, Xeloda, Herceptin, Tamiflu and Tarceva. Dr. Magni currently serves on the board of Aprea AB, Nouscom GmbH, Piqur Therapeutics AG, Tardeva and AM Pharma B.V. Dr. Magni has an M.D. degree from the University of Padua and a Ph.D. in neuropharmacology.

Maïlys Ferrère, is the Director of the Large Venture Investment pole of Bpifrance. A graduate of IEP *(Institut d'Études Politiques)* in Paris, she began her career in 1985 with the General Inspectorate of Société Générale before joining Worms Bank two years later, first as financial secretary then as originator in the equity capital markets activity. In 1993 she became Deputy Director of Client Services at Crédit National and was appointed four years later project Leader at Natexis. In 2000, she was recruited by KBC Securities as senior ECM originator. Two years later, Ms. Ferrère joined Ixis and Natixis as head of midcaps in the ECM origination department. From 2009 to 2013 she was director of investment at the FSI *(Fond Stratégique d'Investissement)*.

14.1.3 BALANCE IN THE COMPOSITION OF THE BOARD OF DIRECTORS

The Board of Directors will use its best efforts to complete as soon as possible its composition so that it will reflect a balanced representation of men and women, in proportions that comply with applicable legal requirements, including French law No. 2011-103 dated January 27, 2011, in particular its Article 5, II, first paragraph, which provides that the proportion of directors of each gender shall be no less than 40%.

Insofar as such requirement was not met on January 1, 2017, the Company has suspended the payment of attendance fees to the directors. It being specified that when the composition of the Board of Directors complies with applicable legal requirements, the payment of attendance fees will be authorized, including overdue fees.

14.1.4 STATEMENT REGARDING THE EXECUTIVE OFFICERS OR DIRECTORS

As of the date of this 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 convicted of fraud; (ii) none of the above persons has been associated with any bankruptcy, receivership or liquidation; (iii) no accusations or official public sanctions have been brought against any of the above persons 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 being involved in the management or performance of business of any company.

14.1.5 SUMMARY STATEMENT REGARDING TRANSACTIONS BY EXECUTIVE OFFICERS AND DIRECTORS INVOLVING SHARES OF THE COMPANY DURING THE FISCAL YEAR ENDED DECEMBER 31, 2016

During the fiscal year ended December 31, 2016, the executive officers and directors performed the following transactions on the Company's shares:

Name, position	Nature of the transaction	Number of transactions	Number of shares involved	Average price (€)	Amount (€)
Genghis Lloyd-Harris	Purchase of shares	7	48,000	9.08	435,893
Total		**7**	**48,000**	**9.08**	**435,893**

14.2 CONFLICTS OF INTEREST

To our knowledge, and subject to the relationships described in Section 19, "Related Party Transactions" and Section 4.2, "Risk Related to Our Business Operations," as of the date of this Registration Document there are no potential conflicts of interest between the duties of the members of our Board of Directors and officers 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 Registration Document, there are no conflicts of interest between Bernard Gilly's position in the Company and his positions as Chairman of the Board of Directors of Brain Ever SAS, Gecko Biomedical S.A., Chronocam S.A., Eye TechCare S.A., Chronolife SAS, IBionext SAS, Tilak Healthcare SAS and Brainiac SAS.

In addition, following his resignation as President of SAS 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 Registration Document, there are no agreements or undertakings of any kind with shareholders, clients, suppliers or others pursuant to which any member of our Board of Directors or officers has been appointed to such position.

As of the date of this Registration Document, the members of the Board of Directors have not agreed to any restriction on their right to transfer shares of the Company, 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 Registration Document and subject to certain customary lockup agreements entered into with the underwriters in connection with the listing of our shares on Euronext Paris (a description of which has 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.

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COMPENSATION AND BENEFITS

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, 2016, was €2,866,060. For the year ended December 31, 2016, no amounts have been set aside or accrued to provide pension, retirement or similar benefits to our employees was attributable to our executive officers.

15.1 COMPENSATION AND BENEFITS OF SENIOR EXECUTIVES

15.1.1 SUMMARY TABLE OF COMPENSATION, OPTIONS AND SHARES GRANTED TO SENIOR EXECUTIVES FOR THE FISCAL YEARS 2015 AND 2016

Table 1 (AMF definition)

(in euros)	Fiscal year ending December 31, 2015	Fiscal year ending December 31, 2016
Michael Wyzga Chairman		
Compensation for the fiscal year *(as detailed in Section 15.1.2 of this Registration Document)*	—	193,982
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 15.3.2 of this Registration Document)*	—	91,140
Valuation of share warrants for founders granted during the fiscal year *(as detailed in Section 15.3.2 of this Registration Document)*	—	—
Valuation of shares warrants granted during the fiscal year *(as detailed in Section 15.3.2 of this Registration Document)*	—	—
TOTAL	—	285,122

(in euros)	Fiscal year ending December 31, 2015	Fiscal year ending December 31, 2016
Bernard Gilly Chief Executive Officer		
Compensation for the fiscal year *(as detailed in Section 15.1.2 of this Registration Document)*	366,278	416,280
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 15.3.2 of this Registration Document)*	—	—
Valuation of share warrants for founders granted during the fiscal year *(as detailed in Section 15.3.2 of this Registration Document)*	895,160	—
Valuation of performance shares granted during the fiscal year *(as detailed in Section 15.3.2 of this Registration Document)*	—	2,000,000
TOTAL	1,261,438	3,311,440

15.1.2 COMPENSATION OF SENIOR EXECUTIVES

Table 2 (AMF definition)

	Fiscal year ending December 31, 2015		Fiscal year ending December 31, 2016	
(in euros)	Due	Paid	Due	Paid
Michael Wyzga Chairman				
Fixed Compensation[1]	—	—	193,982	193,982
Variable Compensation	—	—	—	—
Valuation of multi-year variable compensation granted in the course of the fiscal year	—	—	—	—
Exceptional Compensation	—	—	—	—
Directors' Fees	—	—	—	—
Benefits in Kind	—	—	—	—
TOTAL	—	—	193,982	193,982

	Fiscal year ending December 31, 2015		Fiscal year ending December 31, 2016	
(in euros)	Due	Paid	Due	Paid
Bernard Gilly Chief Executive Officer				
Fixed Compensation	250,008	250,008	250,008	250,008
Variable Compensation[2]	75,002	112,504	125,004	75,002
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	366,278	403,780	416,280	366,278

(1) Mr. Wyzga was appointed Chairman of the Board of Directors on March 2, 2016. On May 2, 2016, the Board of Directors set Mr. Wyzga's fixed compensation at €102,500 NET for the fiscal year ended December 31, 2016.

(2) On March 2, 2016, the Board of Directors of the Company awarded Mr. Gilly a variable compensation of €75,002 as a bonus for achieving qualitative and quantitative objectives regarding the fiscal year ended December 31, 2015, mainly related to research and development programs progressing as planned.
On December 1, 2016, the Board of Directors of the Company awarded Mr. Gilly a variable compensation of €125,004 as a bonus for achieving qualitative and quantitative objectives regarding the fiscal year ended December 31, 2016, mainly related to research and development programs progressing as planned, as well as to the successful IPO of the Company conducted in July 2016 on Euronext Paris.

(3) Consisting of a housing allowance.

15.2 DIRECTORS' COMPENSATION

Our shareholders at the ordinary shareholders' general meeting of 2016 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. As of the date of this Registration Document, upon recommendation of the compensation committee, the Board of Directors set the annual attendance fee for an independent director at €45,000 as a director, and an additional €15,000 as a chair of a committee, independently of the number of meetings held. The following table sets forth information regarding the compensation earned by our directors who are not executive officers or affiliated with one of our significant shareholders for service on the Board of Directors during the year ended December 31, 2016. Mr. Wyzga and Mr. Gilly, respectively 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 a director.

Table 3 (AMF definition)

(in euros)	Paid 2015	Paid 2016
Florent Gros[1]		
Directors' fee	–	–
Other Compensation	–	–
Peter Goodfellow		
Directors' fee	34,713	36,503
Other Compensation[2]	37,170	20,580
Genghis Lloyd-Harris		
Directors' fee	–	–
Other Compensation	–	–
Guido Magni		
Directors' fee	–	–
Other Compensation	–	–
Michael Wyzga[3]		
Directors' fee	–	–
Other Compensation[4]	212,400	91,140
Earl M. Collier[5]		
Directors' fee	–	19,397
Other Compensation[6]	–	138,180
Maïlys Ferrère[7]		
Directors' fee	–	–
Other Compensation	–	–
TOTAL	284,283	214,660

(1) Mr. Gros resigned from the board of directors on July 12, 2016.
(2) Consisting of 7,000 and 7,000 share warrants (BSA) granted in 2015 and 2016, respectively.
(3) Mr. Wyzga was appointed Chairman of the board of directors on March 2, 2016.
(4) Consisting of 40,000 share warrants (BSA) granted in 2015 and 31,000 share warrants (BSA) granted in 2016.
(5) Mr. Collier resigned from the board of directors on April 19, 2017.
(6) Consisting of 47,000 share warrants (BSA) granted in 2016.
(7) Ms. Ferrère joined the board of directors on July 12, 2016.

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.

15.3 SHARE WARRANTS, SHARE WARRANTS FOR FOUNDERS AND PERFORMANCE SHARES GRANTED TO SENIOR EXECUTIVES AND DIRECTORS

15.3.1 PRINCIPLES GOVERNING THE GRANTING OF SHARE WARRANTS, SHARE WARRANTS FOR FOUNDERS AND PERFORMANCE SHARES

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, historically typically granted only to non-employee directors not eligible for share warrants for founders; and
- performance 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 employee share options and bonus shares authorized by the shareholders.

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.

As of March 31, 2017, BCE warrants and BSA warrants held by our directors could be exercised for the purchase of an aggregate of 357,464 ordinary shares at a weighted average exercise price of €0.8130 per share. In addition, BCE warrants and BSA warrants could be exercised for the purchase of an aggregate of 1,048,039 ordinary shares at a weighted average exercise price of €0.9635 per share.

15.3.2 SHARE WARRANTS OR SHARE WARRANTS FOR FOUNDERS GRANTED TO SENIOR EXECUTIVES AND DIRECTORS IN 2015 AND 2016

Table 4 (AMF definition)

Name	Grant Date	Type of Grant	Number of Ordinary Shares Underlying Awards (#)	Exercise Price (€)	Expiration Date
Bernard Gilly	07/08/2015	BCE[1]	161,000	3.275	07/07/2025
Peter Goodfellow	07/08/2015	BSA[1]	7,000	3.275	07/07/2025
	07/26/2016	BSA[1]	7,000	8.080	07/25/2026
Michael Wyzga	07/08/2015	BSA[1]	40,000	3.275	07/07/2025
	07/26/2016	BSA[1]	31,000	8.080	07/25/2026
Earl M. Collier[2]	07/26/2016	BSA[1]	47,000	8.080	07/25/2026

(1) BCE refers to share warrants for founders. BSA refers to share warrants. AGA refers to performance shares.
(2) Mr. Collier resigned from the board of directors on April 19, 2017.

15.4 SHARE WARRANTS OR SHARE WARRANTS FOR FOUNDERS EXERCISED BY SENIOR EXECUTIVES AND DIRECTORS IN 2015 AND 2016

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	—	—	—
Earl M. Collier[1]	—	—	—

(1) Mr. Collier resigned from the board of directors on April 19, 2017.

15.5 PERFORMANCE SHARES GRANTED IN 2015 AND 2016

Table 6 (AMF definition)

Name	Grant Date	Number of Shares Granted	Value of shares according to IFRS2	Beginning of Acquisition Period	End of Lock-up Period	Performance Criteria
Bernard Gilly	07/26/2016	250,000	2,000,000	07/26/2017[1]	[2]	[3]

(1) If the performance criteria are not fulfilled by July 26, 2018 at the latest, the performance 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 2016 performance shares granted to Key Managers, including Mr. Gilly, are subordinate to the achievement of the following performance criteria at the latest on July 26, 2018:
- 50% of AGA 2016 will be acquired at the later of the two following dates, either (i) the expiry of a period of one year from the date of grant or (ii) the completion of enrollment in RESCUE and REVERSE clinical trials;
- 50% of AGA 2016 will be acquired at the later of the two following dates, either (i) the expiry of a period of one year from the date of grant or (ii) the enrollment of the first patient in a Phase I/II clinical trial with GS030 in retinitis pigmentosa.

15.6 PERFORMANCE SHARES AVAILABLE IN 2015 AND 2016

No performance shares have become available during the fiscal years ended December 31, 2015 and December 31, 2016. Therefore, table 7 of the AMF recommendation n° 2014-14 is not applicable.

15.7
HISTORY OF ALLOCATION OF SHARE WARRANTS AND SHARE WARRANTS FOR FOUNDERS

Table 8 (AMF definition)

15.7.1 HISTORY OF SHARE WARRANTS FOR FOUNDERS (BCE)

	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
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 exercised as of March 31, 2017	422,642	—	—	14,432
Total number of BCE canceled or obsolete as of March 31, 2017	—	—	—	96,866
Total number of BCE outstanding as of March 31, 2017	469,358	193,800	60,000	622,000
Total number of shares available for subscription as of March 31, 2017	469,358	193,800	60,000	622,000

15.7.2 HISTORY OF SHARE WARRANTS (BSA)

	BSA Issued July 2013	BSA Issued April 2014	BSA Issued July 2015	BSA Issued July 2016
Date of shareholders' meeting	02/05/2013	02/05/2013	06/29/2015	05/19/2016
Date of allocation by the Board of Directors	07/08/2013	04/09/2014	07/08/2015	07/26/2016
Total number of BSA authorized	2,334,959	2,334,959	856,000	680,456
Total number of BSA granted	328,000	33,000	121,000	205,000
Including those granted to Mr. Gilly	—	—	—	—
Start date for the exercise of the BSA	07/08/2013	04/09/2014	07/08/2015	07/26/2016
BSA expiry date	07/07/2023	04/08/2024	07/07/2025	07/25/2023
BSA exercise price	€0.025	€0.025	€3.275	€8.080
Number of shares subscribed as of March 31, 2017	67,960	—	—	—
Total number of BSA canceled or obsolete as of March 31, 2017	—	—	—	—
Total number of BSA outstanding as of March 31, 2017	260,040	33,000	121,000	205,000
Total number of shares available for subscription as of March 31, 2017	260,040	33,000	121,000	205,000

15.8 SHARE WARRANTS OR SHARE WARRANTS FOR FOUNDERS 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
Options granted during the fiscal year ended December 31, 2016 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, 2016 by the ten employees of the Company who purchased or subscribed for the greatest number of options (overall figure)	32,720	0.12

15.9 HISTORY OF ALLOCATION OF PERFORMANCE SHARES

Table 10 (AMF definition)

	AGA Issued July 2016
Date of shareholders' meeting	05/19/2016
Date of allocation by the Board of Directors	07/26/2016
Total number of AGA authorized	10% share capital
Total number of AGA granted	766,000
Including those granted to Mr. Gilly	250,000
Date of definitive acquisition of AGA	07/26/2017(1)
End of lock-up period	(2)
Number of shares definitively acquired as of March 31, 2017	—
Total number of AGA canceled or obsolete as of March 31, 2017	118,000
Total number of AGA outstanding as of March 31, 2017	648,000

(1) If the performance terms are not fulfilled by July 26, 2018 at the latest, the performance shares granted will be canceled.
(2) The lock-up period will end one (1) year after the end of the actual acquisition date.

15.10 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: 2012 End of term: 2018		X		X	X(1)		X(2)	
Michal Wyzga Chairman of the Board of Directors Beginning of term: 2016 End of term: 2019		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.
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 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.

Pursuant to French law No. 2016-1691 dated December 9, 2016, the principle of the benefits of the senior executives during 2016 and the compensation policy for our senior executives for 2017 will be subject to a report that will be submitted to the shareholders' meeting called to approve the financial statements for the fiscal year ended December 31, 2016.

15.11 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 16.4, "Statement relating to Corporate governance" of this 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.

15.12 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.

16

BOARD PRACTICES

16.1 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 14.1, "Composition of Management and Supervisory Bodies" of this Registration Document.

16.2 INFORMATION ON SERVICE CONTRACTS BETWEEN MEMBERS OF THE ADMINISTRATIVE AND MANAGEMENT BODIES AND THE COMPANY

To our knowledge, apart from the contract mentioned in the paragraph below, there are no service contracts between the members of our Board of Directors and us as of the date of registration of this Registration Document.

On December 3, 2012, we entered into a consulting agreement with UPMC, Le *Centre Hospitalier National d'Ophtalmologie des XV-XX* and *Institut National de la Santé et de la Recherche Médicale*, providing for consulting services by Dr. José-Alain Sahel, professor at UPMC, for a period of five years. Pursuant to this agreement, Dr. Sahel may only spend 5% of his working time with the Company. Dr. Sahel is entitled to monthly consulting fees of €4,000.

Dr. Sahel was appointed as non-voting observer *(censeur)* of our Board of Directors in 2013. His term expires in 2018.

16.3 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 nomination committee. The composition and duties of these committees are described below. The composition and functioning of all of our committees complies 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.

16.3.1 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.

16.3.1.1 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, Dr. Lloyd-Harris and Bpifrance Participations represented by Ms. Ferrère. Mr. Wyzga is the Chairman of the audit committee. Mr. Wyzga is an independent member of the Board of Directors.

16.3.1.2 Duties

Under French law, the audit committee oversees matters related to the preparation and control of accounting and financial information. Without limiting the powers of the Board of Directors, the audit committee's duties include:

- 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;
- 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;
- regularly reviewing the status of major disputes;
- approving the provision of non-audit services; 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.

16.3.2 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.

16.3.2.1 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.

As of the date of this Registration Document, we have a compensation committee composed of Dr. Seiter, Dr. Magni and Dr. Goodfellow. Dr. Magni 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 19, "Related-Party Transactions" of this Registration Document.

16.3.2.2 Duties

The compensation committee's duties 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.

16.3.3 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.

16.3.3.1 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 Registration Document, we have an appointments committee composed of Dr. Goodfellow, Mr. Wyzga, and Bpifrance Participations represented by Ms. Ferrère. Dr. Goodfellow is the chairman of the nominations committee.

16.3.3.2 Duties

The nominations committee's duties 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.

16.4 STATEMENT RELATING TO CORPORATE GOVERNANCE

16.4.1 CORPORATE GOVERNANCE

We comply with the MiddleNext Code, as amended on September 2016, to the extent that such principles are compatible with our organization, size, means and shareholding structure.

For the fiscal year ended December 31, 2016, 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	

Recommendations of the MiddleNext Code	Adopted	Will be adopted
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	

16.4.2 CODE OF BUSINESS CONDUCT AND ETHICS

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.

16.4.3 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 Chairman of the Board of Directors and Chief Executive Officer. As of the date of this Registration Document, Bernard Gilly is director and Chief Executive Officer and Michael Wyzga is the Chairman of our Board of Directors.

16.4.4 DIRECTOR INDEPENDENCE

We consider that, under the recommendations of the MiddleNext Code, three current directors are "independent directors."

The MiddleNext Code set out the five following criteria justifying the independence of directors, characterised 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 the Company and must not have held such a position within the last five years;
- they must not be a significant client, supplier or banker of the Company, or a client, supplier or banker for whom our Company represents a significant share of its business;
- they must not be a reference shareholder or hold a significant number of voting rights of the Company;
- they must not have a close family relationship with our corporate officer or reference shareholder; and
- they must not have been an auditor of the Company in the course of the previous six years.

Based on those criteria, our board of directors determined that Mr. Wyzga, Dr. Seiter and Dr. Goodfellow are "independent directors." In making such determination, the board of directors considered the relationships that each non-employee director has with the Company 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).

16.5 INTERNAL CONTROLS

16.5.1 INTERNAL CONTROL PROCEDURES

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

- The Company maintains, internally, a separation between the production and the control of financial operations, accounting procedures and the preparation of financial statements;
- All accounting procedures and operations are sub-contracted to an independent certified public accounting firm. This firm also provides for 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 sub-contracted 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; and
- 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.

16.5.2 CHAIRMAN'S REPORT ON CORPORATE GOVERNANCE AND INTERNAL CONTROL AND RISK MANAGEMENT PROCEDURES

Dear shareholders,

The law requires the chairman of the board of directors of companies whose shares are publicly listed on a regulated market (Euronext Paris) to provide the following information in a report attached to the Board's report:

- references made to a code of corporate governance,
- board composition and application of the principle of balanced representation between women and men,
- conditions for preparing and organizing the Board's work,
- specific conditions on shareholder participation in the general shareholders' meeting,
- any restrictions made on the authority of the chief executive officer,
- principles and rules applied to set compensation and benefits of any kind awarded to corporate directors,
- factors likely to have an impact in the event of a public offering,
- internal control and risk management procedures implemented by the company,
- financial risk related to climate change.

This report was prepared and elaborated by the chairman of the board of directors, with the involvement of the executive and management committees.

The report was then subject to approval by the board of directors on March 9, 2016, upon recommendation of the audit committee, which met on March 9, 2016, and was sent to the statutory auditors.

I - 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.

16.5.2.1 Board of directors

16.5.2.1.1 Composition of the board of directors

The Board of Directors consists of seven members:

- Mr. Michael Wyzga, age 62, U.S. citizen, chairman of the board of directors and independent director;
- Mr. Bernard Gilly, age 60, French citizen, co-founder and chief executive officer;
- Dr. Guido Magni, age 63, Italian citizen;
- Dr. Genghis Lloyd-Harris, age 60, British citizen;
- Dr. Peter Goodfellow, age 65, British citizen, independent director;
- Bpifrance Participations, represented by Ms. Maïlys Ferrère, age 54, French citizen;
- Mr. Earl. M. Collier, age 69, U.S. citizen, independent director.

Two non-voting observers are also attending board meetings:

- Pr. José-Alain Sahel, co-founder;
- Bpifrance Investissements, represented by Mr. Thibaut Roulon.

On July 12, 2016, Mr. Florent Gros resigned from his director position. Bpifrance Participations, represented by Ms. Maïlys Ferrère, was coopted by the board as director on the same day.

Mr. Francesco De Rubertis resigned from his non-voting observer position on March 10, 2017.

Independence of the board of directors' members

We consider that, under the recommendations of the MiddleNext Code, three current directors are "independent directors."

The MiddleNext Code set out the five following criteria justifying the independence of directors, characterised 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 the Company and must not have held such a position within the last five years;
- they must not be a significant client, supplier or banker of the Company, or a client, supplier or banker for whom our Company represents a significant share of its business;
- they must not be a reference shareholder or hold a significant number of voting rights of the Company;
- they must not have a close family relationship with our corporate officer or reference shareholder; and
- they must not have been an auditor of the Company in the course of the previous six years.

Based on those criteria, our board of directors determined that Mr. Wyzga, Mr. Collier and Dr. Goodfellow are "independent directors." In making such determination, the board of directors considered the relationships that each non-employee director has with the Company 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).

Representation of women and men on the board

The board of directors will use its best efforts to complete as soon as possible its composition so that it will reflect a balanced representation of men and women, in proportions that comply with applicable legal requirements, including French law No. 2011-103 dated January 27, 2011, in particular its Article 5, II, first paragraph, which provides that the proportion of directors of each gender shall be no less than 40%.

16.5.2.1.2 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 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.

16.5.2.1.3 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 twelve times in 2016.

During this period, members' attendance at Board meetings was as follows:

- 100% of directors at the meeting on March 2, 2016;
- 100% of directors at the meeting on April 12, 2016;
- 100% of directors at the meeting on May 2, 2016;
- 71% of directors at the meeting on May 19, 2016;
- 100% of directors at the meeting on June 21, 2016;
- 100% of directors at the meeting on June 24, 2016;
- 100% of directors at the meeting on July 3, 2016;
- 100% of directors at the meeting on July 12, 2016;
- 100% of directors at the meeting on July 26, 2016;
- 57% of directors at the meeting on August 10, 2016;
- 100% of directors at the meeting on September 29, 2016;
- 100% of directors at the meeting on December 1, 2016.

Average attendance was thus 94% 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 financial statements.

They effectively attended them.

16.5.2.1.4 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).

16.5.2.1.5 Management of conflicts of interest within the board of directors

To the best of the Company's knowledge, there are no conflict of interest between the responsibilities assigned and the board members' private interests and other duties.

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."

16.5.2.1.6 Topics discussed during board meetings and activity report

During fiscal year 2016, in addition to all subjects in connection with the IPO of the Company, the board of directors specifically discussed the following subjects:

- **Financial:** preparation of the annual and half-year financial statements, examination of draft management documents, and approval of the 2017 budget;
- **Compensation:** examination and modification of the compensation of the chairman and chief executive officer, grant of performance shares to all employees, grant of share purchase warrants to independent directors, and certain consultants, review of corporate objectives and grant of 2015 performance bonuses, implementation and review of 2016 corporate objectives, review of compensation for independent directors and officers;
- **Strategy:** review of the medium- and long-term strategic plan.
- **Governance:** separation of roles of chairman of the board of directors and chief executive officer.

16.5.2.1.7 Self-evaluation of the board of directors

In accordance with the recommendation of the Code of Practice, at its meeting of March 9, 2016 the doard of directors undertook a review, followed by an evaluation, of its work and activities, and that of its special committees, as described in Paragraph 16.3 of this 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.

16.5.2.2 Organization and operation of special committees

The board of directors has established three special committees. See Section 16.3 of this Registration Document for more information.

The Audit Committee met four times in 2016. The main topics discussed by the Committee, and on which it made recommendations to the board of directors, were the review and approval of 2015 full year financial statements, 2016 half year financial statements, and 2017 budget.

The Compensation Committee met four times in 2016. The main topics discussed by the Committee, and on which it made recommendations to the board of directors, were the annual review of the compensation for the chairman of the board of directors, the chief executive officer, independent directors and officers, the grant of share options (BSA) to independent directors and consultants, and performance shares (AGA) to employees and senior executives, as well as the review of corporate objectives achievement for 2015 and 2016 and the related variable compensation for officers.

The Nomination Committee met once in 2016. The main topics discussed by the Committee, and on which it made recommendations to the board of directors, were the review of the board of directors and special committees composition, and notably the identification of candidates to comply with new legal requirements on balanced representation of men and women.

16.5.2.3 General management

16.5.2.3.1 Conditions for serving in general management

Mr. Bernard Gilly serves as chief executive officer.

16.5.2.3.2 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."

16.5.2.4 Principles and rules for calculating compensation of independent directors and senior executives

16.5.2.4.1 Compensation of independent directors (attendance fees)

Our shareholders at the ordinary shareholders' general meeting of 2016 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. As of the date of this Registration Document, upon recommendation of the compensation committee, the board of directors set the annual attendance fee for an independent director at €45,000 as a director, and an additional €15,000 as a chair of a committee, independently of the number of meetings held.

16.5.2.4.2 Compensation of senior executives

The board of directors sets the compensation policy for both the chairman of the board of directors and the chief executive officer, based on a recommendation from the compensation committee.

It also refers to the Middlenext Corporate Governance Code for Small and Medium-Sized Companies as amended in September 2016.

This policy applies exhaustively to fixed, variable and extraordinary compensation, as well as benefits of all kinds granted by the company (retirement, severance, etc.).

It is set not only as a function of work performed, results achieved and responsibility assumed, but also with regard to practices observed in comparable companies and the compensation of other business managers. In this context, when reviewing the annual compensation structure of our chief executive officer, the compensation committee uses a specialized third-party to survey market practices and provide recommendations in line with those of the AMF.

16.5.2.4.2.1 Determination of fixed compensation

For the fiscal year 2016, the board of directors set the fixed part of Mr. Bernard Gilly's compensation at €250,008 for his term as chief executive officer.

16.5.2.4.2.2 Determination of variable compensation

For the fiscal year 2016, the board of directors set the variable part of Mr. Bernard Gilly's compensation at 50% of its fixed compensation, based on the achievement of corporate objectives.

On December 1, 2016, the board of directors of the Company awarded Mr. Gilly a variable compensation of €125,004 as a bonus for achieving qualitative and quantitative objectives regarding the fiscal year ended December 31, 2016, mainly related to research and development programs progressing as planned, as well as to the successful IPO of the Company conducted in July 2016 on Euronext Paris.

16.5.2.4.2.3 Grant of share purchase warrants and performance shares

Senior executives receive share purchase warrants and/or performance shares.

These grants are described in Paragraph 15.3 of this Registration Document.

16.5.2.4.2.4 Severance payments, benefits and compensation awarded to senior executives for the cessation or change of their duties

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.

Under the provisions of article 17 of the shareholders' agreement which terminated as from the listing of our shares on Euronext Paris, except this provision which remains into effect, Mr. Gilly agreed not to engage in certain competitive activities for a period of one year in the event that he terminates his duties with the Company. For a period of one year from the termination of this undertaking, and unless the board of directors elect to waive these restrictions, the Company will be required to make a monthly payment of 40% of his total net monthly compensation excluding any bonuses for a period of 12 months following his termination.

16.5.2.4.2.5 Retirements

None.

16.5.2.4.2.6 Benefits in kind

As part of its compensation, Mr. Bernard Gilly is eligible to receive a housing allowance that amounted to €41,268 for the fiscal year 2016.

16.5.2.4.2.7 Employment contract

Neither Mr. Michael Wyzga nor Mr. Bernard Gilly are subject to an employment contract (see also Paragraph 15.10, Table 11 of this Registration Document).

16.5.2.5 Shareholder participation in the General Shareholders Meeting

The conditions for shareholder participation in general shareholders meetings are described in Section V of the Company's by-laws.

16.5.2.6 Factors likely to have an impact in the event of a public offering

Pursuant to Article L. 225-100-3, 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 paragraph 18.1 of this Registration Document.
- There are no statutory restrictions on the exercise of double vorights, 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 by-laws).
- 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 rightsnot 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 by-laws.
- With regard to authority of the board of directors, current delegations are described in paragraph 21.1.3 of this Registration Document (share purchase program) and in the table of delegations for capital increases appearing in Paragraph 21.1.6 of this same document.
- The Company's by-laws 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 Paragraph 15.1 of this Registration Document (Table 11).

II – INTERNAL CONTROL AND RISK MANAGEMENT PROCEDURES – FINANCIAL RISK RELATED TO CLIMATE CHANGE

As part of its listing on the Euronext market in 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.

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 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.

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 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.

The Company's risk mapping is detailed in Chapter 4 of this Registration Document.

2.1 Operational risk management

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

- Pre-clinical and toxicity studies of drug candidates;
- Pharmaceutical and clinical development of drug candidates.

2.1.1 Pre-clinical 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. (see Paragraph 8.2.3).

2.1.2 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).

2.2 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.

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 "management control" function.

Payroll management

Payroll is also subcontracted in its entirety to an accounting firm.

3. Financial risk related to climate change

Given the nature of its activities, GenSight Biologics is not exposed to any environment-specific risk. The Company's environmental responsibility is further described in section 8.2.2 of this Registration Document.

The chairman of the board of directors

16.5.3 STATUTORY AUDITORS' REPORT ON THE CHAIRMAN'S REPORT ON CORPORATE GOVERNANCE AND INTERNAL CONTROL AND RISK MANAGEMENT PROCEDURES

This is a free translation into English of the statutory auditors' report issued in French prepared in accordance with Article L.225-235 of the French Commercial Code on the report prepared by the Chairman of the Supervisory Board of on the internal control procedures relating to the preparation and processing of accounting and financial information issued in French and is provided solely for the convenience of English speaking users.
This report should be read in conjunction with, and construed in accordance with, French law and the relevant professional standards applicable in France.

BECOUZE
45, rue Boissière
75116 Paris

Deloitte & Associés
106, cours Charlemagne
69002 Lyon

GenSight Biologics
Société Anonyme – 74 rue du Faubourg Saint-Antoine – 75012 PARIS

STATUTORY AUDITORS' REPORT PREPARED IN ACCORDANCE WITH ARTICLE L.225-235 OF THE FRENCH COMMERCIAL CODE *(CODE DE COMMERCE)*, ON THE REPORT PREPARED BY THE CHAIRMAN OF THE BOARD OF DIRECTORS

YEAR ENDED DECEMBER 31, 2016

To the Shareholders,

In our capacity as Statutory Auditors of GenSight Biologics and in accordance with Article L.225-235 of the French Commercial Code (*Code de commerce*), we hereby report to you on the report prepared by the Chairman of your Company in accordance with Article L.225-37 of the French Commercial Code for the year ended December 31, 2016.

It is the Chairman's responsibility to prepare, and submit to the Supervisory Board for approval, a report on the internal control and risk management procedures implemented by the Company and containing the other disclosures required by Article L.225-37 of the French Commercial Code, particularly in terms of corporate governance.

It is our responsibility:

- to report to you on the information contained in the Chairman's report in respect of the internal control and risk management procedures relating to the preparation and processing of accounting and financial information, and
- to attest that this report contains the other disclosures required by Article L.225-37 of the French Commercial Code, it being specified that we are not responsible for verifying the fairness of these disclosures.

We conducted our work in accordance with professional standards applicable in France.

Information on the internal control and risk management procedures relating to the preparation and processing of accounting and financial information

The professional standards require that we perform the necessary procedures to assess the fairness of the information provided in the Chairman's report in respect of the internal control and risk management procedures relating to the preparation and processing of the accounting and financial information. These procedures mainly consisted in:

- obtaining an understanding of the internal control and risk management procedures relating to the preparation and processing of the accounting and financial information on which the information presented in the Chairman's report is based and the existing documentation;
- obtaining an understanding of the work involved in the preparation of this information and the existing documentation;
- obtaining an understanding of the evaluation process implemented and assessing the sufficiency of its documentation as regards the information related to the evaluation of the internal control and risk management procedures;
- determining if any significant weaknesses in the internal control procedures relating to the preparation and processing of the accounting and financial information that we would have noted in the course of our engagement are properly disclosed in the Chairman's report.

On the basis of our work, we have nothing to report on the information in respect of the Company's internal control and risk management procedures relating to the preparation and processing of the accounting and financial information contained in the report prepared by the Chairman of the Supervisory Board in accordance with Article L.225-37 of the French Commercial Code.

Other disclosures

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

Paris and Lyon, March 15, 2017

The Statutory Auditors

BECOUZE
Fabien BROVEDANI

DELOITTE & ASSOCIÉS
Dominique VALETTE

17

EMPLOYEES

17.1 HUMAN RESOURCES MANAGEMENT

17.1.1 NUMBER AND BREAKDOWN OF EMPLOYEES

As of December 31, 2016, we had 27 employees, 21 of whom are full-time, 14 of whom hold Ph.D., Pharm.D. or M.D. degrees, 20 of whom are engaged in preclinical development and regulatory affairs, clinical development, research, engineering and production, and seven of whom are engaged in management and administration.

The table below shows the changes in the number of our employees over the last two years.

	2015	2016
As of January 1	17	25
New hires	8	5
Departures[1]	—	3
Dismissals[2]	—	—
As of December 31	25	27

(1) This category includes both voluntary and involuntary departures.
(2) Individual dismissals (for cause).

All of our employees are located in France.

17.1.2 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 5% and 50% of their fixed salary.

17.2 CORPORATE SOCIAL RESPONSIBILITY

Employment

As at December 31, 2016, GenSight Biologics personnel totaled 27, distributed by contract type, sex and age range as follows:

	2015	2016
Headcount as at December 31	25	27
of which permanent	24	26
of which fixed-term	1	1
of which women	16	15
of which men	9	12
< 35 years old	5	6
> 35 years old	20	21

Employee movements during the fiscal year ended December 31, 2016 (hirings and departures) may be broken down as follows:

	2015	2016
Number of hirings	8	5
of which permanent	8	5
of which fixed-term	—	—
Number of departures	—	3

One fixed-term recruitment was converted into a permanent contract within the year.

There were no layoffs during the period.

Compensation

The payroll expense for the fiscal year ended December 31, 2016 was the following:

	2015	2016
Payroll expense (in thousand euros)	3,554	4,244

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 performance shares (*attributions gratuites d'actions*, or AGA).

Organization of work

As at December 31, 2016, out of 27 employees, 6 were senior managers (*"cadre dirigeant"*), 20 were managers (*"cadre"*) and one was a non-manager (*"non-cadre"*). Managers and non-managers

worked 37 hours weekly and were compensated by 12 days of additional holiday (*"Réduction du Temps de Travail"*).

As at December 31, 2016, 78% of employees were full-time and 22% were part-time.

The table below presents the absenteeism rate for the years 2015 and 2016:

	2015	2016
Absenteeism rate	0.45%	1.75%

An extended sick leave explains the significant increase of absenteeism in 2016.

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 April 3, 2015. 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.

No accident at work nor any work-related disease was declared in 2016.

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. Given the average high level of qualification within the Company, individual requests for training were limited in 2015 and 2016.

	2015	2016
Number of training hours taken	77	27

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:

	2015	2016
Percentage of female employees	64%	56%

The proportion of women within the management committee was 38% in 2016, unchanged from 2015.

GenSight Biologics does not employ any disabled persons, but does pay an annual financial contribution to the *Agefiph*, the French public agency that promotes integration into the workplace of disabled people.

All employees of 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.

17.3 SHAREHOLDINGS AND SHARE WARRANTS OR SHARE WARRANTS FOR FOUNDERS HELD BY MEMBERS OF THE BOARD OF DIRECTORS AND SENIOR MANAGEMENT

See Section 15, "Compensation and Benefits" of this Registration Document.

17.4 EMPLOYEE SHAREHOLDING PLAN AND LONG-TERM INCENTIVE PLANS

See Section 15, "Compensation and Benefits" of this Registration Document.

17.5 PROFIT-SHARING AGREEMENTS AND INCENTIVE SCHEMES

None.

18

MAJOR SHAREHOLDERS

18.1 ALLOCATION OF SHARE CAPITAL

18.1.1 SHAREHOLDERS

As of the date of this Registration Document, we are not controlled by any majority shareholder and our share capital is equal to €488,511.33, divided into 19,540,453 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 Registration Document.

Shareholders	Number of shares/ voting rights	% of share capital/ voting right (non-diluted)
5% Shareholders:		
Novartis Pharma AG	3,521,774	18.02%
Versant	2,947,048	15.08%
Abingworth Bioventures VI LP	2,873,306(1)	14.70%
Fidelity Management & Research Company	1,860,895(2)	9.52%
Bpifrance Participations	1,500,000	7.68%
Vitavest S.à.r.l	1,206,373	6.17%
Bpifrance Investissement	975,666	4.99%
Directors and Executive Officers:		
Bernard Gilly	259,802	1.33%
Thomas Gidoin	–	–
Didier Pruneau	95,880	0.49%
Nitza Thomasson	95,880	0.49%
Peter Goodfellow	–	–
Michael Wyzga	–	–
Employee Shareholding	**61,680**	**0.32%**
Other Shareholders (total)	**4,142,149**	**21.20%**
TOTAL	**19,540,453**	**100%**

(1) This amount does not include 1.60 partial shares resulting from the share split on September 3, 2015.
(2) This amount does not include 6.80 partial shares resulting from the share split on September 3, 2015.

The table below sets forth our fully-diluted share capital structure, based on available information as of the date of this Registration Document.

Shareholders	Number of shares/ voting rights	% of share capital/ voting right (fully diluted)
5% Shareholders:		
Novartis Pharma AG	3,521,774	15.90%
Versant	2,947,048	13.30%
Abingworth Bioventures VI LP	2,873,306(1)	12.97%
Fidelity Management & Research Company	1,860,895(2)	8.40%
Bpifrance Participations	1,500,000	6.77%
Vitavest S.à.r.l	1,206,373	5.45%
Bpifrance Investissement	975,666	4.40%
Directors and Executive Officers:		
Bernard Gilly	908,600	4.10%
Thomas Gidoin	310,000	1.40%
Didier Pruneau	198,000	0.89%
Nitza Thomasson	198,000	0.89%
Peter Goodfellow	47,000	0.21%
Michael Wyzga	71,000	0.32%
Employee Shareholding	**648,000**	**2.93%**
Other Shareholders (total)	**4,839,979**	**21.85%**
TOTAL	**22,152,651**	**100%**

(1) This amount does not include 1.60 partial shares resulting from the share split on September 3, 2015.
(2) This amount does not include 6.80 partial shares resulting from the share split on September 3, 2015.

To our knowledge, at the time of this Registration Document, Bpifrance Participations and Bpifrance Investissement are not acting in concert.

18.1.2 HISTORY OF ALLOCATION OF SHARE CAPITAL

Shareholders	As of December 31, 2014			As of December 31, 2015		As of December 31, 2016	
	Number of shares/ voting rights pre-reverse stock split	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	**3,800,000**	**1,520,000**	**17.36%**	**1,710,684**	**12.57%**	**1,710,684**	**8.81%**
Novartis Pharma AG	5,608,948	2,243,579	25.63%	2,771,774	20.37%	3,521,774	18.14%
Abingworth Bioventures VI LP	4,580,357	1,832,143	20.93%	2,322,056	17.06%	2,873,306	14.80%
Versant	4,580,357	1,832,143	20.93%	2,322,048	17.06%	2,947,048	15.18%
Vitavest S.à.r.l	2,008,929	803,572	9.18%	1,018,440	7.48%	1,206,373	6.22%
Bpifrance Investissement	1,308,132	523,253	5.98%	663,166	4.87%	975,666	5.03%
Fidelity	—	—	0%	1,284,680	9.44%	1,860,895	9.59%
Bpifrance Participations	-	—	0%	—	0%	1,500,000	7.73%
Other investors	—	—	0%	1,516,274	11.14%	2,813,955	14.50%
Total	**21,886,723**	**8,754,689**	**100.00%**	**13,609,122**	**100%**	**19,409,701**	**100%**

During the last three years, the following events have changed the number and classes of the issued and our outstanding shares:

- In 2014:
  - During the month of December 2014 (recorded by the Board of Directors in February 2015), BCE and BSA warrants were exercised at an exercise price of €0.01 (corresponding to €0.025 post reverse stock split) per share. Pursuant to these exercises, we issued an aggregate of 573,900 (corresponding to 229,560 post reverse stock split) ordinary shares.
- In 2015:
  - On July 7, 2015, we cancelled all share warrants attached to the Series A preferred shares.
  - On July 7, 2015, we issued 11,562,178 (corresponding to 4,624,871 post reverse stock split) Series B preferred shares in a private placement to 19 investors pursuant to an investment agreement dated June 30, 2015 which terminated upon completion of the listing of our shares on Euronext Paris.
- 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.

18.2 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.

18.3 CONTROL STRUCTURE

As of the date of this Registration Document, no shareholder has exclusive control over the Company.

18.4 SHAREHOLDERS' AGREEMENT

The pre-IPO shareholders' agreement was automatically terminated as of the date of the listing of our shares on Euronext Paris.

In the context of the listing of our shares on Euronext Paris and subject to its completion, 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 Rare*, major shareholders of the Company have entered into a shareholders' agreement to organize their relationship as shareholders of the Company.

18.5 AGREEMENTS LIKELY TO LEAD TO A CHANGE OF CONTROL

To our knowledge, there was no agreement as of the date of this Registration Document the implementation of which might, at a later date, lead to a change in control.

18.6 LOCK-UP AGREEMENT

In the context of the listing of our shares on Euronext Paris, each of our financial shareholders have agreed to a lock-up agreement for a period ending 540 calendar days after the settlement date. The terms of this lock-up agreement are described in Section 7.3, "Lock-Up Agreement" of the Prospectus which received visa n°.16-228 from the AMF on July 4, 2016. Moreover, it should be noted that, pursuant to the terms of this lock-up agreement, some of the securities are no longer bound by any restrictions.

18.7 PLEDGES ON COMPANY'S SHARES

We are not aware of any pledge relating to our shares.

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RELATED PARTY TRANSACTIONS

Since our inception in April 2012, 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 are referred to as related parties.

19.1 AGREEMENTS WITH THE COMPANY'S MAJOR SHAREHOLDERS

19.1.1 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 the product candidate known as GS020, 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 19 to our financial statements as of December 31, 2016 and Section 6.7, "Our Second Product Candidate: GS030 for the Treatment of RP" of this Registration Document.

19.2 TRANSACTIONS WITH KEY MANAGEMENT PERSONS

19.2.1 LEASE AGREEMENT WITH SAS *PASSAGE DE L'INNOVATION*

On January 1, 2015, we entered into a sublease agreement for our new premises with *SAS Passage de l'Innovation*, amended on October 1, 2015 and January 1, 2016. Pursuant to this agreement, we will have to pay €707,247 excluding taxes, on an annual basis, comprised of €410,561 for rent, €26,950 for rental charges and up to €269,736 for other services provided by the lessor through the end of 2023. In 2016, we paid an amount of €749,362, comprised of €410,561 for rent, €23,801 for rental charges and €315,000 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 President of the *SAS Passage de l'Innovation* and one of its shareholders was Bernard Gilly, our Chief Executive Officer, until he resigned from this position in *SAS Passage de l'Innovation* on June 30, 2016. Bernard Gilly has retained shareholding interest in this company. The amounts the SAS Passage de l'Innovation charged us are at fair market value.

The terms of the lease agreement will be submitted to the shareholders' meeting called to approve the financial statements for the fiscal year ended December 31, 2016.

19.2.2 EMPLOYMENT ARRANGEMENTS

Bernard Gilly

Dr. Gilly, our Chief Executive Officer, does not have an employment agreement with us. Dr. 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 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 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.

Pursuant to French law No. 2016-1691 dated December 9, 2016, the terms of Bernard Gilly's employment arrangement will be submitted to the shareholders' meeting called to approve the financial statements for the fiscal year ended December 31, 2016.

Employment Agreements with Key Management Persons

We have entered into employment agreements with Thomas Gidoin, Didier Pruneau and Nitza Thomasson. These agreements have standard terms relating to base salary, bonuses, equity grants, termination and restrictions on competitive activities.

19.3 AUDITORS' REPORTS ON RELATED PARTY AGREEMENTS FOR THE FISCAL YEARS ENDING DECEMBER 31, 2016 AND 2015

19.3.1 AUDITORS' REPORT ON RELATED PARTY AGREEMENTS FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

To the Shareholders,

In our capacity as Statutory Auditors of your Company, we hereby report to you on the regulated agreements and commitments.

The terms of our engagement require us to communicate to you, based on information provided to us, the principal terms and conditions of those agreements and commitments brought to our attention or which we may have discovered during the course of our audit, as well as the reasons justifying that such commitments and agreements are in the company's interest, 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 for the purpose of approving them.

Our role is also to communicate the information provided for in Article R.225-31 of the French Commercial Code in respect of the performance of agreements and commitments already approved by General Shareholders' Meetings and having continuing effect during the year, if any.

We conducted our procedures in accordance with the professional guidelines of the French National Institute of Statutory Auditors *(Compagnie Nationale des Commissaires aux Comptes)* relating to this engagement. These guidelines require that we verify the consistency of the information provided to us with the relevant source documents.

1- AGREEMENTS AND COMMITMENTS SUBMITTED TO THE GENERAL SHAREHOLDER'S MEETINGS

1-1 Agreements and commitments authorized during the fiscal year

In accordance with Article L. 225-38 of the French Commercial Code, we inform you that we have not been advised of any agreement or commitment which has been submitted for approval to the General Shareholders' Meeting.

1-2 Agreements and commitments authorized since the end of the fiscal year

We have been advised of the following agreements and commitments, authorized since the end of the fiscal year, which were previously approved by the Board of Directors.

1-2-1 Type and purpose: granting of a severance payment

Person concerned: Mr. Bernard GILLY, Chief Executive Officer of GENSIGHT BIOLOGICS

Terms and conditions: it was decided that a severance payment, equal to twelve months of remuneration and calculated on the basis of the last annual remuneration (fixed and variable) will be granted to Mr. Bernard GILLY in the case of termination of his duties as Chief Executive Officer (or of Chairman-Chief Executive Officer, should the Board of Directors decide subsequently to combine the duties of Chairman of the Board of Directors and Chief Executive Officer) regardless of the reason.

As an exception to the above, the severance payment will not be paid:

(i) Should Mr. Bernard GILLY be removed from his duties as Chief Executive Officer for serious misconduct or gross negligence, as these notions are defined by applicable jurisprudence in French labor law, or

(ii) Should Mr. Bernard GILLY resign from his term of office as Chief Executive Officer, except if this resignation relates to sickness or family matters, it being specified that in these two cases, the severance payment will be paid to Mr. Bernard GILLY.

Furthermore, it is specified that the severance payment will not be paid if Mr. Bernard GILLY changes his duties within the Group or if he leaves the company, at his initiative, to perform new duties elsewhere.

Payment of the severance pay will be subject to the following performance condition: achieving at least 50% of the annual objectives with respect to the previous fiscal year.

Reason justifying the interest of this agreement for the company:

The granting of this severance payment is justified insofar as it allows for, under certain conditions, a compensation mechanism for the Chief Executive Officer in the event of the loss of his term of office, by offering a protection to a corporate officer who does not have an employment contract and as a result, who is excluded from the protection and compensation provided by the existence of an employment contract.

(Agreement authorized by the Board of Directors on March 9, 2017).

1-2-2 Type and purpose: non-compete clause

Person concerned: Mr. Bernard GILLY, Chief Executive Officer of GENSIGHT BIOLOGICS

Terms and conditions: it was decided to grant a monthly non-compete payment during one year, as from the departure of Mr. Bernard GILLY from the company, equal to 40% of his last monthly net remuneration, excluding all bonuses (less any other amount received irrespective of the reason in respect of a non-compete obligation), in consideration of the commitment made by Mr. Bernard GILLY, during the same period of one year as from his date of departure from the company:

- Not to hold in Europe, Canada, the United States and in any country where the company carries out its business activities, a term of office as a director, or a job position as senior executive, employee or consultant in any company performing the activity, or
- Not to own shares in the share capital of a company performing the activity, excluding the holding of an interest in any listed company representing at the most 1% of the share capital held exclusively for personal financial reasons.

It being specified that:

- The term activity means "the research and development, and the future marketing of all gene therapy products and equipment for orphan ophthalmic diseases",
- The Board of Directors decided to release Mr. Bernard GILLY from this non-compete obligation; this decision should take place at the latest before the expiration of the first month following the date of departure, in which case no amount will be owed by the company.

as provided for in Article 17 of the *"Third Amendment and Restatement Shareholders' Agreement"* of June 30, 2015.

Reason justifying the interest of this agreement for the company:

The stipulation of such a non-compete clause and its related compensation is justified insofar as it offers the company the possibility to protect its interest should the Chief Executive Officer subsequently leave the company.

(Agreement authorized by the Board of Directors on March 9, 2017).

1-3 Agreements and commitments not previously authorized

Pursuant to Articles L.225-42 and L.823-12 of the French Commercial Code, we inform you that following agreements and commitments have not been previously authorized by the Board of Directors.

Our role is to provide you with information describing the circumstances under which the authorization procedure was not followed.

Type and purpose: amendment n° 2 to the agreement for making available premises and provision of services with the company *PASSAGE DE L'INNOVATION*.

Person concerned: Mr. Bernard GILLY, President of the company *PASSAGE DE L'INNOVATION* and Chief Executive Officer of GENSIGHT BIOLOGICS.

Terms and conditions:

On May 2, 2016, your company signed an amendment (amendment n° 2) to the agreement for making available the premises and provision of services.

The agreement took effect on January 1, 2016.

The total annual rent amounts to €410,560.88, excluding taxes to which is added a provision for annual overhead expenses of €26,950.24, excluding taxes.

The provision of services may be modified depending on the prices charged by suppliers and service providers. The quarterly provision for "flat rate for access to services" is €67,433.97, excluding taxes, *i.e.* €269,735.88, excluding taxes annually.

Pursuant to this agreement, GENSIGHT BIOLOGICS recognized the following items in expenses:

- For rental of the premises: €410,560.88,
- For rental charges: €23,801.40 following a 2015 adjustment,
- For provision of services: €315,000.00.

Reason justifying the interest of this agreement for the company:

This agreement allows GENSIGHT BIOLOGICS to use premises in an eco-system bringing together a group of companies working in the biotechnologies sector.

(Agreement authorized by the Board of Directors on May 2, 2016).

The subsequent *a posteriori* authorization is due to an omission.

2- AGREEMENTS AND COMMITMENTS ALREADY APPROVED BY THE GENERAL SHAREHOLDERS' MEETING

Agreements and commitments approved during previous fiscal years and having continuing effect during the year

Pursuant to Article R.225-30 of the French Commercial Code, we have been informed of the following agreements and commitments, previously approved by the General Shareholders' Meeting in prior years and having continuing effect during the year.

Type and purpose: granting of a severance payment

Person concerned: Mr. Bernard GILLY, Chief Executive Officer of GENSIGHT BIOLOGICS

Terms and conditions: the granting of a severance payment equal to one year of remuneration to the Chief Executive Officer, previously authorized by the Board of Directors on February 14, 2013 and confirmed by the Board of Directors on May 2, 2016.

This agreement allows a compensation mechanism to be provided to the Chief Executive Officer in the event of the loss of his term of office as a result of his removal and represents a standard recognized protection for corporate officers who cannot have employment contracts, in particular in companies where the profit is "at risk" which is the case for GENSIGHT BIOLOGICS.

This agreement terminated on March 9, 2017 considering the decision of the Board of Directors to replace it with a severance payment fulfilling the requirements of Article L.225-42-1 of the French Commercial Code.

Signed in PARIS and in LYON, March 15, 2017

The Statutory Auditors

BECOUZE	DELOITTE & ASSOCIÉS
F. BROVEDANI Partner	D. VALETTE Partner

19.3.2 AUDITOR'S REPORT ON RELATED PARTY AGREEMENTS FOR THE FISCAL YEAR ENDING DECEMBER 31, 2015

To the Shareholders,

In our capacity as Statutory Auditor of your Company, we hereby report to you on regulated agreements with third-parties.

The terms of our engagement require us to communicate to you, based on information provided to us, the principal terms and conditions of those agreements brought to our attention or which we may have discovered during the course of our audit, as well as the reasons justifying that such agreements are in the Company's interest, without expressing an opinion on their usefulness and appropriateness or identifying other such 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 for the purpose of approving them.

Our role is also to provide you with the information stipulated in Article R.225-31 of the French Commercial Code relating to the implementation during the past year of agreements previously approved by the Shareholders' Meeting, if any.

We performed the procedures that we considered necessary in accordance with the professional guidelines of the French National Institute of Statutory Auditors *(Compagnie Nationale des Commissaires aux Comptes)* applicable to this engagement. These procedures consisted in agreeing the information provided to us with the relevant source documents.

AGREEMENTS SUBMITTED TO THE APPROVAL OF THE SHAREHOLDERS' MEETING

Agreements authorized during the fiscal year

We hereby inform you that we have not been advised of any agreement authorized during the year to be submitted to the approval of the Shareholders' Meeting pursuant to Article L.225-38 of the French Commercial Code.

Agreements not previously authorized

Pursuant to Articles L.225-42 and L.823-12 of the French Commercial Code, we bring to your attention the following agreement which was not previously authorized by your Board of Directors.

Our role is to communicate to you the circumstances which explain why the authorization procedure was not followed.

Agreement with Passage de l'Innovation for the provision of premises

Person concerned: Mr. Bernard Gilly, Chairman of *Passage de l'Innovation* and Chief Executive Officer of GenSight Biologics.

Nature and purpose: On October 1, 2015, your Company signed an amendment (Amendment no.1) to the agreement with *Passage de l'Innovation* for the provision of premises. This amendment concerns the addition to the initial agreement of a services package for 2015.

Terms and conditions: The services package is billed up to an annual ceiling of €311,164, excluding VAT, payable quarterly. An expense of €250,000, excluding VAT, was recognized in respect of 2015.

Reasons justifying that the agreement is in the Company's interest: The services package allows the company to benefit, at the 74 rue du Faubourg Saint-Antoine premises, from shared reception desk, switchboard and mail services and access to meeting rooms and relaxation areas.

The above agreement was not authorized in advance as it took effect retroactively.

During its meeting on May 2, 2016, your Board of Directors decided to authorize this agreement ex post.

AGREEMENTS PREVIOUSLY APPROVED BY SHAREHOLDERS' MEETING

Agreements approved in prior years without effect during the fiscal year

We have been informed of the continuation of the following agreements, previously approved by Shareholders' Meetings of prior years, that had no effect during the year.

Grant of severance compensation to the Chief Executive Officer

Person concerned: Mr. Bernard Gilly, Chief Executive Officer of GenSight Biologics

Nature, purpose and terms and conditions: Payment of gross severance compensation to the Chief Executive Officer equal to 12 months' remuneration calculated based on the last annual remuneration (fixed and variable), in the event of termination of Mr. Bernard Gilly's duties as Chief Executive Officer for whatever reason.

As an exception to the above, it is nonetheless stipulated that this severance compensation will not be payable:

(i) in the event of termination of Mr. Bernard Gilly's duties as Chief Executive Officer for gross negligence or serious misconduct, as defined by applicable employment legislation case law; or

(ii) in the event of resignation by Mr. Bernard Gilly from his duties as Chief Executive Officer, unless this resignation is due to illness or for family reasons, it being stipulated that in these two situations the severance compensation will be payable to Mr. Bernard Gilly.

Agreements approved during the fiscal year

We were also informed of the implementation during the year of the following agreements approved by the Shareholders' Meeting of June 25, 2015 based on the Statutory Auditor's special report of June 10, 2015.

Agreement with PASSAGE DE L'INNOVATION for the provision of premises:

Person concerned: Mr. Bernard Gilly, Chairman of *Passage de l'Innovation* and Chief Executive Officer of GenSight Biologics.

Nature, purpose and terms and conditions: Nine-year agreement effective from January 1, 2015, that may be terminated at the end of three-year periods, for an annual rent of €443,733, excluding VAT, plus an annual provision for general expenses of €29,233. The Combined Shareholders' Meeting of June 25, 2015 voted on this agreement.

Lyon, May 4, 2016

The Statutory Auditor

DELOITTE & ASSOCIÉS

Dominique Valette

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FINANCIAL INFORMATION CONCERNING THE GROUP'S ASSETS AND LIABILITIES, FINANCIAL POSITION AND PROFITS AND LOSSES

20.1 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 Registration Document includes our annual financial statements prepared in accordance with French accounting standards for the fiscal year ended December 31, 2016. Only these annual financial statements are legally binding. These financial statements are presented in Section 20.1.3, "Company's Annual Financial Statements (French GAAP) for the Fiscal Year Ending December 31, 2016" of this Registration Document.

The Company, which does not have any subsidiaries or any investment interests, has prepared, in addition to its annual financial statements in compliance with the French accounting standards, on a voluntary basis, corporate financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal year ended December 31, 2016 presented in this Registration Document in Section 20.1.1, "Company's Annual Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2016."

Unless otherwise indicated, the selected financial information as of and for the fiscal year ended December 31, 2016 has been derived from our financial statements prepared in accordance with IFRS as adopted by the European Union as of and for the fiscal years ended December 31, 2016. These financial statements for the fiscal year ended December 31, 2016 have been audited by Deloitte & Associés and Becouze, statutory auditors. The statutory auditors' report on the financial statements as of and for the fiscal year ended December 31, 2016 is included in Section 20.1.2, "statutory auditors' Report on the Company's Annual Financial Statements (IFRS) for the Fiscal Year Ending December 31, 2016" of this Registration Document.

The information in this section should be read together with (i) our financial statements contained in Section 20.1.1, "Company's Annual Financial Statements (IFRS) for the Fiscal Years Ending December 31, 2016" of this Registration Document, (ii) our analysis of our results presented in Section 9, "Operating and Financial Review," and (iii) our analysis of our liquidity and capital resources presented in Section 10, "Capital Resources."

20.1.1 COMPANY'S ANNUAL FINANCIAL STATEMENTS (IFRS) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

STATEMENTS OF FINANCIAL POSITION

(Amounts in Euros)	Note	As of December 31, 2015 €	2016 €
ASSETS			
Non-current assets			
Intangible assets	4	225,137	203,556
Property, plant and equipment	5	860,961	858,198
Other non-current financial assets	6	110,933	103,164
Total non-current assets		**1,197,030**	**1,164,917**
Current assets			
Customer accounts receivable and related receivable	7	27,499	30,419
Other current assets	7	5,025,836	4,053,077
Cash and cash equivalents	8	30,059,909	53,982,212
Total current assets		**35,113,245**	**58,065,708**
TOTAL ASSETS		**36,310,275**	**59,230,624**

(Amounts in Euros)	Note	As of December 31, 2015 €	2016 €
LIABILITIES			
Shareholders' equity	9		
Share capital		340,228	485,243
Premiums related to the share capital		49,795,709	91,230,210
Reserves		(7,155,890)	(16,293,473)
Net income (loss)		(13,653,620)	(22,081,663)
Total shareholders' equity		**29,326,426**	**53,340,317**
Non-current liabilities			
Conditional advances - non-current portion	10	622,190	2,922,448
Non-current provisions	11	68,209	72,967
Total non-current liabilities		**690,399**	**2,995,415**
Current liabilities			
Conditional advances - current portion	10	—	—
Supplier accounts payable and related payables	12	5,192,665	1,734,062
Other current liabilities	12	1,100,785	1,160,830
Total current liabilities		**6,293,450**	**2,894,892**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		**36,310,275**	**59,230,624**

STATEMENTS OF INCOME (LOSS)

(Amounts in Euros)	Note	Year Ended December 31, 2015 €	2016 €
Operating income			
Revenues		—	—
Other income	14	3,559,998	3,000,665
Total Operating Income		**3,559,998**	**3,000,665**
Operating expenses			
Research and development	15	10,722,104	18,529,135
General and administration	15	6,499,188	6,490,216
Total Operating expenses		**17,221,292**	**25,019,351**
Operating income (loss)		**(13,661,294)**	**(22,018,686)**
Financial income	17	41,308	26,491
Financial expenses	17	(33,634)	(89,468)
Financial income (loss)		**7,674**	**(62,977)**
Income tax	18	—	—
Net income (loss)		**(13,653,620)**	**(22,081,663)**
Basic/Diluted earnings per share (€ / share)	**21**	**(1.21)**	**(1.36)**

STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31,	
(Amounts in Euros)	2015 €	2016 €
Net income (loss)	(13,653,620)	(22,081,663)
Actuarial gains and losses on employee benefits, net of income tax	1,607	26,740
Other comprehensive income	1,607	26,740
Other items	—	—
Total comprehensive income (loss)	**(13,652,013)**	**(22,054,923)**

		Year Ended December 31,	
(Amounts in Euros)	Note	2015 €	2016 €
Cash flows from operating activities			
Net profit (loss)		(13,653,620)	(22,081,663)
Reconciliation of net profit (loss) and the cash used for operating activities			
Amortization and depreciation		138,650	202,712
Retirement pension obligations		29,348	31,498
Expenses related to share-based payments	15/16	1,531,876	4,634,525
Other financials items		(11,929)	(144)
Operating cash flows before change in working capital		**(11,965,676)**	**(17,213,072)**
Accounts receivable		502,961	(2,920)
Other receivables		(3,360,623)	972,759
Accounts payable		3,283,459	(3,458,603)
Other current liabilities		(554,675)	60,045
Change in working capital		**(128,877)**	**(2,428,718)**
Net cash flows from operating activities		**(12,094,554)**	**(19,641,790)**
Cash flows from investment activities			
Acquisitions of property, plant, and equipment		(699,427)	(188,177)
Acquisitions of intangible assets		(7,517)	(1,047)
Acquisitions/reimbursement of non-current financial assets		(79,545)	7,770
Sales of property, plant, and equipment		—	11,000
Purchase/sale of short-term investments		1,403,938	—
Net cash flows from investment activities		**617,449**	**(170,454)**
Cash flows from financing activities			
Conditional advances received	10	—	2,300,258
Treasury shares		115,622	(145,227)
Warrants issuance		—	140,118
Capital increases, net of transaction costs	9	30,751,921	41,439,398
Net cash flows from financing activities		30,867,543	43,734,547
(Decrease)/Increase in cash and cash equivalents		**19,390,438**	**23,922,303**
Cash and cash equivalents at the beginning of the period		10,669,471	30,059,909
Cash and cash equivalents at the close of the period		30,059,909	53,982,211

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(Amounts in Euros)	Share Capital		Premiums related to the share capital	Reserves	Net income (loss)	Total Shareholders' Equity
	Number of shares	Amount				
At January 1, 2015	**8,984,249**	**224,606**	**19,043,787**	**(2,018,232)**	**(6,671,142)**	**10,579,019**
Net income (loss)	—	—	—	—	(13,653,620)	(13,653,620)
Other comprehensive income	—	—	—	1,607	—	1,607
Total comprehensive income (loss)				**(2,016,625)**	**(13,653,620)**	**(13,652,014)**
Allocation of prior period net income (loss)	—	—	—	(6,671,142)	6,671,142	—
Capital increase by issuance of Series B preferred shares	4,624,871	115,622	32,027,233		—	32,142,854
Series B transaction costs	—	—	(1,305,562)			(1,305,562)
Issue of ordinary shares	2		—			—
Issue of share warrants			30,250			30,250
Share-based payments	—	—	—	1,531,877	—	1,531,877
At December 31, 2015	**13,609,122**	**340,228**	**49,795,709**	**(7,155,890)**	**(13,653,620)**	**29,326,426**
At January 1, 2016	**13,609,122**	**340,228**	**49,795,709**	**(7,155,890)**	**(13,653,620)**	**29,326,426**
Net income (loss)	—	—	—		(22,081,663)	(22,081,663)
Other comprehensive income	—	—	—	26,740	—	26,740
Total comprehensive income (loss)	**—**	**—**	**—**	**(7,129,150)**	**(22,081,663)**	**(22,054,923)**
Allocation of prior period income (loss)	—	—	—	(13,653,620)	13,653,620	—
Allocation to reserves						—
Capital increase by issuance of Ordinary shares	5,800,579	145,015	45,108,725			45,253,740
Capital increase transaction costs			(3,807,474)			(3,807,474)
Issue of ordinary shares			—			—
Issue of share warrants			133,250			133,250
Autocontrol				(145,227)		(145,227)
Share-based payments	—	—	—	4,634,525	—	4,634,525
At December 31, 2016	**19,409,701**	**485,243**	**91,230,210**	**(16,293,472)**	**(22,081,663)**	**53,340,317**

NOTES TO THE FINANCIAL STATEMENTS

Note 1: General information about the Company

Incorporated in 2012, GenSight Biologics S.A. (hereinafter referred to as **"GenSight Biologics"** or the **"Company"**) is a clinical-stage biotechnology company 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 for retinitis pigmentosa, to help preserve or restore vision in patients suffering from severe degenerative retinal diseases. The Company's focus is in ophthalmology where the Company 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 had shareholders' equity of €53,340,317 at December 31, 2016 as a result of several financing rounds (see Note 9). The Company 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 Company'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 Company'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 accompanying financial statements as of December 31, 2015 and 2016 and related notes (the **"financial statements"**) present the operations of the Company. The Company is a *société anonyme* governed by French law and has its registered office located at 74 rue du Faubourg Saint-Antoine, 75012 Paris — France. The Company presents individual financial statements as it had no subsidiaries as of December 31, 2016.

The financial statements have been prepared under the responsibility of management of the Company. The financial statements were approved by the Board of Directors of the Company on March 9, 2017.

All amounts are expressed in euros, unless stated otherwise.

Note 2: Statement of compliance

2.1 Statement of compliance

The financial statements have been prepared in accordance with International Financial Reporting Standards (**"IFRS"**) as issued by the International Accounting Standard Board (**"IASB"**) and adopted by the European Union, which is mandatory for the year ended December 31, 2016. Comparative figures are presented for the 12-month period ended December 31, 2015.

IFRS include International Financial Reporting Standards, International Accounting Standards (**"IAS"**), as well as the interpretations issued by the Standing Interpretations Committee (**"SIC"**) and the International Financial Reporting Interpretations Committee (**"IFRIC"**). The main accounting methods used to prepare the financial statements are described below. These methods were used for all periods presented.

These financial statements constitute a set of financial statements that are supplemental to the historical corporate financial statements of the company which are prepared in accordance with French financial principles.

Recently issued accounting pronouncements that may be relevant to the Company's operations but have not yet been adopted are as follows:

- On May 12, 2014, the IASB issued amendments to IAS 16 and IAS 38 *Clarification of Acceptable Methods of Depreciation and Amortisation*¸ applicable from January 1, 2016. The Company currently has not capitalized any development costs and does not expect that the adoption of this amendment will be material to its financial statements.
- On May 28, 2014, the IASB issued IFRS 15 *Revenue from Contracts* with Customers which specifies how and when to recognize revenue as well as requiring entities to provide users of financial statements with more informative and relevant disclosures. The standard supersedes IAS 18 *Revenue*, IAS 11 *Construction Contracts* and a number of revenue-related interpretations. This standard is effective for annual periods beginning on or after January 1, 2017. The Company is still in the process of assessing whether there will be a material change to its financial statements upon adoption of this new standard.
- On July 24, 2014, the IASB issued the final version of IFRS 9 *Financial Instruments (2014)* which replaces IAS 39 *Financial instruments: recognition and measurement* (**"IAS 39"**), bringing together the classification and measurement, impairment and hedge accounting. IFRS 9 is effective for annual periods beginning on or after January 1, 2018, with early adoption permitted. The Company is still in the process of assessing whether there will be a material change to its financial statements upon adoption of this new standard.
- On August 12, 2014, the IASB issued amendments to IAS 27 *Equity Method in Separate Financial Statements* which is effective for annual periods beginning on or after January 1, 2016, with earlier adoption permitted. The Company does not expect that the adoption of this amendment will be material to its financial statements.

- On September 25, 2014, the IASB issued *Annual improvements to IFRSs (2012-2014)* which includes various amendments to IFRSs. The Company does not expect that the adoption of these amendments will be material to its financial statements.
- On December 18, 2014, the IASB issued amendments to IAS 1 *Presentation of Financial Statements* which clarifies various presentation and disclosure requirements related to materiality, subtotals, disaggregation and accounting policies. These amendments are effective for annual periods beginning on or after January 1, 2016, with early adoption permitted. The adoption of these new amendments will not have a material impact on the financial statements of the Company.

The Company does not plan to early adopt the new accounting standards, amendments and interpretations.

The accounting policies and measurement principles adopted for the financial statements as of and for the year ended December 31, 2016 are the same for the comparative period presented.

2.2 Going concern

- The historical deficit position of the Company is explained by the innovative character of the products developed, which thus involved a research and development phase of several years preceding the marketing thereof,
- the available cash and cash equivalents as of December 31, 2016 in the amount of €54.0M and the reimbursement of the 2015 Research Tax Credit in the amount of €2.9M expected during the second half year of 2017 should enable the company to cover its cash requirements through the next twelve months.

Note 3: Accounting principles

3.1 Intangible assets

Pursuant to IAS 38 *Intangible Assets* (**"IAS 38"**), intangible assets acquired are recognized as assets on the 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 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 *Share-based payment* (**"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.

3.2 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. 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	5 to 10 years
Research and development / production tools	5 years
Computer equipment	3 years
Office equipment and furniture	5 years

3.3 Financial assets

Financial assets include assets available for sale, assets owned until maturity, loans and receivables, cash and cash equivalents.

The valuation and the accounting treatment of the financial assets and liabilities are defined by IAS 39 *Financial Instruments: Recognition and Measurement* (**"IAS 39"**), with the exception of deposits and guarantees in relation to lease agreements, which are classified under non-current financial assets on the statement of financial position and measured at cost.

Assets owned until maturity

These securities are exclusively fixed income or determinable income and have fixed maturities, other than loans and accounts receivable, that the Company has the intention and the ability to keep until maturity. After their initial posting at their fair value, they are valued and recognized in the financial statements at the amortized cost on the basis of the effective interest rate (**"EIR"**) method.

The assets owned until maturity are monitored for any objective indication of impairment. A financial asset is impaired if its carrying value is greater than its recoverable amount as estimated during impairment tests. The impairment is recognized in the statement of income (loss).

Loans and receivables

This category includes other loans and accounts receivable and commercial receivables.

These instruments are initially recognized in the financial statements at their fair value and then at the amortized cost calculated with the EIR method. The short-term receivables without an interest rate are valued at the amount of the original invoice, unless the application of an implicit interest rate has a significant effect. For the loans and variable-rate accounts receivable, a periodic re-estimation of the cash flows, in order to reflect the change in the market interest rate, modifies the effective interest rate and therefore the valuation of the loan or of the receivable.

The loans and receivables are monitored for any objective indication of impairment. A financial asset is impaired if its book value is greater than its recoverable amount as estimated during impairment tests. The impairment is recognized in the statement of income (loss).

Assets at fair value through the statement of income (loss)

The assets considered to be held for trading purposes include the assets that the Company intends to resell in the near future in order to realize a capital gain, which is part of a managed portfolio of financial instruments classified as cash, cash equivalents and marketable securities for which there exists a practice of selling in the short term. The assets held for trading may also include assets voluntarily classified in this category, in a manner that is independent of the criteria listed above, in accordance with the fair value option accounting principle under IFRS.

Assets available for sale

The assets available for sale include, primarily, securities that do not meet the criteria of the definition of the other categories of financial assets. They are valued at their fair value, and the changes in value are recognized in other comprehensive income within shareholders' equity.

The fair value corresponds to the market price for those securities that are listed on a stock exchange or to an estimate of the value for unlisted securities, determined on the basis of the financial criteria most appropriate for the specific security. When there is an objective indication of the impairment of these securities, the accumulated impairment is recognized in shareholders' equity in the statement of income (loss).

3.4 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.

3.5 Cash and cash equivalents and short-term investments

Cash equivalents and short-term investments are owned for the purpose of meeting short-term cash commitments rather than for the objective of investment or for other purposes. They are readily convertible into a known amount of cash and are subject to a negligible risk of change in value. Cash and cash equivalents are liquid assets that are available immediately, long-term investments that can be liquidated immediately without a penalty and money market funds, which are readily convertible into a known amount of cash and are subject to a negligible risk of change in value. Cash equivalents are valued on the basis of the IAS 39 categories under which they fall.

Short-term investments are generally comprised of term deposits that have a maturity exceeding three months and are measured on the basis of the IAS 39 categories under which they fall.

Cash equivalents and short-term investments are measured at their fair value, and the changes in value are recognized through financial income or loss. Given the nature of these assets, their fair value is generally close to their net carrying value.

3.6 Share capital

Common 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.

3.7 Share-based payment

Since its formation, the Company has established several plans for compensation paid in equity instruments in the form of employee warrants (*bons de souscription de parts de créateur d'entreprise* or "BCEs") granted to employees and/or executives and in the form of "share warrants" (*bons de souscription d'actions* or "BSAs") granted to non-employee members of the board of directors and scientific consultants. Pursuant to IFRS 2, the cost of the transactions paid with equity instruments is recognized as an expense in exchange for an increase in the shareholders' equity for the period during which the rights to be enjoyed from the equity instruments are acquired.

The Company has applied IFRS 2 to all equity instruments granted since its inception in 2012 to its employees, members of the Board of Directors, other individuals, or to companies.

The warrants are not subject to any market conditions. The warrants are described in Note 9.2.

3.8 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.

3.9 Research tax credit, subsidies and conditional advances

Research tax credit

The research tax credit *(Crédit d'Impôt Recherche)* (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 2015 during the year 2016. It will request the reimbursement of the 2016 Research Tax Credit under the Community tax rules for small and medium firms in compliance with the regulatory texts in effect.

The CIR is presented under other income in the 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 for such conditional advances in cash based on a repayment schedule. Each award of an advance is made to help fund a specific development milestone. The details concerning the conditional advances are provided in Note 10. Receipts or reimbursements of conditional advances are reflected as financing transactions in the statement of cash flows.

The amount resulting from the benefit of conditional advances that do not bear interest at market rates is considered a subsidy.

This benefit is determined by applying a discount rate equal to the rate the Company would have to pay for a bank borrowing over a similar maturity.

The implicit interest rate resulting from taking into account the whole repayments plus the additional payments due in case of commercial success as described in Note 10 is used to determine the amount recognized annually as a finance cost.

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 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 10.1.

3.10 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 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 Company appoints external actuaries to conduct an annual review of the valuation of these plans.

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 actual gains and losses.

The Company's payments for the defined-contribution plans are recognized as expenses on the statement of income (loss) of the period during which they become payable.

3.11 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 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.

The amount recognized in the financial statements as a provision is the best estimate of the expenses necessary to extinguish the obligation.

3.12 Leases

The leases involving property, plant and equipment are classified as finance lease agreements when the Company bears substantially all the benefits and risks inherent in the ownership of the property. The assets that are covered under finance lease agreements are capitalized as of the beginning date of the rental agreement on the basis of the fair value of the rented asset or the discounted values of the future minimum payments, whichever is lower. Each rental payment is distributed between the debt and the financial cost in such a manner to determine a constant interest rate on the principal that remains due. The corresponding rental obligations, net of the financial expenses, are classified as financial liabilities. The property, plant and equipment acquired within the framework of a finance lease agreement is amortized over the use period or the term of the lease agreement, whichever is shorter.

The rental agreements for which a significant portion of the risks and advantages is preserved by the lessor are classified as operating leases. The payments made for these operating leases, net of any incentive measures, are recognized as expenses on the statement of income (loss) in a linear manner over the term of the agreement.

3.13 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 Company has not recognized deferred tax assets in relation to tax loss carryforward in the statement of financial position.

3.14 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 in France.

3.15 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;
- 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.

3.16 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 Company 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 measurement of the fair value of the employee warrants (BCEs) granted to employees and/or executives and share warrants (BSAs) granted to non-employee members of the Board of Directors and scientific consultants and to service providers, 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 16);
- 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);
- the estimate of the amount of the intangible asset recognized in the context of a license agreement. The acquisition of this license 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).

3.17 Events after the close of the fiscal year

The statement of financial position and the statement of income (loss) of the Company are adjusted to reflect the subsequent events that alter the amounts related to the situations that exist as of the closing date. The adjustments are made until the date the financial statements are approved and authorized for issuance by the Board of Directors.

Subsequent events following December 31, 2016 that have not resulted in adjustments are presented in Note 23.

Note 4: Intangible assets

The intangible assets are broken down as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Patents, licenses, trademarks	274,941	274,941
Software	9,165	10,212
Total historical cost	**284,106**	**285,153**
Accumulated amort. of patents, licenses, and trademarks	53,231	71,560
Accumulated depreciation of softwage packages	5,739	10,038
Accumulated amortization and depreciation	**58,970**	**81,598**
Net total	**225,137**	**203,556**

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 €274,941 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

(Amounts in Euros)	As of January 1, 2015	Increase	Decrease	As of December 31, 2015
Technical equipment and installations	133,320	451,854	—	585,174
Leasehold improvement	7,194	95,237	—	102,432
Office and computer equipment	48,996	28,493	—	77,490
Furniture	124,402	129,376	—	253,778
Other property, plant and equipment	5,534	—	5,534	—
Total gross property, plant and equipment	**319,447**	**704,961**	**5,534**	**1,018,874**
Accumulated depreciation of technical equipment and installations	13,637	49,946	—	63,583
Accumulated depreciation of leasehold improvement	2	6,370	—	6,372
Accumulated depreciation of office and computer equipment	16,616	20,175	—	36,791
Accumulated depreciation of furniture	11,410	39,757	—	51,167
Accumulated depreciation of other property, plant and equipment	—	—	—	—
Total accumulated amortization and depreciation	**41,665**	**116,248**	**—**	**157,913**
Total net property, plant and equipment	**277,782**			**860,961**

(Amounts in Euros)	As of January 1, 2016	Increase	Decrease	As of December 31, 2016
Technical equipment and installations	585,174	102,279	—	687,453
Leasehold improvement	102,432	40,082	—	142,513
Office and computer equipment	77,490	24,606	—	102,096
Furniture	253,778	21,210	19,188	255,800
Other property, plant and equipment	—	—	—	—
Total gross property, plant and equipment	**1,018,874**	**188,177**	**19,188**	**1,187,862**
Accumulated depreciation of technical equipment and installations	63,583	44,891	—	108,474
Accumulated depreciation of leasehold improvement	6,372	60,650	—	67,022
Accumulated depreciation of office and computer equipment	36,791	24,835	—	61,627
Accumulated depreciation of furniture	51,167	49,708	8,332	92,542
Accumulated depreciation of other property, plant and equipment	—	—	—	—
Total accumulated amortization and depreciation	**157,913**	**180,084**	**8,332**	**329,665**
Total net property, plant and equipment	**860,961**			**858,198**

Over the two periods presented, the increase primarily relates to technical equipment and installations and to furniture. The increase in the building fixtures item is related to the improvements made in the Company's premises.

Note 6: Non-current financial assets

	As of December 31,	
(Amounts in Euros)	2015	2016
Security deposits	110,933	103,164
Total non-current financial assets	**110,933**	**103,164**

The non-current financial assets correspond to the deposit paid to the lessor for the registered offices of the Company.

Note 7: Accounts receivable and other current assets

7.1 Accounts receivable and related receivables

	As of December 31,	
(Amounts in Euros)	2015	2016
Accounts receivable and related receivables	27,499	30,419
Valuation allowance (charges to income statement)	—	—
Total net value of accounts receivable	**27,499**	**30,419**

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.

7.2 Other current assets

The other current assets are broken down as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Prepayments	420,531	132,596
Research tax credit	2,874,069	2,929,874
Other tax claims	953,890	397,903
Other receivable	3,000	—
Liquidity contract	—	151,170
Prepaid expenses	774,345	441,534
Total	**5,025,836**	**4,053,077**

Prepayments are primarily related to the premises.

The other tax claims are primarily related to deductible VAT as well as to the reimbursement of VAT that has been requested.

As of December 31, 2016, prepaid expenses were primarily 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 3.9, the Research Tax Credit is recognized in the 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 euros
Opening balance sheet receivable as of January 1, 2015	911,682
Other operating income	2,874,069
Payment received	(911,682)
Closing balance sheet receivable as of December 31, 2015	2,874,069

	Amounts in euros
Opening balance sheet receivable as of January 1, 2016	2,874,069
Other operating income	2,929,874
Payment received	(2,874,069)
Closing balance sheet receivable as of December 31, 2016	2,929,874

Note 8: Cash and cash equivalents and short-term investments

Cash, cash equivalents and short-term investments items are broken down as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Cash	1,050,204	53,982,212
Cash equivalents	29,009,706	—
Total cash and cash equivalent as reported in the statements of financial position	30,059,909	53,982,212
Bank overdrafts	—	—
Total net cash and cash equivalents as reported in the statements of cash flows	30,059,909	53,982,212

Note 9: Capital

9.1 Share capital issued

The share capital as of December 31, 2016 was €485,242.53. It is divided into 19,409,701 fully authorized, subscribed and paid-up ordinary shares with a nominal value of €0.025.

On February 14, 2013 and March 20, 2013, the Company completed a financing round divided into three tranches and the Company issued 6,443,201 Series A preferred shares (ABSA 1) each with a nominal value of €0.025 and a share premium of €2.78 per share. In the event of an initial public offering, each Series A preferred share will be converted into one ordinary share.

On December 19, 2013, the Company raised additional financing divided into three tranches and the Company issued 523,253 Series A preferred shares (ABSA 1) with a nominal value of €0.025 and a share premium of €3.20 per share.

On July 7, 2015, the Company completed a financing round of €32.1 million and the Company issued 4,624,870 Series B preferred shares each with a nominal value of €0.025 and a share premium of €6.925 per share (after taking into account the reverse share split on September 3, 2015).

On July 13, 2016, the Company completed its Initial Public Offering (IPO) on Euronext Paris, raising €40.0 million, 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, and the Company issued 655,859 ordinary shares with a nominal value of €0.025 and a share premium of €7.975 per share.

The 19,409,701 outstanding shares does not include non-employee share warrants (**"BSA"**) and employee share warrants (**"BCE"**). BSA are granted to investors and other individual non-employees and BCE are granted to employees only.

On August 17, 2015, our shareholders approved a 5-for-2 reverse split of our outstanding shares. Under French law, the reverse share split became effective on August 17, 2015 which was 15 days after notice of the split was published in the French *Bulletin des Annonces Légales Obligatoires*, or BALO. All share-related disclosures, including par values, share prices, number of ordinary shares, preferred shares, share options and warrants, exercise prices of share options and warrants and related fair values per share, and net income (loss) per share calculations, have been recast to reflect the 5-for-2 reverse share split for all periods presented.

The table below presents the historical changes in the share capital of the Company as of December 31, 2015 and 2016:

	Share Capital	Share premium	Number of shares
Balance as of January 1, 2015	**€224,606**	**€19,043,787**	**8,984,249**
Capital increase by issuance of Series B preferred shares	€115,622	€32,027,233	4,624,870
Less cost of issuance of shares		(1,305,561)	
Capital increase by issuance of ordinary shares			3
Issue of shares upon exercise of subscription warrants[(1)]		€30,250	
Total as of December 31,2015	€340,228	€49,795,709	13,609,122
Balance as of January 1, 2016	**€340,228**	**€49,795,709**	**13,609,122**
Capital increase by issuance of ordinary shares	€141,397	€45,108,725	5,655,859
Less cost of issuance of shares		(3,807,474)	
Issue of shares upon exercise of subscription warrants[(1)]	€3,618	€133,250	144,720
Total as of December 31, 2016	€485,243	€91,230,210	19,409,701

(1) The share premium corresponds to both the subscription of granted warrants and the exercise of warrants.

9.2 Warrants issued

The company has issued non-employee warrants, or BSA, and employee warrants, or BCE.

The following two tables relate to warrants to purchase ordinary shares.

Date	Type	Number of warrants issued as of 12/31/2015	Number of warrants null and void as of 12/31/2015	Number of warrants exercised	Number of warrants outstanding as of 12/31/2015	Maximum numbe of shares to be issued	Strike price per share
07/08/13	BCE 2013-02	892,000	—	161,602	730,398	730,398	€0.025
07/08/13	BSA 2013-02	328,000	—	67,960	260,040	260,040	€0.025
04/09/14	BCE 2013-02	193,800	—	—	193,800	193,800	€0.025
04/09/14	BSA 2013-02	33,000	—	—	33,000	33,000	€0.025
12/03/14	BCE 2014-06	60,000	—	—	60,000	60,000	€0.025
08/07/15	BSA 2015-06	121,000	—	—	121,000	121,000	€3.275
08/07/15	BCE 2015-06	733,298	—	—	733,298	733,298	€3.275
	Total	**2,361,098**	**—**	**229,562**	**2,131,536**	**2,131,536**	

Date	Type	Number of warrants issued as of 12/31/2016	Number of warrants null and void as of 12/31/2016	Number of warrants exercised	Number of warrants outstanding as of 12/31/2016	Maximum number of shares to be issued	Strike price per share
07/08/13	BCE 2013-02	892,000	—	305,322	586,678	586,678	€0.025
07/08/13	BSA 2013-02	328,000	—	67,960	260,040	260,040	€0.025
04/09/14	BCE 2013-02	193,800	—	—	193,800	193,800	€0.025
04/09/14	BSA 2013-02	33,000	—	—	33,000	33,000	€0.025
12/03/14	BCE 2014-06	60,000	—	—	60,000	60,000	€0.025
08/07/15	BSA 2015-06	121,000	—	—	121,000	121,000	€3.275
08/07/15	BCE 2015-06	733,298	—	1,000	732,298	732,298	€3.275
07/26/15	BSA 2016	205,000	—	—	205,000	205,000	€8.080
	Total	**2,566,098**	**—**	**374,282**	**2,191,816**	**2,191,816**	

9.3 Performance shares granted

The company has granted performance shares, or AGA, to employees.

The following table relate to performance shares granted.

Date	Type	Number of performance shares granted as of 12/31/2016	Number of performance shares cancelled as of 12/31/2016	Number of performance shares acquired	Maximum number of shares to be acquired
07/26/15	AGA 2016	766,000	—	—	766,000
	Total	**766,000**	**—**	**—**	**766,000**

The impact of the share-based payments on the net loss is presented in Note 16.

Note 10: Financial liabilities

10.1 Conditional advances

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 amount of the conditional advances granted was €5,685,975, of which €678,000 was received in December 2014, and €2,278,914 in July 2016, both recognized as non-current liabilities in the statement of financial position, as this conditional advance is repayable by the Company according to a repayment schedule.

The contract with Bpifrance Financement sets forth a repayment schedule that totals €6,490,000. 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 €2.72 million, depending on whether the Company reaches cumulative revenues, excluding taxes, of €80 million by 2029. 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.

This program will be funded according to the following schedule, subject to completion of milestones:

- €678,000 received in December 2014;
- €2,278,914 received in July 2016[(1)];
- €494,000 to be received in November 2017;
- €852,975 to be received in November 2018; and
- €986,000 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 €6,490,000 (including interest at an annual rate of 1.44%) is as follows:

- €550,000 on or before June 30, 2022;
- €1,000,000 on or before June 30, 2023;
- €1,500,000 on or before June 30, 2024;
- €1,700,000 on or before June 30, 2025; and
- €1,740,000 on or before June 30, 2026.

Portions of the conditional advances with terms longer than one year are classified as non-current liabilities, while the portions with terms of less than one year are classified as current liabilities.

The table below presents the details of the debts recorded on the statements of financial position:

	in €
Opening Balance sheet debt as of January 1, 2015	**632,332**
Receipts	—
Repayments	—
Other transactions	(10,142)
Closing Balance sheet as of December 31, 2015	**622,190**
Non-current portion	622,190
Current portion	—
Opening Balance sheet debt as of January 1, 2016	**622,190**
Receipts	2,278,914
Repayments	—
Other transactions	21,344
Closing Balance sheet as of December 31, 2016	**2,922,448**
Non-current portion	2,922,448
Current portion	—

The deduction that appears in other transactions is the effect of discounting of the conditional advance.

(1) The estimated amount from the initial payment schedule was €2,675,000. The costs occurred by Company amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.

10.2 Maturity dates

Maturity dates of financial liabilities as of December 31, 2015, are as follows:

(Amounts in Euros)	Gross amount	Less than one year	One to five years	More than five years
Financial liabilities				
Non-current conditional advances	622,190	—	—	622,190
Accounts payable and related payables	5,192,665	5,192,665	—	—
Total financial liabilities	**5,814,855**	**5,192,665**	**—**	**622,190**

Maturity dates of financial liabilities as of December 31, 2016 are as follows:

(Amounts in Euros)	Gross amount	Less than one year	One to five years	More than five years
Financial liabilities				
Non-current conditional advances	2,922,448	—	—	2,922,448
Accounts payable and related payables	1,734,062	1,734,062	—	—
Total financial liabilities	**4,656,510**	**1,734,062**	**—**	**2,922,448**

Note 11: Non-current provisions

Non-current provisions as of December 31, 2015, and December 31, 2016 are as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Pension and employee benefits	68,209	72,967
Miscellaneous	—	—
Total	**68,209**	**72,967**

The commitments for compensation payable to employees upon their retirement as of December 31, 2015 and December 31, 2016 are as follows:

	Amounts in euros
As of January 1, 2015	**40,468**
Costs of services rendered (operating expense)	28,845
Interest expense	503
Benefit paid	—
Actuarial gain (loss)	(1,607)
As of December 31, 2015	**68,209**
Costs of services rendered (operating expense)	30,079
Interest expense	1,419
Benefit paid	—
Actuarial gain (loss)	(26,740)
As of December 31, 2016	**72,967**

As part of the estimate of the retirement commitments, the following assumptions were used for all categories of employees:

- Social security contribution: 45% in 2015 and 2016;
- Salary increase: 3% in 2015 and 2016;
- Discount rate: 2.08% and 1.31% in 2015 and 2016, respectively;
- Retirement age: 67;
- Terms of retirement: voluntary retirement;
- Life table: INSEE 2011-2013;
- Collective agreement: *Convention Collective Nationale de l'Industrie Pharmaceutique* (National Collective Agreement in the Pharmaceutical Industry); and
- Turn-over of personnel: 10% (20-49), 0% above 50.

No retirement was recorded during any of the periods presented.

Note 12: Accounts payable and other current liabilities

12.1 Accounts payable and related parties

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.

12.2 Other current liabilities

	As of December 31,	
(Amounts in Euros)	2015	2016
Due to employees	531,412	654,518
Social security and payroll contribution liabilities	447,513	448,286
Other taxes	5,634	17,156
Other debts	29,593	7,499
Deferred revenues from subsidies	86,634	33,371
Total	**1,100,785**	**1,160,830**

As mentioned in Note 10, in addition to the conditional advance, the Company has received one non-refundable subsidy from Bpifrance Financement in connection with its development of product candidates using its optogenetics technology platform as follows:

- €865,000 received in December 2014;
- €172,471 to be received in November 2018; and
- €110,000 to be received in November 2019.

As a result, an amount of €31,029, €642,960 and €191,011 was recorded in other income in the statement of income (loss) for the year ended December 31, 2016, 2015 and 2014, respectively.

The remaining balance of €31,029 as of December 31, 2015 and €673,989 as of December 31, 2014 is recorded in deferred revenue in the statements of financial position.

Note 13: Financial instruments recognized in the statements of financial position and related effect on the statement of income (loss)

(Amounts in 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, 2015					
Financial assets					
Non-current financial assets	110,933			110,933	110,933
Accounts receivable and related receivables	27,499		27,499		27,499
Cash and cash equivalent	30,059,909	30,059,909			30,059,909
Total financial assets	**30,198,342**	**30,059,909**	**27,499**	**110,933**	**30,198,342**
Financial liabilities					
Conditional advances (non-current portion)	622,190			622,190	622,190
Accounts payable and related payables	5,192,665			5,192,665	5,192,665
Total financial liabilities	**5,814,855**	—	—	**5,814,855**	**5,814,855**

(Amounts in 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, 2016					
Financial assets					
Non-current financial assets	103,164			103,164	103,164
Accounts receivable and related receivables	30,419		30,419		30,419
Cash and cash equivalent	53,982,212	53,982,212			53,982,212
Total financial assets	**54,115,795**	**53,982,212**	**30,419**	**103,164**	**54,115,795**
Financial liabilities					
Conditional advances (non-current portion)	2,922,448			2,922,448	2,922,448
Accounts payable and related payables	1,734,062			1,734,062	1,734,062
Total financial liabilities	**4,656,510**	—	—	**4,656,510**	**4,656,510**

(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 14: Other income

	As of December 31,	
(Amounts in Euros)	2015	2016
Research tax credit (see note 7.2)	2,874,069	2,929,874
Subsidies (see note 12.2)(1)	685,929	70,791
Total	**3,559,998**	**3,000,665**

(1) Includes €642,960 and €31,029, in 2015 and 2016, respectively, related to the subsidy received from Bpifrance Financement.

Note 15: Operating expenses

The research and development expenditures are broken down as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Personnel expenses(1)	3,066,853	4,375,276
Sub-contracting, collaboration and consultants	6,449,199	11,357,583
Licensing and intellectual property	173,340	1,075,087
Real estate property rental, net	628,442	615,111
Conferences and travel expenses	245,289	814,610
Allowance for provisions, amortizations and depreciations	111,597	173,172
Others	47,383	118,296
Total	**10,722,104**	**18,529,135**

(1) Includes €579,687 and €1,846,464 related to share-based payments for 2015 and 2016, respectively.

The distribution of general and administrative expenses is as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Personnel expenses(1)	2,047,893	4,532,907
Fees(2)	3,273,420	698,830
Communication and travel expenses	744,546	683,579
Real estate property rental, net	202,192	198,350
Office furniture and small equipment	43,516	64,439
Postal and telecommunication expenses	59,387	84,168
Allowance for provisions, amortizations and depreciations	27,072	29,396
Directors attendance fees	34,713	85,900
Insurance and banking fees	26,394	79,309
Equipment rental	19,296	20,671
Others	20,760	12,667
Total G&A expenses	**6,499,188**	**6,490,216**

(1) Includes €952,189 and €2,788,061 related to share-based payments as of December 31, 2015 and 2016, respectively.
(2) Includes €2.9 million related to third-party legal, accounting and advisory fees incurred in 2015 for the preparation of our initial public offering on the Nasdaq Global Market

Personnel expenses

The Company had 25 and 27 employees as of December 31, 2015, and 2016, respectively.

The personnel expenses are broken down as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Wages and salaries	2,606,573	3,076,487
Social security and payroll related contributions	947,452	1,167,092
Service cost related to employee benefit	28,845	30,079
Share-based payments	1,531,876	4,634,525
Total	**5,114,746**	**8,908,182**

Note 16: Share-based payments

The Board of Directors has been authorized by the general meeting of the shareholders to grant employee warrants (*Bons de Souscription de Parts de Créateur d'Entreprise* or "BCE"), non-employee warrants (*Bons de Souscription d'Actions* or "BSA") and performance shares (*Attributions Gratuites d'Actions* or "AGA"), 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 BCE 2013-02 warrants on July 8, 2013;
- with the authorization of the General Meeting of Shareholders on February 5, 2013, the Board of Directors issued 328,000 BSA 2013-02 warrants 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 on April 9, 2014;
- with the authorization of the General Meeting of Shareholders on February 5, 2013, the Board of Directors issued 33,000 BSA 2013-02 warrants on April 9, 2014; and
- 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 the authorization of the General Meeting of Shareholders on June 29, 2015, the Board of Directors issued 121,000 BSA 2015-06 warrants on July 7, 2015.
- with the authorization of the General Meeting of Shareholders on June 29, 2015, the Board of Directors issued 733,298 BCE 2015-06 warrants on July 7, 2015.
- with the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors issued 121,000 BSA 2016 warrants on July 26, 2016.
- with the authorization of the General Meeting of Shareholders on May 19, 2016, the Board of Directors issued 733,298 AGA 2016 performance shares on July 26, 2016.

16.1 BCE 2013-02 warrants

Date of Grant July 8, 2013 and April 9, 2014

The BCE 2013-02 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 of the BCE 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.

Details of BCE 2013-02 warrants

	Date of grant	
	July 8, 2013	April 9, 2014
Plan expiration date	07/07/2023	04/08/2024
Number of BCE 2013-02 warrants granted	892,000	193,800
Exercise price	€0.025	€0.025
Valuation method	Black and Scholes	Black and Scholes
Expected volatility	42.50%	42.50%
Expected dividend	0%	0%
Fair value per BCE 2013-02 warrants	€0.44	€0.44

BCE 2013-02 warrants outstanding

	Year ended December 31,	
	2015	2016
Balance outstanding at beginning of period	924,200	924,198
Granted during the period	—	—
Forfeited during the period	—	—
Exercised during the period	2	143,720
Expired during the period	—	—
Balance outstanding at end of period	924,198	780,478

BCE 2013-02 warrants closing balance

	Year ended December 31,			
	2015		2016	
	Outstanding	Exercisable	Outstanding	Exercisable
BCE 2013-02 warrants with exercise price of €0.025	924,198	458,065	780,478	780,478
Total	**924,198**	**458,065**	**780,478**	**780,478**

16.2 BSA 2013-02 warrants

Date of grant July 8, 2013 and April 9, 2014

The BSA 2013-02 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 of the BSA 2013-02 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 of BSA 2013-02 warrants

	Date of grant	
	July 8, 2013	April 9, 2014
Plan expiration date	07/07/2023	04/08/2024
Number of BSA 2013-02 warrants granted	328,000	33,000
Exercise price	€0.025	€0.025
Valuation method	Black and Scholes	Black and Scholes
Expected volatility	42.50%	42.50%
Expected dividend	0%	0%
Fair value per BSA 2013-02 warrants	€0.36	€0.36

BSA 2013-02 warrants outstanding

	Year ended December 31,	
	2015	2016
Balance at beginning of period	293,040	293,040
Granted during the period	—	—
Forfeited during the period	—	—
Exercised during the period	—	—
Expired during the period	—	—
Balance at end of period	293,040	293,040

BSA 2013-02 warrants closing balance

	Year ended December 31,			
	2015		2016	
	Outstanding	Exercisable	Outstanding	Exercisable
BSA 2013-02 warrants with exercise price of €0.025	293,040	143,957	293,040	293,040
Total	**293,040**	**143,957**	**293,040**	**293,040**

16.3 BCE 2014-06 warrants

Date of grant December 3, 2014

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.

Details of BCE 2014-06 warrants

	Date of grant
	December 3, 2014
Plan expiration date	12/02/2024
Number of BCE 2014-06 warrants granted	60,000
Exercise price	€0.025
Valuation method	Black and Scholes
Expected volatility	75.21%
Expected dividend	0%
Fair value per BCE 2014-06 warrants	€2.15

BCE 2014-06 warrants outstanding

	Year ended December 31,	
Number of BCE 2014-06 Warrants	2015	2016
Balance outstanding at beginning of period	60,000	60,000
Granted during the period	—	—
Forfeited during the period	—	—
Exercised during the period	—	—
Expired during the period	—	—
Balance outstanding at end of period	60,000	60,000

BCE 2014-06 warrants closing balance

	Year ended December 31,			
	2015		2016	
	Outstanding	Exercisable	Outstanding	Exercisable
BSA 2014-06 warrants with exercise price of €0.025	60,000	—	60,000	60,000
Total	**60,000**	**—**	**60,000**	**60,000**

16.4 BCE 2015-06 warrants

Date of grant July 8, 2015

The BCE 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 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.

Details of BCE 2015-06 warrants

	Date of grant
	July 8, 2015
Plan expiration date	7/7/2025
Number of BCE 2015-06 warrants granted	733,298
Exercise price	€3.275
Valuation method	Black and Scholes
Expected volatility	76.49%
Expected dividend	0%
Fair value per BCE 2015-06 warrants	€5.56

BCE 2015-06 warrants outstanding

	Year ended December 31,	
Number of BCE 2015-06 Warrants	2015	2016
Balance outstanding at beginning of period	—	733,298
Granted during the period	733,298	—
Forfeited during the period	—	—
Exercised during the period	—	—
Expired during the period	—	—
Balance outstanding at end of period	733,298	733,298

BCE 2014-06 warrants closing balance

	Year ended December 31,			
	2015		2016	
	Outstanding	Exercisable	Outstanding	Exercisable
BCE 2015-06 warrants with exercise price of €3.275	733,298	—	733,298	259,709
Total	**733,298**	**—**	**733,298**	**259,709**

16.5 BSA 2015-06 warrants

Date of grant July 8, 2015

The BSA 2015-06 warrants may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 1/4 of the 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.

Details of BSA 2015-06 warrants

	Date of grant
	July 8, 2015
Plan expiration date	7/7/2025
Number of BSA 2015-06 warrants granted	121,000
Exercise price	€3.275
Valuation method	Black and Scholes
Expected volatility	76.49%
Expected dividend	0%
Fair value per BSA 2015-06 warrants	€5.31

BSA 2015-06 warrants outstanding

	Year ended December 31,	
Number of BSA 2015-06 Warrants	2015	2016
Balance outstanding at beginning of period	—	121,000
Granted during the period	121,000	—
Forfeited during the period	—	—
Exercised during the period	—	—
Expired during the period	—	—
Balance outstanding at end of period	121,000	121,000

BSA 2014-06 warrants closing balance

	Year ended December 31,			
	2015		2016	
	Outstanding	Exercisable	Outstanding	Exercisable
BSA 2015-06 warrants with exercise price of €3.275	121,000	—	121,000	42,854
Total	**121,000**	**—**	**121,000**	**42,854**

16.6 AGA 2016 performance shares

Date of grant July 26, 2016

The AGA 2016 performance shares may be fully acquired at the end of an acquisition period of one year. In addition, the acquisition of performance shares by Key Managers, including Mr. Gilly, is subordinate to the achievement of the following performance criteria at the latest on July 26, 2018:

- 50% of AGA 2016 will be acquired at the later of the two following dates, either (i) the expiry of a period of one year from the date of grant or (ii) the completion of enrollment in RESCUE and REVERSE clinical trials;
- 50% of AGA 2016 will be acquired at the later of the two following dates, either (i) the expiry of a period of one year from the date of grant or (ii) the enrollment of the first patient in a Phase I/II clinical trial with GS030 in retinitis pigmentosa.

Details of AGA 2016 performance shares

	Date of grant
	July 8, 2015
Number of AGA 2016 performance shares granted	766,000
Vesting period (years)	1
Grant date fair value	€8.08
Performance conditions	Yes

AGA 2016 performance shares outstanding

	Year ended December 31,	
Number of AGA 2016 performance shares	2015	2016
Balance outstanding at beginning of period	—	—
Granted during the period	—	766,000
Forfeited during the period	—	3,000
Exercised during the period	—	—
Expired during the period	—	—
Balance outstanding at end of period	—	763,000

16.7 BSA 2016 warrants

Date of grant 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 10 years from the date of grant.

Details of BSA 2016 warrants

	Date of grant
	July 26, 2016
Plan expiration date	7/25/2026
Number of BSA 2015-06 warrants granted	205,000
Exercise price	€8.08
Valuation method	Black and Scholes
Expected volatility	62.46%
Expected dividend	0%
Fair value per BSA 2015-06 warrants	€2.94

BSA 2016 warrants outstanding

	Year ended December 31,	
Number of BSA 2016 Warrants	2015	2016
Balance outstanding at beginning of period	—	—
Granted during the period	—	205,000
Forfeited during the period	—	—
Exercised during the period	—	—
Expired during the period	—	—
Balance outstanding at end of period	—	205,000

BSA 2016 warrants closing balance

	Year ended December 31,			
	2015		2016	
	Outstanding	Exercisable	Outstanding	Exercisable
BSA 2016 warrants with exercise price of €8.08	—	—	205,000	—
Total	**—**	**—**	**205,000**	**—**

Note 17: Financial income and expenses

The financial income and expenses are broken down as follows:

	As of December 31,	
(Amounts in Euros)	2015	2016
Financial income	41,308	26,491
Financial expenses	(33,634)	(89,468)
Total	**7,674**	**(62,977)**

The financial income and expenses are primarily foreign exchange gains and losses related to the purchase of services denominated in foreign currencies, notably in U.S. dollars.

Note 18: Income tax expense

As mentioned in Note 3.9 — Accounting Principles — Other Income, the French Research Tax Credit is not included in the line item income taxes but included in the line item other income.

18.1 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 33.33%, excluding additional contributions:

	As of December 31,	
(Amounts in Euros)	2015	2016
Income before taxes	**(13,653,620)**	**(22,081,663)**
Statutory tax rate	33.33%	33.33%
Nominal tax expense	4,550,752	7,359,818
Increase/decrease in tax expense arising from:	—	—
Research tax credit	958,023	976,625
Share-based compensation	(510,625)	(1,544,842)
Non recognition of deferred tax assets related to tax losses and temporary differences	(4,997,307)	(6,791,940)
Other differences	(843)	339
Income tax expense	(0)	(0)
Effective tax rate	0%	0%

18.2 Deferred tax assets and liabilities

As mentioned in Note 3.13, the Company has not recognized deferred tax assets in the statement of financial position. As of December 31, 2016, the amount of accumulated tax loss carryforwards since inception was €51,264,135, in accordance with current French tax laws.

Note 19: Commitments

Commitments under operating leases

The Company has signed various ordinary rental agreements for office equipment and long-term car rental. The amount of the future rents under those agreements is broken down as follows as of December 31, 2016:

(Amounts in Euros)	As of December 31, 2016
2017	751,825
2018	745,765
2019	736,584
2020	734,197
2021	734,197
2022	734,197
2023	734,197
Total	**5,170,962**

Commitments related to R&D operations

The Company has signed various licensing and collaboration agreements:

- In October 2012, the Company entered into a license agreement with Inserm Transfert S.A. ("Inserm"), a French public scientific and technological institute. The Company paid a license fee of €40,000 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 Company will pay non-refundable fees up to €2,750,000 in the aggregate. 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 December 2013, the Company entered into a license agreement for use of scientific data with the *Association Française contre les Myopathies*, or 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*, or UPMC, a French university. The Company paid a license fee of €10,000 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 Company will pay non-refundable fees up to €687,500. 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 December 2013, the Company entered into a 3-year research collaboration agreement with UPMC, a French

university and the Institut de la Vision. The Company has the exclusive right to use the developed shared patents. In October 2014, November 2014 and June 2015, respectively, the Company has entered into three specific agreements superseding the initial agreement. In relation to these specific agreements, the Company will have to pay a total amount of €2,275,920, excluding tax, at its discretion, over a three-year period starting 2014 to 2018. As of December 31, 2015, the remaining payments under the agreement, representing an amount of €1,477,920 are to be paid over years 2016 to 2018, at sole discretion of the Company if the Company decides to continue to use UPMC for conducting research activities.

- In February 2013, the Company 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 €274,941 (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 Adverum Technologies, or Adverum, (formerly Avalanche Biotechnologies), a biotechnology company. The annual license fee payable by the Company is U.S.$30,000, which was a €27,273 payment in 2014 and €27,680 payment in 2015 recognized as research and development expenses in the statement of income. Upon completion of development milestones, the Company will pay specified non-refundable fees of up to U.S.$5,900,000. 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 March 2014, the Company entered into a research collaboration agreement with Friedrich Miescher Institute, or FMI, a biomedical research institute under which the parties agreed to collaborate in research comprising the design, planning and carrying out of experiments on different animal models with the aim of testing new therapeutic approaches, including the development and testing of optogenetic tools. Under the terms of this research collaboration agreement, the Company agreed to pay €111,240 to FMI in each of 2014, 2015 and 2016 as a contribution to the cost of the research work. The amount paid to FMI for 2014 has been recognized as research and development expenses in the statement of income.
- In January 2016, the Company 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 Company, dated January 9, 2015. Under the terms of this license agreement, the Company agreed to pay a license issue fee of $45,000, license maintenance fees up to $100,000 per year and variable payments up to $7,300,000 depending on the achievement of milestone events. The Company will also pay running mid-single-digit royalties on future net sales.

For each of these licensing and collaboration agreements, based on the significant uncertainties in the development of the product candidates as well as the Company having sole discretion to decide whether it would like to proceed with the research and development activities, the Company has concluded, based on the stage of development of its product candidates, that it is remote that a payment will be made by the Company to the parties under these licensing and collaboration agreements.

Note 20: Relationships with related parties

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 Company, were recognized as expenses during the period presented:

	As of December 31,	
(Amounts in Euros)	2015	2016
Short-term employee benefits	419,163	634,911
Share-based payments benefits	277,355	1,356,792
Total	**696,518**	**1,991,703**

The methods and assumptions used for the measurement of share-based payments are described in Note 16.

Liabilities to key management personnel as of December 31, 2015 and 2016 are set forth below:

	As of December 31,	
(Amounts in Euros)	2015	2016
Variable compensation[1]	106,253	125,004
Pension obligations[2]	21,921	—
Total	**128,174**	**125,004**

(1) For the year 2015, the variable compensation for Mr Gilly was accrued for 85% of its theoretical amount, based on internal assumptions. Upon recommendation of the Compensation Committee, the Board of Directors set Mr Gilly's objectives as 60% achieved for the year 2015, granting a variable compensation amounting to €75,002 to be paid in 2016.
For the year 2016, upon recommendation of the Compensation Committee, the Board of Directors set Mr Gilly's objectives as 100% achieved for the year 2016, granting a variable compensation amounting to €125,004 to be paid in 2017 and fully accrued for in 2016.

(2) None of our directors have an employment contract with us. As a result, the provision for pension obligations recorded in 2015 has been written off in 2016, and no further provision has been made.

Transactions with related parties

Mr Bernard Gilly, CEO of Gensight Biologics, was president and shareholder (27%) of the *SAS Passage de l'Innovation*. He resigned on June 30, 2016. On January 15, 2015 Gensight Biologics entered into an agreement with *SAS Passage de l'Innovation* for the rental of its new premises. An amendment was signed on January 1, 2016. The related amounts presented below were recognized as expenses during the period presented:

	As of December 31,	
(Amounts in Euros)	2015	2016
Rent and services	722,966	752,511
Total	**722,966**	**752,511**

No liabilities are due to related parties as of December 31, 2015 and December 31, 2016, respectively.

Note 21: Earnings per share

The basic earnings per share is calculated by dividing the net income for the period attributable to the shareholders of the Company by the weighted average number of common shares outstanding during the period. Preferred shares had the same rights and dividends as ordinary shares for purposes of calculating earnings per share. As a result, all outstanding ordinary and preferred shares have been taken into consideration for purposes of calculating basic earnings per share. The weighted average number of shares was 11,239,666 and 16,252,765 in 2015 and 2016, respectively.

The diluted earnings per share is calculated by dividing the net income for the period attributable to shareholders of the Company by the weighted average number of shares outstanding plus any potentially dilutive shares not yet issued from share-based compensation plans (see Note 16).

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 2,957,816 potential additional ordinary shares, have been considered anti-dilutive.

	As of December 31,	
(Amounts in Euros)	2015	2016
Net income (loss) of the reporting period	(13,653,620)	(22,081,663)
Adjusted weighted average number of outstanding shares	11,239,666	16,252,765
Basic and diluted earnings (loss) per share	**(1.21)**	**(1.36)**

Note 22: Management of financial risks

The principal financial instruments held by the Company are cash, cash equivalents and short-term investments. The purpose of holding these instruments is to finance the ongoing business activities of the Company. It is not the Company's policy to invest in financial instruments for speculative purposes. The Company does not utilize derivatives.

The principal risks to which the Company is exposed are liquidity risk, foreign currency exchange risk, interest rate risk and credit risk.

Liquidity risk

The Company does not believe that it is exposed to short-term liquidity risk, considering the cash and cash equivalents that it had available as of December 31, 2016, amounting to €53,982,212 which was primarily cash and term deposits that are convertible into cash immediately without penalty and the reimbursement of the 2016 Research Tax Credit amounting to €2,929,874 expected during the second half year of 2017.

Management believes that the amount of cash, cash equivalents available and the expected reimbursement of the 2016 Research tax credit are sufficient to fund the Company's planned operations through the next twelve months.

Foreign currency exchange risk

The Company is exposed to foreign exchange risk inherent in certain services provided in the United States, which have been invoiced in U.S. dollars. The Company does not currently have revenues in euros, 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 Company. The Company's exposure to currencies other than the U.S. dollar is negligible. For the year ended December 31, 2015 and 2016, less than 8% and 22% of its purchases and other external expenses were made in U.S. dollars, generating a foreign exchange loss of €22,391 and €59,181, respectively. In light of these insignificant amounts, the Company has not adopted, at this stage, a hedging mechanism in order to protect its business activity against fluctuations in exchange rates. As the Company further increases its business, particularly in the United States, the Company 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 very low exposure to interest rate risk. Such exposure primarily involves money market funds and time deposit accounts. Changes in interest rates have a direct impact on the rate of return on these investments and the cash flows generated.

The Company has no credit facilities. The repayment flows of the conditional advances from Bpifrance Financement are not subject to interest rate risk.

Credit risk

The credit risk related to the Company's cash, cash equivalents and short-term investments securities is not significant in light of the quality of the co-contracting financial institutions.

Fair value

The fair value of financial instruments traded on an active market, such as the securities available for sale, is based on the market rate as of December 31, 2016. 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.

Note 23: Auditor's fees

The auditors' fees paid by the Company for the fiscal year ending December 31, 2016 amounted to €313,500:

	Becouze		Deloitte & Associés	
	Amount	%	Amount	%
(in euros, excluding tax)	2016	2016	2016	2016
Audit certification	46,000	33%	51,000	29%
Social and Environnemental ResponsIbility certification	5,000	4%		
Other report for French legal purposes	3,250	2%	3,250	2%
Procedures related to the IPO	85,000	61%	120,000	69%
Total	**139,250**	**100%**	**174,250**	**100%**

Note 24: Events after the close of the fiscal year

On January 31, 2017, GenSight Biologics announced that the 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.

On February 21, 2017, GenSight Biologics announced that enrollment in REVERSE, a Phase III clinical trial of GS010 in the treatment of Leber's Hereditary Optic Neuropathy (LHON), has been successfully completed.

20.1.2 STATUTORY AUDITORS REPORT ON THE COMPANY'S ANNUAL FINANCIAL STATEMENTS (IFRS) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

This is a free translation into English of the statutory auditors' report issued in French and is provided solely for the convenience of English speaking readers. This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

BECOUZE
45, rue Boissière
75116 Paris

Deloitte & Associés
106, cours Charlemagne
69002 Lyon

GenSight Biologics
Société Anonyme — 74 rue du Faubourg Saint-Antoine — 75012 PARIS

STATUTORY AUDITORS' REPORT ON THE FINANCIAL STATEMENTS PREPARED IN ACCORDANCE WITH IFRS

YEAR ENDED DECEMBER 31, 2016

To the Board of Directors,

In our capacity as statutory auditors of GenSight Biologics and at your request, we have audited the accompanying financial statements of GenSight Biologics prepared in accordance with IFRS as adopted by the European Union for the year ended December 31, 2016.

These financial statements have been prepared under the responsibility of the Board of Directors. Our role, based on our audit, is to express an opinion on these financial statements.

We conducted our audit in accordance with professional standards applicable in France. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, using sample testing techniques or other selection methods, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made, as well as evaluating the overall financial statement presentation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

In our opinion, the financial statements give a true and fair view of the assets and liabilities and the financial position of the Company as of December 31, 2016 and of the results of its operations for the year then ended in accordance with IFRS, as adopted by the European Union.

This report does not constitute an audit report as described in Article L.823-9 of the French Commercial Code *(Code de commerce)* on annual financial statements prepared in accordance with French generally accepted accounting principles.

This report is governed by French law. French courts shall have exclusive jurisdiction to rule on any litigation, claim or difference arising from the procedures described above in this report.

Paris and Lyon, March 15, 2017

The statutory auditors

BECOUZE
Fabien BROVEDANI

DELOITTE & ASSOCIÉS
Dominique VALETTE

20.1.3 COMPANY'S ANNUAL FINANCIAL STATEMENTS (FRENCH-GAAP) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

Our annual financial statements (French-GAAP) for the fiscal year ended December 31, 2016 can be found in Annex I of this Registration Document.

20.1.4 STATUTORY AUDITORS' REPORTS ON THE COMPANY'S ANNUAL FINANCIAL STATEMENTS (FRENCH-GAAP) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

The statutory auditors' report on our annual financial statements (French-GAAP) for the fiscal year ended December 31, 2016 can be found in Annex II of this Registration Document.

20.2 DATE OF LATEST FINANCIAL INFORMATION

Our latest financial information is the annual financial statements (French-GAAP and IFRS) for the fiscal year ended December 31, 2016.

20.3 HISTORICAL FINANCIAL INFORMATION FOR THE FISCAL YEARS ENDING DECEMBER 31, 2014 AND 2015

In accordance with provisions of Article 28 of the Commission Regulation (EC) No 809/2004 of April 29, 2004, as amended, (i) the selected financial information, (ii) the Company's annual financial statements (IFRS) for the fiscal years ended December 31, 2014 and 2015 and the statutory auditor's report on the Company's annual financial statements (IFRS) for the fiscal years ending December 31, 2014 and 2015 and (iii) the Company's annual financial statements (French-GAAP) for the fiscal years ended December 31, 2014 and 2015 and the statutory auditor's report on the Company's annual financial statements (French-GAAP) for the fiscal years ending December 31, 2014 and 2015 are incorporated by reference in this Registration Document.

This information is included in the Base Prospectus registered with the AMF on May 24, 2016 under number I.16-049.

This Documents may be consulted on the Company's website (www.gensight-biologics.com) and on the AMF's website (www.amf-france.org).

20.4 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.

20.5 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.

Except as set forth below, as of the date of this 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.

On November 5, 2015, we were notified that our Community Trade Mark application for "GenSight" was the subject of an opposition from Assurex Health, Inc., a company based in the United States that provides medical testing services relating to genes. The opposition is currently in a cooling-off period, which has been extended at the request of both parties until November 21, 2017 to allow for negotiation. Unless we settle the opposition with the opponent or either party elects to opt out before the expiration of the cooling-off period, the adversarial phase of the proceedings will commence on November 22, 2017. See Section 4.8, "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" of this Registration Document.

No provisions or liabilities have been recorded in connection therewith in our financial statements.

20.6 SIGNIFICANT CHANGE IN FINANCIAL OR TRADING POSITION

To our knowledge, there has been no material change in our financial or trading position since December 31, 2016, other than those described in this Registration Document.

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ADDITIONAL INFORMATION

21.1 SHARE CAPITAL

21.1.1 AMOUNT OF ISSUED CAPITAL

As of the date of this Registration Document, our share capital is equal to €488,511.33, divided into 19,540,453 shares, with nominal value of €0.025 per share, fully authorized, subscribed and paid-up.

21.1.2 SECURITIES NOT REPRESENTING SHARE CAPITAL

As of the date of this Registration Document, we have not issued any securities not representing the share capital.

21.1.3 SHARES CONTROLLED BY THE COMPANY, TREASURY SHARES AND PURCHASE BY THE COMPANY OF ITS OWN SHARES

Our Combined General Shareholders' Meeting of May 19, 2016 authorized our Board of Directors to implement a buyback program of our shares, according to the provisions of Article L.225-109 of the French Commercial Code.

The maximum number of shares that can be purchased is 10 % 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:

- remitting the shares at the time of the exercise of the rights attached to the securities granting rights, whether immediately or in the future, by way of repayment, conversion, exchange, presentation of a warrant or in any other manner to the allocation of shares of the Company, as well as to carry out all hedging transactions in relation to the issue of such securities, pursuant to the conditions provided for by the market authorities and at the times decided upon by the Board of Directors;
- conserving the shares and to remit them subsequently in payment or exchange in the context of any external growth, merger, spin-off or contribution transactions, in compliance with the market practices permitted by the AMF;
- favor the liquidity of the transactions and the regularity of the quotations of the Company's securities or to avoid price discrepancies not justified by market trends in the context of a liquidity contract entered into an investment service provider acting independently, in accordance with the terms and conditions determined by the regulations and recognized market practices, in particular the decisions of the AMF dated March 21, 2011, in accordance with the AMF code of ethics dated March 8, 2011 recognized by the decision of the AMF dated March 21, 2011;
- honoring the obligations relating to option programs over shares, allocation of free shares, salaried employee savings schemes or other allocations of shares to the salaried employees and/or the corporate officer of the Company and/or companies or organizations relating thereto, including (i) the implementation of any share purchase option scheme of the Company in the context of articles L.225-177 *et seq.* of the French Commercial Code, (ii) the allocation shares to the salaried employees pursuant to the company expansion profit sharing scheme and the implementation of any company savings scheme under the conditions provided for by the law, in particular articles L.3332-1 to L.3332-8 *et seq.* of the French Employment Code or (iii) the free allocation of shares in the context of the provisions of articles L.225-197-1 *et seq.* of the French Commercial Code

The maximum purchase price is 300% of the price of the shares offered to the public in the context of the listing on Euronext Paris, such that the price has been set out in the statement relating to the definitive characteristic of the share offer of the Company and their listing on Euronext Paris excluding acquisition costs and that (ii) the maximum amount of the funds intended for the program of the repurchase of the shares shall amount to €5,000,000.

During the fiscal you ended December 31, 2016, 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	65,175
Average purchase price	8.4414
Number of shares sold	46,436
Average selling price	8.6429
Total amount of negotiation costs	€25,000
Number of shares used in 2016	—
Number of shares owned as of December 31, 2016	18,739
Value at average purchase price	158,183.39
Nominal value	468.48

21.1.4 PERFORMANCE SHARES

(a) Performance shares granted by the Company

We have granted performance shares (*Attributions Gratuites d'Actions*, or AGA) since July 26, 2016.

As of the date of this Registration Document, none of the granted performance shares have been definitively acquired.

AGA 2016

With the authorization of the general meeting of shareholders on May 19, 2016, the Board of Directors granted 766,000 AGA 2016 on July 26, 2016.

The AGA 2016 performance shares may be fully acquired by Key Managers, including Mr. Gilly, at the earliest at the end of an acquisition period of one year after their grant date subject to the achievement of the following performance criteria at the latest on July 26, 2018:

- 50% of AGA 2016 will be acquired at the later of the two following dates, either (i) the expiry of a period of one year from the date of grant or (ii) the completion of enrollment in RESCUE and REVERSE clinical trials;
- 50% of AGA 2016 will be acquired at the later of the two following dates, either (i) the expiry of a period of one year from the date of grant or (ii) the enrollment of the first patient in a Phase I/II clinical trial with GS030 in retinitis pigmentosa.

In addition, the AGA 2016 performance shares will be issued at their nominal value and will be subject to a lock-up period of one year after their actual acquisition date.

(b) Conditions governing the performance shares granted by the Company

Performance shares are free shares 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) Performance shares holders

The table below sets forth the warrants granted by us to our executive officers and directors as of the date of the registration of this Registration Document:

Name	Grant Date	Number of Performance Shares	Performance condition
Bernard Gilly	07/26/2016	250,000	Yes
Thomas Gidoin	07/26/2016	150,000	Yes
Didier Pruneau	07/26/2016	10,000	Yes
Nitza Thomasson	07/26/2016	10,000	Yes
Total		**420,000**	

21.1.5 OTHER SECURITIES GIVING ACCESS TO SHARE CAPITAL

As of December 31, 2016, 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 2,612,198, or a maximum dilution of 13.37% on the basis of the capital and voting rights existing to date and 11.79% on the basis of the capital and the fully diluted voting rights.

21.1.5.1 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), since July 8, 2013.

As of the date of this Registration Document, 829,608 share warrants for founder will give right to 829,608 ordinary shares with nominal value of €0.025 at an average exercise price of €1.201 per share.

As of the date of this Registration Document, 345,977 share warrants will give right to 345,977 ordinary shares with nominal value of €0.025 at an exercise price of €0.522 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;
- at the latest within 7 years from the date of grant.

See also Section 15.7.1, "History of Share Warrants for Founders (BCE)" and Section 15.7.2, "History of Share Warrants (BSA)" of this 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 growth 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 the registration of this 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
Didier Pruneau	07/08/2013	BCE	96,000	0.025	07/07/2023
	07/08/2015	BCE	16,000	3.275	07/07/2025
Nitza Thomasson	07/08/2013	BCE	96,000	0.025	07/07/2023
	07/08/2015	BCE	16,000	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	07/25/2026
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	07/25/2026
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	07/25/2026
Earl M. Collier[2]	07/26/2016	BSA	47,000	8.08	07/25/2026
Total			**1,458,000**		

(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 or €8.08 per share.
(2) Mr. Collier resigned from the Board of Directors on April 19, 2017.

21.1.6 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[1] regarding issuance of shares, share warrants and performance shares of the extraordinary general shareholders' meeting held on May 19, 2016:

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Delegation of powers to be conferred upon the Board of Directors in the context of the provisions of article L.225-129-2 of the French Commercial Code for the purposes of deciding on the issue of ordinary shares and/or securities giving access, whether immediately and/or in the future to equity securities to be issued by the Company, without preferential subscription rights by public offering (in the context of the listing of the shares of the Company to the listing on the Paris Euronext market as well as the listing and the first quotation of the shares of the shares of the Company) with the option of conferring a priority right	Capital increase: **€187,125** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until July 19, 2018	Capital increase: **€340,228** Debt instruments giving access to equity securities: **€50,000,000**	Date of use by the Board of Directors: July 12, 2016 Capital increase: **€125,000** consisting of the issue of **5,000,000** new ordinary shares, at a price of **€8** per share, with a nominal value of **€0.025** (issue premium of €7.975)	Capital increase: **€174,556,525** Debt instruments giving access to equity securities: **€50,000,000**
Delegation of powers to be conferred upon the Board of Directors for the purposes of deciding, subject to the condition precedent of the listing and the first quotation of the shares of the Company on the Paris Euronext market, the issue, with preferential subscription rights of the shareholders, of ordinary shares and/or securities giving access, whether immediately and/or in the future to equity securities to be issued by the Company	Capital increase: **€68,045** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until July 19, 2018			
Delegation of powers to be conferred upon the Board of Directors for the purposes of deciding, subject to the condition precedent of the listing and the first quotation of the shares of the Company on the Paris Euronext market, the issue of ordinary shares and/or securities giving access, whether immediately and/or in the future to equity securities to be issued by the Company[2], without preferential subscription rights of the shareholders in favor of categories of beneficiaries[3]	Capital increase: **€68,045** Debt instruments giving access to equity securities: **€50,000,000**	18 months *i.e.* until November 19, 2017			
Delegation of powers to be conferred upon the Board of Directors for the purposes of deciding, subject to the condition precedent of the listing and the first quotation of the shares of the Company on the Paris Euronext market, the issue of ordinary shares and/or securities giving access, whether immediately and/or in the future to equity securities to be issued by the Company without preferential subscription rights of the shareholders, by one or several offers by private placement as defined in paragraph II of article L.411-2 of the French Monetary and Financial Code and subject to the limit of 20 % of the share capital per year	Capital increase: **€68,045** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until July 19, 2018			

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Authorization to be granted to the Board of Directors, in the case of the issue of ordinary shares and/or securities giving access, whether immediately or in the future to equity securities to be issued by the Company, without preferential subscription rights of the shareholders, without any indication of beneficiaries by public offering or by one or several offers referred to in article L.411-2 II of the French Monetary and Financial Code, in view of fixing the issue price according to the terms and conditions determined by the General Meeting, subject to the limitation of 10 % of the share capital per year, subject to the condition precedent of the listing and the first quotation of the shares of the Company on the Euronext Paris market	Capital increase: **10% of the share capital for 12 month periods** (assessed as at the date of implementation of the delegation) Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until July 19, 2018	Capital increase: **€340,228** Debt instruments giving access to equity securities: **€50,000,000**		Capital increase: **€174,556,525** Debt instruments giving access to equity securities: **€50,000,000**
Authorization to be granted to the Board of Directors for the purposes of increasing the number of securities issued in accordance with the provisions of article L.225-135-1 of the French Commercial Code, in the event of the implementation of the delegations of powers referred to in the previous resolutions with or without preferential subscription rights of the shareholders as the case may be	Within the periods and limitations provided for by the applicable law and regulations on the date of the issue (as at today's date at the same price as that retained for the initial issue and subject to the limitation of 15 % of the latter in accordance with the provisions of article R 225-118 of the French Commercial Code) or any other applicable provisions	26 months *i.e.* until July 19, 2018		Date of use by the Board of Directors: August 10, 2016 Capital increase: **€16,396,475** consisting of the issue of **655,859** new ordinary shares, at a price of **€8** per share, with a nominal value of **€0.025** (issue premium of €7.975)	
Delegation of powers to be conferred upon the Board of Directors for the purposes of deciding the capitalization of profits, reserves, premiums or any other amounts, the capitalization of which is allowed, subject to the condition precedent of the listing and the first quotation of the shares of the Company on the Paris Euronext market	Capital increase: **€68,045**	26 months *i.e.* until July 19, 2018			
Delegation of powers to be conferred upon the Board of Directors for the purposes of deciding, subject to the condition precedent of the listing and first quotation of the shares of the Company on the Paris Euronext market, the issue of ordinary shares and/or securities giving access, whether immediately and/or in the future to equity securities, intended to remunerate contributions of securities in the event of public exchange offerings to be initiated by the Company, without preferential subscription rights of the shareholders	Capital increase: **€340,228** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until July 19, 2018			

Purpose	Maximum amount	Period of validity	Global maximum amount in euros	Use of the delegations	Residual maximum amount in euros
Delegation of powers to be conferred upon the Board of Directors for the purposes of deciding, subject to the condition precedent of the listing and first quotation of the shares of the Company on the Paris Euronext market, for the purposes of increasing the share capital through the issue of ordinary shares and/or securities giving access, whether immediately and/or in the future to the capital of the Company, without preferential subscription rights of the shareholders, as remuneration for contributions in kind subject to the limitation of 10 % of the share capital outside the event of a public exchange offering	Capital increase: **10% of the share capital at the date of the transaction** Debt instruments giving access to equity securities: **€50,000,000**	26 months *i.e.* until July 19, 2018			
Delegation of powers to be conferred upon the Board of Directors, subject to the condition precedent of the listing and the first quotation of the shares of the Company on the Paris Euronext market, for the purposes of deciding on the issue of share warrants *(bons de souscription d'actions)* (the "2016 BSA") without preferential subscription rights in favor of a category of persons	**680,456 share warrants** Capital increase: **€17,011.40**	18 months *i.e.* until November 19, 2017	Capital increase: **€340,228** Debt instruments giving access to equity securities: **€50,000,000**	Date of use of the delegation by the Board of Directors: July 26, 2016 Number of share warrants issued: **205,000** corresponding to a potential capital increase of €5,125	Capital increase: **€174,556,525** Debt instruments giving access to equity securities: **€50,000,000**
Authorization to be conferred upon the Board of Directors, subject to the condition precedent of the listing and first quotation of the shares of the Company on the Paris Euronext market, for the purposes of the free of charge allocation of the ordinary shares of the Company (the "AGA 2016" — *attribution gratuite d'actions*) in favor of salaried employees and the executive directors	**10 % of the share capital** as of the date of the decision of the allocation by the Board of Directors	38 months *i.e.* until September 19, 2019		Date of use of the delegation by the Board of Directors: July 26, 2016 Number of share warrants issued: **766,000** corresponding to approximately **4.116%** of the share capital as of the date of the decision of the Board of Directors and consisting of a potential capital increase of **€19,150**	

(1) These resolutions will be replaced by the resolutions that will be submitted to the shareholders' meeting called to approve the financial statements for the fiscal year ended December 31, 2016.

(2) The issue price shall at least have to be equal to the weighted average of the prices of the last three trading sessions preceding the determination of the issue price, decreased as the case may be by a maximum discount of 15%.

(3) The present delegation shall be made in favor of the following categories of persons:
- investment companies, investment funds, trusts investing mainly in so-called growth companies (*i.e.* which are unlisted or for which the market capitalization does not exceed €500 million where they are listed) having their registered office or their management company on the territory of the European Union, Israel, Switzerland or the United States (including, in particular any FCPR (venture capital fund), FCPI (mutual fund for innovation) or FIP (local investment fund)) for a minimum individual subscription amount of €100,000 (including the issue premium); or
- companies, organizations, institutions or entities of whatever form, whether French or foreign working in the pharmaceutical, bio-technological or ophthalmological or neurodegenerative diseases research areas.

21.1.7 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 Registration Document, our share capital is not the subject of any option or any agreement to put it under option.

21.1.8 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
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

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 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
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
TOTAL		**19,540,453**			**91,273,864.48**	**97,386,638.20**		**488,511.33**	

(1) The company issued 268,235 ordinary shares for the benefit of Novartis in payment for intellectual property rights (see Section 6.7). In compliance with IFRS 2, the acquired license was valued at the fair value of issued shares, as assessed by an independant expert, at €1.025 per share.

21.2 CONSTITUTIVE DOCUMENTS AND BYLAWS

21.2.1 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 and 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 industrial, commercial, real estate, financial and civil 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.

21.2.2 ADMINISTRATIVE AND MANAGEMENT BODIES

21.2.2.1 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. 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 not prevail.

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 French law, 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.

21.2.2.2 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.

21.2.2.3 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.

21.2.3 RIGHTS, PREFERENCES AND RESTRICTIONS ATTACHING TO ORDINARY SHARES

21.2.3.1 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.

21.2.3.2 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.

21.2.3.3 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.

21.2.3.4 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.

21.2.4 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.

21.2.5 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.

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.

21.2.6 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.

21.2.7 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.

21.2.8 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.

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MATERIAL CONTRACTS

As of the date of this Registration Document, we are a party to the following material contracts:

22.1 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

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 11.4, "Collaboration agreements" of this Registration Document.

Agreements Relating to GS030

- Research collaboration agreement relating to the development and testing of optogentic tools between the Friedrich Miescher Institute and the Company dated March 1, 2014

On March 1, 2014, we entered into a research collaboration agreement with the FMI, under which the parties agreed to collaborate in research comprising the design, planning and carrying out of experiments on different animal models with the aim of testing new therapeutic approaches, including the development and testing of optogenetic tools. For more details, see Section 11.4, "Collaboration agreements" of this Registration Document.

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 11.4, "Collaboration agreements" of this 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. For more details, see Section 11.4, "Collaboration agreements" of this 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. For more details, see Section 11.4, "Collaboration agreements" of this Registration Document.

Agreements Relating to GS010 and GS030

- Cooperation agreement relating to research and development in ophtalmic diseases between UPMC, INSERM, CNRS, Institut de la Vision and the Company dated December 19, 2013

In December 2013, we entered into a framework agreement with UPMC, Institut National de la Santé et de la Recherche Médicale, Centre National de la Recherche Scientifique and Centre de Recherche Institut de la Vision under which the parties agree to create a partnership in the field of research and development in ophthalmic diseases. As part of the framework agreement, we also entered into three specific research agreements between UPMC, INSERM, CNRS and the Company in October 2014, November 2014 and June 2015. For more details, see Section 11.4, "Collaboration agreements" of this Registration Document.

22.2 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 11.5, "Intellectual Property" of this 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 11.5, "Intellectual Property" of this 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 11.5, "Intellectual Property" of this 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. For more details, see Section 11.5, "Intellectual Property" of this Registration Document.

22.3 MANUFACTURING AGREEMENT

- Services agreement with Novasep dated June 24, 2015

On June 24, 2015, we entered into a biopharma services agreement with Novasep (through its subsidiary, Henogen) for the manufacturing, development and production of drug products in connection with our product candidate GS010. The performance of the services under the agreement is split into eight work packages, with completion timeframes ranging from one month to six months. The agreement will terminate upon completion of the work packages.

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THIRD PARTY INFORMATION AND STATEMENT BY EXPERTS AND DECLARATIONS OF ANY INTEREST

None.

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DOCUMENTS ON DISPLAY

Copies of this Registration Document are available free of charge at our registered office. This document may also be consulted on our website (www.gensight-biologics.com) and on the AMF's website (www.amf-france.org).

While this Registration Document is valid, the following documents (or a copy of such documents) may be viewed:

- our bylaws;
- any report, correspondence or other historical financial information or document, assessment or statement prepared by an expert upon our request, of which a portion is included or referred to in this Registration Document; and
- the historical financial information included in this Registration Document.

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.

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INFORMATION ON EQUITY INTERESTS

As of the date of this Registration Document we have no equity interest in any other companies.

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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 Drugs 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 Harmonisation
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

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ANNEXES

ANNEX I
COMPANY'S ANNUAL FINANCIAL STATEMENTS (FRENCH-GAAP) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

1. BALANCE SHEET

ASSETS

		12/31/16			12/31/15
(in euros)	Note	Gross	Deprec. Prov.	Net	Net
Non-current assets					
Intangible assets					
Software	1	10,212	10,038	175	3,426
Tangible assets	2				
Property, plant and equipment		829,967	175,496	654,471	617,651
Other tangible assets		357,896	154,169	203,727	243,310
Assets under construction		–	–	–	
Financial assets	3	406,270	6,709	399,561	110,933
Total non-current assets		**1,604,344**	**346,411**	**1,257,933**	**975,320**
Current assets					
Receivables	4				
Down payments		132,079	–	132,079	419,633
Accounts receivable		30,419	–	30,419	27,499
Other receivables		3,327,777	–	3,327,777	3,831,299
Cash					
Short-term investments	5	–	–	–	29,009,249
Cash and cash equivalents		53,982,212	–	53,982,212	1,050,204
Prepaid expenses		441,534	–	441,534	774,345
Total current assets		**57,914,021**	**–**	**57,914,021**	**35,112,229**
Regularisation accounts					
Foreign exchange differences - assets		376	–	376	1,852
TOTAL ASSETS		**59,518,741**	**346,411**	**59,172,330**	**36,089,400**

The attached note forms an integral part of the financial statements.

LIABILITIES

(in euros)	Note	12/31/16	12/31/15
Shareholders' equity	**6**		
Share capital		485,243	340,228
Premiums related to the share capital		91,230,210	49,795,709
Legal reserve		—	—
Restricted reserves		174,161	174,161
Retained earnings		(21,138,967)	(9,065,350)
Net loss		**(17,397,676)**	**(12,073,618)**
Total Shareholders' equity		**53,352,971**	**29,171,131**
Provisions for liabilities and charges:			
Provisions for liabilities		376	1,852
Total provisions for liabilities and charges		**376**	**1,852**
Liabilities	7		
Refundable advances		2,956,914	678,000
Trade payables		1,733,546	5,191,767
Tax and social liabilities		1,119,960	984,558
Other liabilities		7,499	29,932
Deferred income	10	—	31,222
Total liabilities		**5,817,919**	**6,915,479**
Regularisation accounts			
Foreign exchange differences — liabilities		1,064	939
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		**59,172,330**	**36,089,400**

The attached note forms an integral part of the financial statements.

2. STATEMENTS OF INCOME (LOSS)

(in euros)	Note	12/31/16	12/31/15
Sales of services		–	1,234
Income		–	1,234
Operating revenues:			
Grants	10	48,750	676,627
Transferred expenses		7,766	22,926
Other revenues		202	152
Total operating revenues (I)		**56,718**	**700,938**
Operating expenses:			
Purchases of raw material		–	–
Other purchases and external expenses		14,840,762	11,866,586
Tax expenses		74,253	60,219
Payroll expenses		3,084,253	2,629,499
Social charges		1,117,188	915,713
Depreciation and amortization		184,383	120,339
Other expenses		1,043,691	68,947
Total operating expenses (II)		**20,344,530**	**15,661,304**
OPERATING LOSS (I-II)		**(20,287,812)**	**(14,960,365)**
Financial income			
Foreign exchange gains		19,136	13,270
Marketable securities disposal gains		1,333	4,549
Other financial income		3,106	24,335
Total financial income (III)		**23,575**	**42,153**
Financial expenses			
Foreign exchange losses		58,225	22,391
Depreciation and amortization		5,233	1,833
Total Financial expenses (IV)		**63,458**	**24,224**
FINANCIAL INCOME (EXPENSES) (III-IV)		**(39,883)**	**17,929**
EARNING BEFORE TAX (I-II+III-IV)		**(20,327,694)**	**(14,942,437)**
Extraordinary income			
Extraordinary income from operations		11,000	-
Total extraordinary income (V)		**11,000**	**-**
Extraordinary expenses			
Extraordinary charges from operations		10,856	5,250
Extraordinary charges - depreciation and amortization		–	–
Total extraordinary expenses (VI)		**10,856**	**5,250**
EXTRAORDINARY INCOME (EXPENSES) (V-VI)		**144**	**(5,250)**
Income taxes	15	(2,929,874)	(2,874,069)
NET INCOME (LOSS)		**(17,397,676)**	**(12,073,618)**

The attached note forms an integral part of the financial statements.

3.
NOTES TO THE FINANCIAL STATEMENTS

The annual financial statements for the year ended December 31, 2016 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.

The financial statements have been prepared in accordance with the provisions of the Commercial Code, the Accounting Decree of November 9, 1983 and the CRC99-03 Regulation of April 29, 1999 relating to the revised chart of accounts.

MAIN EVENTS OF THE FISCAL YEAR

On **February 29, 2016,** GenSight Biologics started patient enrollment in RESCUE and REVERSE, pivotal studies of Phase III clinical trial of GS010, principal drug candidate, in the treatment of Leber's Hereditary Optic Neuropathy (LHON).

On **June 8, 2016,** GenSight Biologics reported additional promising results of its Phase I/II study, designed to demonstrate the safety and tolerability of GS010 in 15 patients with Leber's Hereditary Optic Neuropathy (LHON).

Each cohort of three patients was administered an escalating dose of GS010 through a single intravitreal injection in the eye most severely affected by the disease. Recruitment was completed in April 2015. These patients had an average onset of disease of 6 years.

At 48 weeks post-injection, in patients with an onset of disease of less than 2 years, a gain of +30 letters (-0.59 LogMAR) was observed in the treated eye and +13 letters (-0.25 LogMAR) in the untreated eye, a difference of 17 letters in favor of the treated eye. No significant difference was observed in patients with an onset of disease of more than two years.

On **July 12, 2016,** GenSight Biologics announced the success of its initial public offering on compartment B of the Euronext regulated market in Paris ("Euronext Paris"), raising €40.0m by means of a capital increase, which may be increased to c. €45.9m if the over-allotment option is fully exercised.

On **September 1, 2016,** GS030 received orphan drug designation (ODD) and Advanced Therapy Medicinal Product classification (ATMP) from the European Medicines Agency (EMA) for the treatment of Retinitis Pigmentosa (RP) in the European Union.

On **September 8, 2016,** GenSight Biologics received approval from regulatory agencies and ethics committees in the United States, France and the United Kingdom to include teenage patients (between 15 and 18 years of age) in RESCUE and REVERSE Phase III trials with GS010 for the treatment of LHON.

On **December 20, 2016,** GenSight Biologics reported additional promising results after 78 weeks of follow-up in its Phase I/II clinical trial. These results confirm the favorable safety and tolerability profile of GS010, while demonstrating sustainable visual acuity improvement in patients with Leber's Hereditary Optic Neuropathy (LHON).

EVENTS AFTER THE CLOSE OF THE FISCAL YEAR

On **January 31, 2017,** GenSight Biologics announced that the 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.

On **February 21, 2017,** GenSight Biologics announced that enrollment in REVERSE, a Phase III clinical trial of GS010 in the treatment of Leber's Hereditary Optic Neuropathy (LHON), has been successfully completed.

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:

a) It is technically feasible to complete the development of the project;

b) Intention 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 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	1 year

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
Research and development equipments	3 to 5 years
Fixtures and improvement in structures	5 to 10 years
Computer equipment	3 years
Office equipment and furniture	5 years

Financial assets

Financial assets include deposits and are recorded at their original value.

Loans and receivable

Loans and receivables 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.

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.

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, as the company has to reimburse the funder. 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.

NOTE 1 — INTANGIBLE ASSETS

Other Intangible assets break down as follows:

(in euros)	01/01/16	Increase	Decrease	12/31/16
Gross	**9,165**	**1,047**	**—**	**10,212**
Software	9,165	1,047	—	10,212
Depreciation	**5,739**	**4,299**	**—**	**10,038**
Software	5,739	4,299	—	10,038
NET	**3,426**	**(3,252)**	**—**	**175**

NOTE 2 — TANGIBLE ASSETS

Tangibles assets break down as follows:

(in euros)	01/01/16	Increase	Decrease	12/31/16
Gross	**1,018,874**	**188,177**	**19,188**	**1,187,862**
Technical equipment and installations	585,174	102,279		687,453
Leasehold improvement	102,432	40,082		142,513
Office and computer equipment	77,490	24,606		102,096
Furniture	253,778	21,210	19,188	255,800
Depreciation	**157,913**	**180,084**	**8,332**	**329,665**
Technical equipment and installations	63,583	44,891		108,474
Leasehold improvement	6,372	60,650		67,022
Office and computer equipment	36,791	24,835		61,627
Furniture	51,167	49,708	8,332	92,542
NET	**860,961**	**8,093**	**10,856**	**858,198**

Purchase of technical equipment and installations primarily consist of research equipment.

NOTE 3 — FINANCIAL ASSETS

Financial assets break down as follows:

(in euros)	01/01/16	Increase	Decrease	12/31/16
Gross	**110,933**	**303,629**	**8,293**	**406,270**
Security deposits	110,933	523	8,293	103,164
Long-term deposits	—	151,170	—	151,170
Own shares	—	151,936	—	151,936
Depreciation	**—**	**6,709**	**—**	**6,709**
Security deposits	—	—	—	—
Long-term deposits	—	—	—	—
Own shares	—	6,709	—	6,709
TOTAL	**110,933**	**296,921**	**8,293**	**399,561**

In the context of its initial public offering, GenSight Biologics implemented a liquidity agreement. As of December 31, 2016, long-term deposits consisted of free cash available within this this liquidity agreement.

NOTE 4 — RECEIVABLES

Breakdown of receivables is summarized in the following table:

(in euros)	Less than one year	More than one year	Total gross
Prepayments	132,079	—	132,079
Accounts receivable and related receivables	30,419	—	30,419
Research tax credit, "CICE"	2,933,882	—	2,933,882
VAT	393,895	—	393,895
Prepaid expenses	441,534	—	441,534
NET	**3,931,809**	**—**	**3,931,809**

As of December 31, 2016, the Company has receivables due to rents re-billed amounting to €30,419.

The Company also has a research tax credit amounting to €2,929,874 and a tax credit for competitiveness and employment of €4,008. In accordance with the legislation in force, the Company is eligible for immediate reimbursement of these tax claims.

Prepayments are made of advances to suppliers.

Prepaid expenses correspond mainly to advances on rents, research contracts, insurance premiums and travel expenses.

NOTE 5 — SHORT-TERM INVESTMENTS

As of December 31, 2016, the Company had no short-term investments compared to €29,009,249 as of December 31, 2015.

NOTE 6 — SHAREHOLDERS' EQUITY

6.1 — Capital social

As of December 31, 2016, share capital amounts to €485,242.53 and consists of 19,409,701 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 classe and number of shares	01/01/16	Conversion of Series A and B shares into ordinary shares	Capital Increase	12/31/16	Share capital in Euro
Ordinary shares	2,017,798	11,591,324	5,800,579	19,409,701	485,243
Series A shares	6,966,454	(6,966,454)	—	—	—
Series B shares	4,624,870	(4,624,870)	—	—	—
TOTAL	**13,609,122**	**—**	**5,800,579**	**19,409,701**	**485,243**

Capital increase resulting from the issuance of ordinary shares

On **July 13, 2016,** the Company completed its Initial Public Offering (IPO) on Euronext Paris, raising €40.0 million, 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, and the Company issued 655,859 ordinary shares with a nominal value of €0.025 and a share premium of €7.975 per share.

Capital increase resulting from the exercise of warrants (BCE)

On **September 3, 2016,** a holder of BCE 2013-02 exercised 112,000 BCE 2013-02 and proceed to the payment of the corresponding subscription.

On **October 6, 2016,** a holder of BCE exercised 31,720 BCE 2013-02 and 1,000 BCE 2015-07 and proceed to the payment of the corresponding subscription.

6.2 — Non-employee share warrants (BSA)

The following table relates to warrants (BSA) to purchase ordinary shares as of December 31, 2016:

Type of warrants	BSA 2013-02	BSA 2013-02	BSA 2015-06	BSA 2016
Number of warrants issued	260,040	33,000	121,000	205,000
Subscription price per warrant (euros)	0.0008	0.0008	0.1000	0.6500
Number of shares to be issued	260,040	33,000	121,000	205,000
Exercise price per share (euros)	0.025	0.025	0.025	8.080
Expiration date	07/08/23	04/09/24	07/07/25	07/25/26

6.3 — Employee share warrants (BCE)

The following table relates to warrants (BCE) to purchase ordinary shares as of December 31, 2016 :

Type of warrants	BCE 2013-02	BCE 2013-02	BCE 2014-06	BCE 2015-06
Number of warrants issued	586,678	193,800	60,000	732,298
Subscription price per warrant (euros)	—	—	—	—
Number of shares to be issued	586,678	193,800	60,000	732,298
Exercise price per share (euros)	0.025	0.025	0.025	0.025
Expiration date	07/08/23	04/09/24	12/03/24	07/07/25

6.4 — Performance shares (AGA)

The following table relates to performance shares (AGA) as of December 31, 2016 :

Performance shares	AGA 2016
Number of granted shares	766,000
Share value at grant	8.800
Acquisition date	07/08/17

6.5 — Statement of changes in shareholders' equity

(in euros)	Share capital	Premiums related to the share capital	Restricted reserves	Reserves	Net income (loss)	Total Shareholders' equity
As of 1/1/2016	340,228	49,795,708	174,161	(9,065,349)	(12,073,618)	29,171,131
Capital increase	145,015	45,108,726	—	—	—	45,253,741
Capital increase related costs	—	(3,807,474)	—	—	—	(3,807,474)
Allocation of prior period income (loss)	—	—	—	(12,073,618)	12,073,618	—
Issue od share warrants	—	133,250	—	—	—	133,250
Net income (loss)	—	—	—	—	(17,397,677)	(17,397,677)
As of 12/31/16	**485,243**	**91,230,210**	**174,161**	**(21,138,967)**	**(17,397,677)**	**53,352,971**

NOTE 7 — LIABILITIES

The breakdown of liabilities is provided by the following table :

(in euros)	Less than one year	Between one and five years	More than five years	Total
Accounts payable and related parties	1,733,546	—	—	1,733,546
Conditional advances	—	—	2,956,914	2,956,914
Due to employees	654,518	—	—	654,518
Social security and payroll contribution	448,286	—	—	448,286
VAT	12,593	—	—	12,593
Other taxes	4,563	—	—	4,563
Other debts	7,499	—	—	7,499
Deferred revenues from subsidies	—	—	—	—
TOTAL	**2,861,005**	**—**	**2,956,914**	**5,817,919**

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.

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 amount of the conditional advances granted was €5,685,975, of which €678,000 was received in December 2014, and €2,278,914 in July 2016, both recognized as non-current liabilities in the statement of financial position, as this conditional advance is repayable by the Company according to a repayment schedule.

The contract with Bpifrance Financement sets forth a repayment schedule that totals €6,490,000. 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 €2.72 million, depending on whether the Company reaches cumulative revenues, excluding taxes, of €80 million by 2029.

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.

This program will be funded according to the following schedule, subject to completion of milestones:

- €678,000 received in December 2014;
- €2,278,914 received in July 2016[(1)];
- €494,000 to be received in November 2017;
- €852,975 to be received in November 2018; and
- €986,000 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 €6,490,000 (including interest at an annual rate of 1.44%) is as follows:

- €550,000 on or before June 30, 2022;
- €1,000,000 on or before June 30, 2023;
- €1,500,000 on or before June 30, 2024;
- €1,700,000 on or before June 30, 2025; and
- €1,740,000 on or before June 30, 2026.

Deferred revenues relate to subsidies (see note 10).

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 2016, R&D expenses amounted to €16,636,226.

(1) The estimated amount from the initial payment schedule was €2,675,000. The costs occurred by Company amounted to a lower amount than expected, therefore the amount of this milestone was reduced accordingly.

NOTE 9 — ACCRUED EXPENSES

The amount of accrued expenses is as follows:

(in euros)	Less than one year	More than one year	Total gross
Accounts payable, accrued expenses	1,057,563	—	1,057,563
Employees, accrued expenses	550,007	—	550,007
Employees, paid vacation	104,511	—	104,511
Social organizations, accrued expenses	193,602	—	193,602
Social organizations, paid vacation	36,788	—	36,788
Government, accrued expenses	300	—	300
Payable interests	2,840	—	2,840
TOTAL	**1,945,611**	**—**	**1,945,611**

NOTE 10 — DEFERRED REVENUES AND GRANTS

As mentioned in Note 7, in addition to the conditional advance, the Company has received one non-refundable subsidy from Bpifrance Financement in connection with its development of product candidates using its optogenetics technology platform as follows :

- €865,000 received in December 2014;
- €172,471 to be received in November 2018; and
- €110,000 to be received in November 2019.

The total amounts to €1,147,471.

As a result, an amount of €642,960 and €190,818 was recorded in other income in the statement of income (loss) for the year ended December 31, 2015 and 2014, respectively.

Gensight Biologics recorded deferred revenue in the balance sheet for €31,222 as of December 31, 2015. This revenue was completely reversed in 2016.

NOTE 11 — FINANCIAL INCOME (LOSS)

Financial income (loss) as of December 31, 2016 is as follows:

(in euros)	12/31/16
Financial revenues	**23,575**
Foreign exchange gains	19,136
Marketable securities disposal gains	1,333
Othe financial income	3,106
Financial expenses	**63,458**
Foreign exchange losses	58,225
Financial deprecition and amortization	5,233
Financial Income(loss)	**(39,883)**

Other financial income represents interest on term deposits.

NOTE 12 — EXTRAORDINARY INCOME (LOSS)

The Extraordinary income corresponds to an income from a disposal of assets, for which the related net gain amounts to €144.

NOTE 13 — HEADCOUNT

	As of 12/31/15	As of 12/31/16
Managers	25	27
NET	**25**	**27**

NOTE 14 — INCREASE AND REDUCTIONS NOT RECOGNIZED IN FUTURE TAX DEBT (IN BASE)

At the close of fiscal year 2016, the amount of deficit being indefinitely carried forward is as follows:

(in euros)	Basis	Potential corporate tax savings
Net Operating Losses	51,264,135	17,088,045

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:

- 2015: €2,874,069, reimbursed in 2016
- 2016: €2,929,874.

NOTE 16 — COMPETITIVENESS AND EMPLOYMENT TAX CREDIT

Tax Credit for Competitiveness and Employment (CICE) is calculated at the end of the year on the basis of eligible pay.

Revenue is recognized as a reduction of personnel expenses in accordance with the recommendation of the Authority Accounting Standards.

The Company recorded income in the amount of €4,008 in tax credit.

NOTE 17 — COMPENSATION PAID TO CORPORATE OFFICERS

The compensation granted to the Directors of the Company amounted to €634,911 for fiscal year 2016.

NOTE 18 — FEES PAID TO THE AUDITORS

The fees of the auditors recognized in fiscal year 2016 amounted to €313,500.

NOTE 19 — COMMITMENTS

19.1 — Commitments under operating leases

The company has signed various ordinary rental agreements for office equipment and long-term car rental. The amount of the future rents under those agreements is broken down as follows as of December 31, 2016:

(in euros)	12/31/16
2017	751,825
2018	745,765
2019	736,584
2020	734,197
2021	734,197
2022	734,197
2023	734,197
TOTAL NET	**5,170,962**

19.2 — 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 €40,000 in 2013 upon the execution of the agreement. Upon completion of development milestones, the Company will pay non-refundable fees up to €2,750,000 in the aggregate. 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 €10,000 upon the execution of the agreement. Upon completion of development milestones, the Company will pay non-refundable fees up to €687,500. 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 research collaboration agreement with a French university. The Company has the exclusive right to use the developed shared patents and committed to pay a total amount of €2,275,920. As of December 31, 2016, the remaining payments under the agreement, representing an amount of €1,105,932 are to be paid over years 2017 and 2018.
- 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.$30,000. Upon completion of development milestones, the Company will pay specified non-refundable fees of up to U.S.$5,900,000. 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 2014, the Company entered into a research collaboration agreement with a biomedical research institute. Under the terms of this research collaboration agreement, the Company agreed to pay €18,540 in 2017.
- 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 $45,000, license maintenance fees up to $100,000 per year and variable payments up to $7,300,000 depending on the achievement of milestone events. The Company will also pay running mid-single-digit royalties on future net sales.

19.3 — 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 €72,967 as of December 31, 2016.

As part of the estimate of the retirement commitments, the following assumptions were used for all categories of employees:

- Social security contribution: 45% in 2015 and 2016;
- Salary increase: 3% in 2015 and 2016;
- Discount rate: 2.08% and 1.31% in 2015 and 2016, respectively;
- Retirement age: 67;
- Terms of retirement: voluntary retirement;
- Life table: INSEE 2011-2013;
- Collective agreement: *Convention Collective Nationale de l'Industrie Pharmaceutique* (National Collective Agreement in the Pharmaceutical Industry); and
- Turn-over of personnel: 10% (20-49), 0% above 50.

ANNEX II
STATUTORY AUDITORS' REPORTS ON THE COMPANY'S ANNUAL FINANCIAL STATEMENTS (FRENCH-GAAP) FOR THE FISCAL YEAR ENDING DECEMBER 31, 2016

The English version is a free translation into English of the statutory auditor's report issued in the French language and is provided solely for the convenience of English speaking readers. The statutory auditor's report includes information specifically required by French law in all audit reports, whether qualified or not, and this is presented below the opinion on the financial statements. This information includes an explanatory paragraph discussing the auditor's assessments of certain significant accounting and auditing matters. These assessments were considered for the purpose of issuing an audit opinion on the financial statements taken as a whole and not to provide separate assurance on information taken outside of the financial statements.
This report should be read in conjunction with, and construed in accordance with, French law and professional auditing standards applicable in France.

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STATUTORY AUDITORS' REPORT ON THE FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2016

To the shareholders,

In compliance with the assignment entrusted to us by your shareholders' Meeting, we hereby report to you, for the year ended December 31, 2016, on:

- The audit of the accompanying financial statements of S.A. GENSIGHT BIOLOGICS,
- The justification of our assessments,
- The specific verifications and information required by law.

These financial statements have been approved by the Board of Directors. Our role is to express an opinion on these financial statements based on our audit.

1 - Opinion on the financial statements

We conducted our audit in accordance with professional standards applicable in France. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit involves performing procedures, using sampling techniques or other methods of selection, to verify the evidence about the amounts and disclosures in the financial statements. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made, as well as the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

In our opinion, the financial statements give a true and fair view of the assets and liabilities of the financial position of the company as of December 31, 2016 and of the results of its operations for the year then ended, in accordance with French accounting principles.

2 - Justification of our assessments

In accordance with the requirements of article L.823-9 of the French Commercial Code *(Code de commerce)* relating to the justification of our assessments, we bring to your attention the following matter:

Research Tax Credit

Your company books a Research Tax Credit, as detailed in Note 15 of the Appendix to the financial statements. We assessed the reasonableness of the information given in the context of this evaluation.

These assessments were performed as part of our audit approach for the financial statements taken as a whole and therefore contributed to the expression of our opinion in the first part of this report.

3 - Specific verifications and information

We have also performed, in accordance with professional standards applicable in France, the specific verifications required by French law.

We have no matter to report regarding the fair presentation and the consistency with the financial statements of the information given in the Board of Directors' management report and in the documents addressed to shareholders with respect to the financial position and the financial statements.

Concerning the information given in accordance with the requirements of article L.225-102-1 of the French Commercial Code *(Code de commerce)* relating to remuneration and benefits received by the Directors and any other commitments made in their favour, we have verified its consistency with the financial statements or with the underlying information used to prepare these financial statements and, where applicable, with the information obtained by your company from companies controlling your company or controlled by it. On the basis of this work, we attest the accuracy and fair presentation of this information.

In accordance with French law, we have verified that the required information concerning the identity of the shareholders or holders of the voting rights has been properly disclosed in the management report.

PARIS and LYON, March 15, 2017

The Statutory Auditors

BECOUZE
Fabien BROVEDANI
Partner

DELOITTE & ASSOCIÉS
Dominique VALETTE
Partner

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