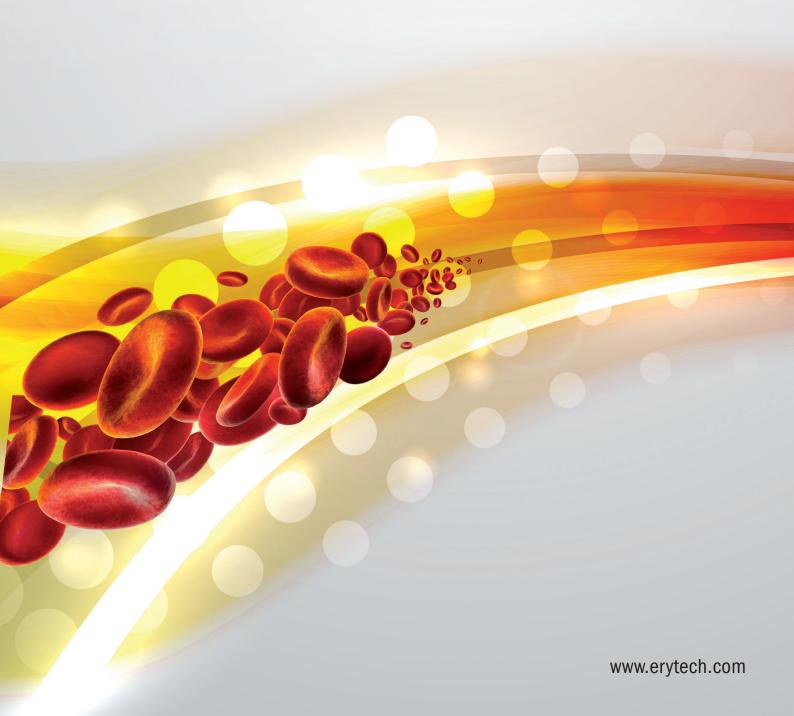


# **2014 REFERENCE DOCUMENT**

Containing the Annual Financial Report and the Management Report





Public limited company with a capital of 688,276.10 Euros Headquarters: Bâtiment Adénine – 60 Avenue Rockefeller 69008 Lyon Trade and Companies Register 479 560 013

# 2014 REFERENCE DOCUMENT CONTAINING THE ANNUAL FINANCIAL REPORT AND THE MANAGEMENT REPORT



In particular application of Article 212-13 of its General Regulations, the French financial market authority (l'Autorité des marchés financiers - "AMF") has assigned this reference document visa no. R.15-048 dated June 4, 2015. This document may only be used in support of a financial transaction if it is completed by a transaction note signed by the AMF. This reference document was written by the issuer and incurs the liability of its signers.

Registration, pursuant to the provisions of article *L*.621-8-1-I of the Monetary and Financial Code was awarded after the AMF checked to see that "the document is complete and comprehensible, and that the information contained therein is consistent." This implies neither approval of the opportuneness of the transaction nor authentication of the accounting and financial documents presented.

This unapproved English translation of the Reference Document is a free translation of the original which was prepared in French, submitted to and registered with the Autorité des marchés financiers (AMF) on June 4, 2015 in accordance with Article 212-13 of the AMF General Regulations. It is not a binding document. In the event of any ambiguity or conflict between corresponding statements or items contained in this English translation and the original French version, the relevant statements or items of the French version shall prevail. The auditor's reports apply to the French version of the Management Report and the financial statements.

Copies of this reference document are available at no cost at the headquarters of ERYTECH Pharma, Bâtiment Adénine, 60, Avenue Rockefeller 69008 in LYON, as well as electronically on the ERYTECH Pharma website (<a href="www.erytech.com">www.erytech.com</a>) and the AMF website (<a href="www.amf-france.org">www.erytech.com</a>)

# TABLE OF CONTENTS

CONCO	RDANCE TABLE	8
1 DE(	SPANCIBLE DADELEC	10
	SPONSIBLE PARTIES	
	Person responsible for the reference document	
	Certification by the responsible party	
1.3. F	Persons responsible for the financial information	12
2. STA	ATUTORY AUDITORS	13
2.1. S	tatutory auditors	13
2.2. I	Deputy auditors	13
2.3. I	Declaration of fees paid to the auditors	14
3. SEI	LECTED FINANCIAL INFORMATION	15
4. RIS	K FACTORS	17
	Operational risks	
	Risks related to product development	
4.1.2.	* *	
4.1.3.		
4.1.4.	* *	
4.1.5.		
4.1.6.		
4.1.7.		
	4.1.7.1. Teva Group	
	4.1.7.2. Orphan Europe (Recordati Group)	
4.1.8.	A · · · · · · · · · · · · · · · · · · ·	
4.1.9.		21
4.1.10	). Risks of conflict of interest	
4.1.11	. Risks of dependence on subcontractors and key raw material suppliers	22
	2. Risks relating to health, safety, and the environment	
4.2. S	strategic risks	24
4.2.1.	Risk related to key personnel	24
4.2.2.	Risks related to key objectives not being reached	24
4.2.3.	Risks related to the management of internal growth	24
4.2.4.	Risks related to competition	25
4.2.5.	Risks related to confidentiality of Company information and knowledge	25
4.2.6.	Risks related to the use of information systems	26
4.2.7.	Risk related to industrial espionage	26
4.2.8.	Specific risks related to the use of technologies owned by third parties	26
4.2.9.	1 1 2	
	egal risks	
4.4. F	Regulatory risks	28
4.4.1.		
4.4.2.		
4.4.3.		
4.4.4.		
	inancial risks	
4.5.1.		
4.5.2.	$\mathcal{E}$	
4.5.3.	<b>3</b>	
4.5.4.		
	ocial and fiscal risks	
4.6.1.	Risks related to research tax credit	31

4.6.2. Risks related to tax fluctuations for medicines	32
4.6.3. Risks related to changes in fiscal or labor legislation	32
4.7. Market risks	
4.7.1. Liquidity risk	
4.7.2. Exchange rate risk	
4.7.3. Interest rate risk	
4.8. Volatility risk	
4.9. Insurance and risk coverage	
4.10. Exceptional events and litigation	
5. INFORMATION ABOUT THE COMPANY	39
5.1. History and evolution of the Company	39
5.1.1. Company name, trade name, and headquarters of the Company	
5.1.2. Location and registration number of the Company	
5.1.3. Date of establishment, duration, and transformation of the Company	
5.1.4. Legal form of the Company and applicable laws	
5.1.5. Financial year	
5.1.6. History	
5.2. Investments	
5.2.1. Principal investments made since 2013	
<ul><li>5.2.2. Principal investments currently being made</li><li>5.2.3. Principal investments planned</li></ul>	
5.2.3. Timelpul investments plained	
6. OVERVIEW OF BUSINESS ACTIVITIES	46
6.1. General presentation	46
6.2. Introduction to cancer treatment	
6.3. Acute leukemia: A significant unmet medical need	
6.3.1. Bone marrow cancer	
6.3.2. An increasing number of patients worldwide	
6.3.3. A lower 5-year survival rate for adults and seniors	
6.4. L-asparaginase: a decisive drug in the treatment of acute leukemias	
<ul><li>6.4.1. Current treatment of patients with acute leukemia</li><li>6.4.2. L-asparaginase's crucial role in the remission of patients</li></ul>	
6.4.2.1 ALL treatment	
6.4.2.2. AML treatment	
6.4.3. Limitations of direct administration of L-asparaginase	
6.4.4. The current market for L-asparaginase	
6.5. ERY-ASP/GRASPA®: An innovative treatment entering the market in A	
6.5.1. L-asparaginase encapsulated for greater efficacy and improved safety	
6.5.2. Clinical results and ongoing clinical programs for acute leukemia	
6.5.3. Obtaining orphan drug designation and its benefits	72
6.5.4. Marketing GRASPA®	72
6.5.5. Positioning of GRASPA® on the market	73
6.6. Marketing GRASPA® in Europe and Israel	
6.7. Development of ERY-ASP for leukemia in the United States	
6.8. Potential new indications for ERY-ASP: Solid tumors	
6.9. ERYTECH's encapsulation technology	
6.9.1. The innovative approach to encapsulate therapeutic enzymes	
<ul><li>6.9.2. Automated and strong industrialized encapsulation process</li><li>6.9.3. Organized production in the United States for future clinical trials</li></ul>	/8 70
6.10. TEDAC and other projects under development	79 70
6.11. The pharmaceutical industry's interest in orphan drugs	
6.12. Environmental, social and corporate responsibility policy	
7 ODCANIZATION CHADT	92

	REAL ESTATE PROPERTY, MANUFACTURING PLANTS AND EQUIPMENT	
8.1.	Real property	82
8.2.	Environmental constraints that may affect the use of assets	83
9.	EXAMINATION OF THE RESULTS AND FINANCIAL POSITION	84
9.1.	Overview	
9.2.	Comparison of the last two years	
	2.1. Operating profit breakdown	
٠.	9.2.1.1. Sales revenue and other income from activity	
	9.2.1.2. Operating expenses	
	9.2.1.3. Net income breakdown	
	9.2.1.4. Net income and net income per share	
9.3.	Non-deductible expenses	
9.4.	Balance sheet analysis	
<i>7</i> . 1.	9.4.1.1. Non-current assets	
	9.4.1.2. Current assets	
	9.4.2.1 Equity	
	9.4.2.2 Non-current liaiblities	
	9.4.2.3 Current liablities	
	7.112.13 Current Indicates	
	CAPITAL RESOURCES AND CASH	
10.1.		
10.2.		
10.3.		
10.4.	1	
10.5.	. Sources of financing needed for the future	92
11.	RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES	93
11.1.		
11.2.		
1.	1.2.1. Patents	
	11.2.1.1. In its own name	
	11.2.1.2. Licenses	
	11.2.2 Trademarks	
1.	1.2.3 Domain Names	
10	TEDENIN INICODALA TIONI	101
	TREND INFORMATION	
12.1	Main trends since the end of the last financial year.	
12.2	, , , , , , , , , , , , , , , , , , ,	
	Company's prospects	101
13	FORECASTS OR ESTIMATES OF EARNINGS	101
14	ADMINISTRATIVE AND MANAGEMENT BODIES	102
14.1	Executive Officers and Directors	
	4.1.1 Composition of the Board of Directors	
	4.1.2 Composition of Senior Management	
	4.1.3 Other corporate duties	
	4.1.4 Experience with administrative and managerial bodies	
14.2	Potential conflicts of interest and agreements	108
15	REMUNERATION AND BENEFITS	
15.1	Compensation and in-kind benefits allocated to the Company's corporate officers for the le	ast financial
	year	108

15.2	Amounts allocated or identified by the Company for the payment of pensions, retirement, or benefits	
15.3	Share subscription warrants, founder subscription warrants, and other securities giving access	
10.0	capital, assigned to directors and executive officers.	116
15.4	Summary statement of transactions by executive officers and persons mentioned in article L.621	
	of the Monetary and Financial Code involving shares of the Company conducted during the	•
	financial year	117
	PERATION OF THE ADMINISTRATIVE AND MANAGEMENT BODIES	
16.1	Term of office for directors	
16.2	Service agreements binding members of the Board of Directors and Senior Management with	
162	Company	
16.3	Corporate governance, internal audit, and risk management	
	3.2 Chairman's report on internal audits	
16.4	Elements capable of having an impact in the event of a public offering	
	4.1 Capital structure of the company	
	4.2 Restrictions resulting from the articles of incorporation respecting the voting rights and trans	
10.	of shares or clauses of which the Company has been informed in application of Article L.233	
	of the Code of Commerce	
16.	4.3 Direct or indirect stakes held in the Company's share capital of which it is aware by virtue of	
	Articles L.233-7 and L.233-12 of the Code of Commerce	
16.	4.4 Parties holding any securities involving special rights of control and description thereof	131
16.	4.5 Control mechanisms provided in any system for employee shareholding, when the controller	
	rights are not exercised by the latter	131
16.	4.6 Agreements between shareholders of which the Company is aware and which may result in	
	restrictions to transfers of shares and the exercise of voting rights	
16.	4.7 Rules applicable to the appointment and replacement of members of the board of directors as	
1.0	as modification of the articles of incorporation	
	4.8 Powers of the board of directors, particularly the issuance or redemption of shares	131
16.	4.9 Agreements stipulated by the Company that have been modified or that will end if there is a	121
16	change in control of the Company	
10.	resign or are dismissed without real or serious cause or if their employment is terminated due	
	public offering	
	public offering	1 3 2
18 D	MDI OVERG	100
17.1 17.1	MPLOYEES	
- /	Personnel	
	1.2 Experience and positions of the principal managers	
	1.3 Personnel distribution	
	1.4 Human Resources Management	
	1.5 Organization of work time	
17.2	Investment stakes held by corporate officers	135
17.3	Investment stakes held by company non-corporate officers	
17.4	Incentive agreement.	
18 N	AAJOR SHAREHOLDERS	136
18.1	Distribution of share capital and voting rights	
18.3	Shareholder voting rights	
18.4	Control of the Company	
18.5	Shareholders' agreement	
18.6	Concerted action	
18.7	Agreements capable of resulting in a change in control.	

<b>19</b> O	PERATIONS WITH RELATED PARTIES	140
19.1	Intra-group transactions	140
19.2	Related party transactions	141
19.2	2.1 Special report by the statutory auditor on regulated agreements – Financial year ended Decer 31, 2014	
19.	2.2 Special report by the statutory auditor on regulated agreements – Financial year ending Dece	ember
	31, 2013	146
	INANCIAL INFORMATION CONCERNING THE COMPANY'S EQUITY, FINANCIAL OSITION, AND RESULTS	
20.1	Financial statements prepared in accordance with IRFS standards for the year ended Decemb 2014	
20.2	Corporate financial statements prepared (French standards) for the years ended December 31, and 2014	
20.3	Statutory auditors' report on the financial statements prepared in accordance with IFRS standar the year ended December 31, 2014	
20.4	Statutory auditors' report on the corporate financial statements for the year ended December 2014	er 31,
20.5	Date of last financial information	
20.6	Table of results for the last five financial years (Erytech Pharma SA, annual financial state	
	prepared in accordance with French accounting standards)	
20.7	Dividend distribution policy	
20.	7.1 Dividends paid during the last three financial years	
	7.2 Dividend distribution policy	
20.8	Legal and arbitration proceedings	
20.9	Significant changes in the financial or commercial situation	
20.10	Report on the economic and financial results (annual financial statements prepared in accordance	
	French accounting standards)	
20.11	Report on the economic and financial results (financial statements consolidated in accordance	
	IFRS framework)	220
20.12	Allocation of the results	222
20.13	Luxury expenditures and non-deductible expenses	222
20.14	Information on payment timeframes	222
20.15	Regulated agreements	223
	DDITIONAL INFORMATION	
21.1	Share capital	
	Amount of subscribed capital	
	Shares not representing the capital	
	Acquisition of shareholder equity by the Company	
	Other securities giving access to the capital	
	Authorized capital not issued	
21.1.6	Company capital forming the object of an option or a conditional or unconditional agree	
	stipulating its placement under option	
	Evolution of the share capital	
21.1.8	Evolution of the shares	
21.2	Main provisions of the articles of incorporation	
	2.1 Corporate purpose (Article 3 of the articles of incorporation)	
21.	2.2 Administration and Senior Management (articles 17 to 24 of the articles of incorporation)	234
21.2	2.3 Rights, privileges, and restrictions attached to shares (Articles 9 to 16 of the articles of incorporation)	238
21.	2.4 General Meetings (Articles 26 to 30 of the articles of incorporation)	
	2.5 Clauses of the articles of incorporation such as may have an effect on the occurrence of a characteristic of control	ange
21 ′	2.6 Crossing of thresholds set by the articles of incorporation	
	2.7 Special provisions governing modifications to the share capital	

22 MA	JOR CONTRACTS	242
22.1 F	Partnership and cooperation agreements	242
22.1.1	Financed agreements	242
	22.1.1.1 Erytech/Inserm/Aphp/Diaxonhit	242
22.1.2	Partnership agreements	245
22.2 I	icense agreement	246
	Erytech/National Institutes of Health (NIH)	
	Supply contracts:	
	Erytech/Établissement Français Du Sang (EFS)	
	2 Erytech/American Red Cross (ARC)	
22.3.3	B Erytech/Medac	246
	Other supply contracts	
	Subcontracting agreements	
	Erytech/American Red Cross (ARC)	
	2 Other subcontracting agreements	
	ORMATION ORIGINATING FROM THIRD PARTIES, EXPERT DECLAR CLARATIONS OF INTERESTS	
44 DO		240
24 DO	CUMENTS ACCESSIBLE TO THE PUBLIC	249
25 INF	ORMATION ON INVESTMENT STAKES	250
26 GL	OSSARY	251
APPENI	DIX 1 – REPORT BY THE STATUTORY AUDITORS ON THE	CHAIRMAN'S
	PORT	
	DIX 2 - POLICY WITH REGARD TO ENVIRONMENTAL, SOCIAL, AN	ND SOCIETAL

# **CONCORDANCE TABLE**

The concordance table below makes it possible to identify in this reference document:

- the information which forms the annual financial report (Article L.451-1-2 of the Monetary and Financial Code and article 222-3 of the General Rules of the AMF), and

- the information which forms the annual management report (Article L. 225-100 et seq. of the Code of Commerce).

Annual financial report	Reference document
1. Certification by the responsible party	See section 1.2
2. Corporate annual financial statements – French standards	See section 20.4
3. Corporate annual financial statements – International Financial Reporting Standards (IFRS)	See section 20.1
4. Management report	See index below
5. Chairman's report on internal audit	See chapter 16
6. Annual information document	See section 5.1.6
7. Statement pertaining to the statutory auditor's fees	See section 2.3
8. Statutory auditor's report on the annual financial statements prepared in accordance with French standards and IFRS standards	See sections 20.2 and 20.5
9. Report by the statutory auditor on the Chairman's report	See appendix 1
Annual management report	Reference document
1. Condition of the Company and activity during the past financial year	See chapters 6
2. Examination of the financial statements and earnings – Allocation of earnings – Review of dividends distributed – Expenses that are not tax-deductible	See chapter 20
3. Information about supplier payment deadlines	See chapter 20
4. Progress made or difficulties encountered	See chapter 6
5. Primary risks and uncertainties faced by the Company – Use of financial instruments by the Company	See chapter 4
6. Research and development activities	See chapters 6 and 11
7. Forecast and outlooks	See chapters 6 and 12
8. Significant events that have occurred since the end of the financial year	See chapter 20
9. Employee investment in share capital	See chapter 17
10. The Company's senior management	See chapters 14, 15 and 16
11. Information concerning the corporate officers	See chapters 14, 15 and 16
12. Acquisition of significant stakes in companies that have their headquarters in France, or acquisition of control over such companies; sales of such stakes	See chapters 7 and 25
13. Activities of subsidiaries and controlled companies	See chapters 7 and 25
<ul> <li>14. Information pertaining to the distribution of capital and cross-holding – Share buyback program</li> <li>15. Changes that occurred during the financial year to the composition of the share capital</li> </ul>	See sections 18.1 and 21.1.2 See sections 18.1 and 21.1.7

16. Changes to the securities – Risk of variation in price	See sections 4.7 and 21.1.8
17. Summary statement of transactions by the executive officers and persons mentioned in article L.621-18-2 of the Monetary and Financial Code involving shares of the Company conducted during the past	See section 15.4
financial year	
18. Information required under article L.225-100-3 of the Code of	See section 16.4
Commerce	
19. Social and environmental information	See section 6.12 and
	chapter 17
20. Table of earnings for the last five financial years	See section 20.7
21. Delegations respecting capital increases	See section 21.1.5

#### NOTE

In this reference document ("the Reference Document"), the terms "ERYTECH" or the "Company" refer to the company ERYTECH Pharma, a public limited company with its headquarters located at 60 Avenue Rockefeller, Bâtiment Adénine, 69008 Lyon, France, registered with the Lyon Trade and Companies Register under number 479 560 013. The term "Group" refers to the Company and its subsidiary, the company ERYTECH Pharma Inc., which headquarters are located at 185 Alewife Brook Pkwy Ste 410, CAMBRIDGE MA 02138, United States of America.

The Reference Document notably presents the annual financial statements for the Company, prepared in accordance with accounting standards applicable in France (the "Financial Statements") for the financial year ending December 31, 2014, as well as a set of financial statements for the same year, in accordance with the IFRS accounting standards adopted by the European Union. In application of article 28 of regulation (EC) no. 809/2004 of the Commission, the following are included as references in this Reference Document:

- the annual financial statements prepared in accordance with accounting standards applicable in France for the financial year ending December 31, 2013, as well as the corresponding audit report from the statutory auditor, found in Section 20 of the Reference Document and registered with the AMF on June 4, 2014 under no. R.14-038;
- the annual financial statements prepared in accordance with accounting standards applicable in France for the financial year ending December 31, 2012, as well as the corresponding audit report from the statutory auditor, found in Section 0 of the Reference Document and registered with the AMF on April 17, 2013 under no. 13-166 and in Section 20 of the Reference Document registered with the AMF on June 4, 2014 under no. R.14-038;
- the annual financial statements restated in accordance with the IFRS for the financial years ending December 31, 2011, 2012, and 2013, as well as the corresponding audit reports from the statutory auditor, found in Section 20 of the Reference Document and registered with the AMF on April 17, 2013 under no. 13-166 and in Section 20 of the Reference Document registered with the AMF on June 4, 2014 under no. R.14-038;
- the key financial information and examination of the financial condition and earnings of the Company shown in Sections 3, 9, and 10 of the Reference document recorded on April 17, 2013 by the AMF under no. 13-166.

The Reference Document may be consulted on ERYTECH Pharma's website (www.erytech.com) and that of the AMF (www.amf-france.org).

Unless stated otherwise, the financial information regarding the Company mentioned in the Reference Document is taken from the IFRS consolidated financial statements. Additionally, the Reference Document contains statements about the Group's objectives, as well as its areas of focus for development. These statements are at times identified by the use of the future tense, the conditional tense, and forward-looking terms such as "consider", "plan", "think", "has as its objective", "expects to", "understand", "must", "strive", "believe", "estimate", "wish", "be able to", or, as applicable, the negative form of these same terms, or even, any other variation or similar terminology. The reader's attention is directed to the fact that these objectives and these directions for development depend on circumstances or facts for which the occurrence or completion is uncertain.

A glossary defining certain technical terms referenced in the Reference Document as well as an index of abbreviations used is found in Chapter 0.

# WARNING

The goals and areas of focus for development presented are not factual historical data and must not be interpreted as being guarantees that the facts and data stated shall occur, that the scenarios have been verified, or that the objectives shall be achieved. Due to their nature, these objectives may not be achieved and the statements or information found in the Reference Document could turn out to be erroneous; the Company shall be under no obligation of any nature to provide an update, except as required by applicable regulations and particularly the General Regulations of the Autorité des Marchés Financiers ("AMF").

The Reference Document furthermore contains information pertaining to the Group's activities, as well as the market and industry in which it operates. Some of this information originates from sources external to the Group and has not been verified independently by the Group.

Investors are invited to carefully weigh the risk factors described in Chapter 4 -"Risk factors" - of this Reference Document before making their investment decision. The occurrence of all or part of these risks may have a negative impact on the Group's activities, circumstances, financial results, or the achievement of its objectives. Additionally, other risks that have not yet been identified or considered by the Group to be significant could have the same negative effect and investors could thus lose all or part of their investment.

#### 1. RESPONSIBLE PARTIES

# 1.1. Person responsible for the reference document

Gil Beyen Chairman and Chief Executive Officer

# 1.2. Certification by the responsible party

"I hereby declare, after having taken all reasonable measures to this effect, that, to my knowledge, the information contained in this Reference Document conforms to reality and does not contain any omissions such as may alter its nature or intent.

We have obtained a certification letter from the statutory auditors, in which they declare that they have performed an audit of the information in the financial statement and the accounts reported in this Reference Document, and have read the entire Reference Document.

The historical financial information presented in the present Reference Document is reported in the statutory auditors' reports provided in Chapters **Erreur! Source du renvoi introuvable.** and 0."

June 3, 2015

Gil Beyen

# 1.3. Persons responsible for the financial information

Gil Beyen Chairman and Chief Executive Officer

Tel.: +33 4 78 74 44 38 Fax: +33 4 78 75 56 29

e-mail: investors@erytech.com

#### 2. STATUTORY AUDITORS

# 2.1. Statutory auditors

**KPMG Audit Rhône Alpes Auvergne,** a simplified limited company, Lyon Trade and Companies Register 512 802 828, 51, rue de Saint Cyr - 69338 Lyon Cedex 9.

Date of first appointment: June 11, 2010.

Expiration date for term of office: The general shareholders' meeting voting on the financial statements for the year ending December 31, 2015.

KPMG SA was the statutory auditor for the period from initial establishment of the Company and up to its replacement by KPMG Audit Rhône Alpes Auvergne on June 11, 2010, upon expiry of its term.

RSM CCI CONSEILS, LYON Trade and Companies Register 398 384 198, 2 bis, rue Tête d'Or, Lyon 6

Date of first appointment: June 17, 2014

Expiration date for term of office: The general shareholders' meeting voting on the financial statements for the year ending December 31, 2019.

#### 2.2. Deputy auditors

**KPMG Audit Sud Est**, a simplified limited company, Marseille Trade and Companies Register 512 802 729, 480, avenue du Prado 13269 Marseille Cedex 08.

Date of first appointment: June 11, 2010.

Expiration date for term of office: The general shareholders' meeting voting on the financial statements for the year ending December 31, 2015.

The deputy statutory auditor from establishment of the Company and up to the expiry of his term on June 11, 2010, was Pierre Duranel, acting in his own name.

Pierre-Michel MONNERET, 2 bis, rue Tête d'Or, 69006 LYON

Date of first appointment: June 17, 2014

Expiration date for term of office: The general shareholders' meeting voting on the financial statements for the year ending December 31, 2019.

# 2.3. Declaration of fees paid to the auditors

The table below presents the auditor fees sustained by the Company in the first three years:

Financial years covered: 01/01/2014 - 12/31/2014

	KMPG F	Rhône-Alpo	es Auverg	ne	RSM CO	CI-Conseils	S	
	Amount (	BT)	9	6	Amount (BT)		%	
	2014	2013	2014	2013	2014	2013	2014	2013
Audit  External auditor, certification, review of individual and consolidated financial statements  Issuer  Subsidiaries consolidated globally	47,550	69,750	82%	97%	35,450		77%	
<ul> <li>Other diligence reviews and services directly associated with the external auditor's assignment</li> <li>Issuer</li> <li>Subsidiaries consolidated globally</li> </ul>	10,200	1,800	18%	3%	10,650		23%	
Subtotal	57,750	71,550	100%	100%	46,100	0	100%	0
Other services provided by the network of globally consolidated subsidiaries Legal, fiscal, social Other (to be specified > 10% of auditor fees)	None	None			None			
Subtotal	0	0	0%	0%	0	0	0%	0
TOTAL	57,750	71,550	100%	100%	46,100	0	100%	0

The other diligence activities and services directly associated with the auditor's assignment include:

- fees corresponding to the preparation of auditor certifications relative to expenses sustained within the context of various R&D projects,
- fees relative to the transaction note of September 2014 on the capital increase of October 2014.

#### 3. SELECTED FINANCIAL INFORMATION

The main financial information presented below is extracted from the consolidated financial statements of the ERYTECH PHARMA Group prepared in accordance with IFRS standards for the financial years ended December 31, 2013 and December 31, 2014, as provided in Section 20.1 of the present Reference Document.

The historical legal financial statements for the parent company, prepared in accordance with French standards, are included in Chapter 0.

This main accounting and operational data should be read alongside the information contained in Chapters 9 "Examination of the Company's financial position and results", 10 "Cash position and capital", and 0 "Financial information concerning the Company's equity, financial position, and results".

# • Simplified balance sheet

as of Dec. 31 in thousands of €	2 013	2 014
NON-CURRENT ASSETS	910	1 080
intangible assets	14	31
tangible fixed assets	813	967
non-current financial assets	83	82
deferred tax assets	-	-
CURRENT ASSETS	17 039	39 526
cash and cash equivalents	15 113	36 988
TOTAL ASSETS	17 949	40 607
SHAREHOLDERS' EQUITY	13 587	35 824
NON-CURRENT LIABILITIES	848	525
CURRENT LIABILITIES	3 515	4 258
TOTAL LIABILITIES AND SHAREHOLDERS	17 949	40 607

# • Simplified income statement

as of Dec. 31 in thousands of €	2 013	2 014
Total income from activities sales revenue	1 802 -	<b>2 026</b>
Operating results	(7,085)	(8,948)
Financial results	(1,100)	68
Net income	(8,145)	(8,860)

# • Simplified cash flow table

as of Dec. 31 in thousands of €	2 013	2 014
Internal financing capacity before financial results and tax	(7,965)	(9,113)
Changes in working capital needs related to business activities	1 492	1 874
Net cash flow generated by business activities	(6,473)	(7,239)
Net cash flow generated by investment operations	(289)	(420)
Net cash flow generated by financing operations	13 999	29 535
capital increase performed in cash, net of costs	14 537	29 173
Variation in net cash position	7 237	21 876

# • Additional information

At March 31, 2015, cash and cash equivalents totaled 33.5 million Euros, compared to 37 million Euros at the end of 2014.

During the first quarter of 2015, the Group did not record any revenue from activities.

# 4. RISK FACTORS

Investors are invited to review all information contained in this Reference Document, including the risk factors described in this section. The Company has performed a review of the risks that could have a significant negative effect on its activities, its financial position, or its results (or on its ability to achieve its objectives), and considers that no significant risks exist other than those presented in this chapter. At the time of filing this Reference Document, those risks are those that the Company believes could have a significant material adverse effect on the Company or its activity, financial position, results or growth.

#### 4.1. Operational risks

#### 4.1.1. Risks related to product development

The development of the Company's products could be delayed or not be completed.

The marketing authorization for ERY-ASP/GRASPA®1 may be delayed, subject to "post-AMM" studies (these two hypotheses may lead to additional costs), or may not be obtained.

To obtain the regulatory approval required to bring a candidate drug to market, the Company must conduct preclinical and clinical studies to show safety and efficacy. These studies entail high costs. The trend for these costs could be on the rise with the growth of the Company and increase in products it develops. If the results of these studies are unsatisfactory or inconclusive, the Company may have to choose between abandoning the program, leading to loss of investment in time and money, or its pursuit, with no guarantee that the additional costs that this would entail would lead to completion.

The Company may choose, or regulatory authorities may force the Company, to suspend or end clinical trials if the patients are or have been exposed to unexpected and serious risks or to clinical ineffectiveness (loss of opportunity) or request additional scientific information/validations. Deaths and other adverse events could occur during a clinical trial as a result of medical problems that may or may not be related to the treatment under study, and force the Company to delay or interrupt the trial. In light of trial results, the Company could also decide to abandon development projects that it initially believed held promise.

Other factors can have a significant material adverse effect on the Company's activities, prospects, financial position, results and growth:

- The early selection of new products or new areas of development could prove to be less relevant and not lead to the launch of new products;
- Research and development teams may not be able to develop the new products required for the Company's objectives, both for new market penetration and for maintaining current opportunities;
- The co-development with other partners could be more difficult than anticipated and the corresponding launches may be delayed or abandoned;
- New regulatory requirements could delay or derail preclinical and/or clinical development of candidate drugs;
- Patient recruitment in trials could also prove difficult, delay the start of the study, prolong its duration or limit its scope due to a low number of patients;
- The patients included in the trial could, at any time and without justification, interrupt their participation; if too many patients withdraw, the study could be discontinued due to lack of feasibility;
- Shortages in raw materials impacting the production of clinical batches could delay or interrupt a planned clinical trial or a clinical trial in progress;
- Phase I trials aim to show the safety of the candidate drug; negative results in Phase I could lead to discontinuation of the trial program; even in future phases, when the Phase I results were positive, tolerance and safety problems or harmful side effects could occur and delay or interrupt the trials; and
- In the event of serious tolerance or toxicity problems, the trials must be interrupted.

<sup>&</sup>lt;sup>1</sup> The GRASPA® brand was licensed to Orphan Europe (Recordati Group) in order to market the product in ALL and AML in Europe and to the Teva Group in Israel.

Finally, no guarantee can be made as to positive preclinical and clinical results. Favorable results during preclinical studies and preliminary clinical trials are not always confirmed during future clinical trials. In addition, clinical trials can produce safety and efficacy results that, while positive, are not sufficient to obtain marketing approval. Positive results in a clinical trial and/or the grant of marketing approval of a product with a given indication does not presume the efficacy, safe use and marketing approval (French AMM) for another indication, even if the latter may be related or linked by scientific rational.

#### 4.1.2. Risks relating to the particular nature of the products

ERY-ASP/GRASPA®, ERYTECH's flagship product, could present certain risks that exist in relation to blood transfusions.

ERY-ASP/GRASPA® must be intravenously injected in the patient in accordance with the rules for administering red blood cells (transfusion) and the notably the compatibility of the donor (blood type). The red blood cells used during the manufacture of ERY-ASP/GRASPA® originate from blood donations prepared and tested by blood banks, notably the Établissement Français du Sang (French national blood service - EFS), known for their high standards of quality and safety.

However, ERY-ASP/GRASPA® could present certain risks that exist in relation to blood transfusions. These risks, while rare, are possible despite having never been observed with ERY-ASP/GRASPA® at the time of filing of the Reference Document:

- Risks from transmission of infectious agents:
  - viral;
  - bacterial;
  - Parasites; and
  - prionic.
- Risks from red blood cells:
  - immunological (allergic) risk is the most concerning in terms of its severity and frequency; and
  - risk of post-transfusion graft-versus-host disease and purpura.

In addition, the blood banks follow a strict red blood cell preparation process, approved by health authorities, to detect and reduce possible risks for contamination by infectious agents.

Risks related to molecules encapsulated in red blood cells could be varied and depend on their known or unknown toxicity. For example, enzymatic biological molecules (such as asparaginase) are immunogenic in humans and promote development of antibodies and allergic reactions, which could lead to anaphylactic shock and death in the patient. The level of knowledge of the risks inherent in encapsulated molecules is greater with a molecule that has already been approved for the market in France or another country than for a new molecule that has never been used in humans. ERY-ASP/GRASPA® uses asparaginase, a product used in Europe since the '70s, the toxicity of which is well known and documented.

#### 4.1.3. Risk related to the production process

#### Production costs may be higher than estimated

ERYTECH manufactures according to manufacturing best practices applicable to drugs for clinical trials and to specifications approved by the regulatory authority. Only products that meet the standards are released for administration to patients. If a product was found to be non-compliant, ERYTECH would be required to manufacture again, which would entail additional costs and may prevent delivery of the product to patients on time.

Other risks may have the same effect, such as:

- Contamination of the controlled atmosphere area
- Unusable premises and equipment;
- New regulatory requirements requiring a partial and/or extended stop to the production unit to meet the requirements;
- Unavailable qualified personnel;
- Power failure of extended duration;
- Logistical error;
- Rupture in cold chain.

These risks, should they occur, could have a material adverse effect on the activities, financial position, results, reputation or growth of the Company.

Moreover, a rise in direct/indirect energy rates may increase product manufacturing and logistical costs, therefore having a negative impact on the activities, financial position, results or growth of the Company.

# 4.1.4. Risks related to production capacity

# The Company's production capacity could be insufficient

The Company's production capacity may prove insufficient in the future to meet the growth of its activity. If the Company must increase production capacity, it could need to make considerable investments that could lead to significant financing needs or to sub-contracting agreements in order to outsource part of the production.

#### 4.1.5. Risk of commercial failure

## The commercial success of the Company's products is not guaranteed.

At this time, none of the products developed by the Company has received marketing approval (AMM). For the development and marketing of products based on these technologies, the Company is confronted with a high level of risk and uncertainty which could slow or suspend the development efforts for its products and negatively affect its activities. Therefore, even if the Company could obtain and maintain regulatory approvals to market these products, it is possible that:

- The marketing approvals (AMM) for its products are not obtained by the Company quickly enough for it to gain a competitive advantage in the targeted markets.
- The health authorities impose restrictions on use that limit the therapeutic value and potential of the product in these targeted markets.
- The Company is not able to successfully manufacture and market its future products at a price, reimbursement rate or scale allowing it to be profitable (see also Section 4.4: Regulatory risks).
- The future products of the Company lose their competitive advantage and are rendered obsolete by third party development of other equally or more innovative products (see also Section 4.2 of the Reference Document);
- The future products of the Company are not marketable due to third party intellectual property rights claims (see also Section 4.2 of the Reference Document).

The level of acceptance of each Company product by the market will also depend on the following factors:

- The prescribing physicians' perception of the product's therapeutic benefit;
- The possible occurrence of adverse effects once marketing approval is obtained;
- The ease of integration of the product into the current care process;
- The efficient implementation of a scientific publication strategy;
- The support of opinion leaders.

These factors could limit or halt product acceptance by the market which would have a significant material adverse effect on the Company's activities, financial position, results and growth.

#### 4.1.6. Risks related to sales, marketing and distribution resources

#### The Company has limited experience in sales, marketing and distribution.

To date, the Company has not invested in sales, marketing and distribution. The Company will have to develop marketing and sales capability either on its own or with strategic partners.

To market its first product, ERY-ASP/GRASPA®, the Company has entered into a partnership with specialists in the sale of orphan drugs, Orphan Europe (Recordati Group) for Europe and Teva Group for Israel (*see also Section 4.1 and Chapter 22 pertaining to major contracts*).

For other products and jurisdictions, the Company will choose to market its products:

- by its own means, or
- through a marketing partnership.

In the first case, the Company will have to organize its own sales and marketing infrastructure.

In the second case, it is possible that:

- the Company may not be able to enter into a partnership under economically reasonable conditions, or;
- such a partnership is re-evaluated, or;
- the partners may face difficulties or do not implement all means necessary to obtain the expected results as per the agreements concluded with the Company. The partners' budget restrictions or priority given to other development programs, for example, could delay the validation of the potential of the Company's products and their marketing, or;
- conflicts could arise between the Company and some of its partners. In particular, the Company cannot guarantee that any of its partners will not design or seek to implement a commercial activity using a competing technology to that of the Company's (see also the section below on the risks related to competition).

Such events may have a significant material adverse effect on the activity, prospects, results, financial position and growth of the Company.

In all cases, it will consequently have to incur additional costs, mobilize management resources, recruit specific personnel, draw on new competencies and take the time required to put in place the appropriate organization and structure to assist the development of the product in accordance with current legislation and, more generally, optimize its marketing efforts.

# 4.1.7. Risk related to dependence on exclusive distributors of GRASPA®

The marketing of GRASPA® in 38 European countries and in Israel is largely dependent on Orphan Europe (Recordati Group) and Teva Group

#### 4.1.7.1. Teva Group

The Company chose Teva Group as exclusive distributor for GRASPA® in the treatment of ALL in Israel (see also Section 22 of the Reference Document).

A licensing and exclusive distribution agreement was reached between the parties on March 28, 2011.

The marketing success of GRASPA® in Israel therefore depends on marketing and commercial efforts deployed by this distributor as well as its capability to sell the treatments developed by the Company. Any failure on the part of Teva Group would have adverse consequences on the Company. The Company has limited these risks by putting in place a steering committee to follow-up on the development and marketing of products developed by the Company.

#### 4.1.7.2. Orphan Europe (Recordati Group)

The Company has chosen Orphan Europe as the exclusive distributor of GRASPA® in the treatment of ALL and AML for 38 countries in Europe, including the European Union (see also Section 22 of the Reference Document).

The risk resulting from this agreement is the risk of dependence where:

- Orphan Europe is the exclusive distributor of GRASPA® for all of Europe. The success of marketing GRASPA® in Europe therefore depends on regulatory, marketing and commercial efforts deployed by this distributor as well as its capability to sell the treatments developed by the Company. Any failure on the part of Orphan Europe would have adverse consequences on the Company. The Company has limited these risks by putting in place a steering committee to follow-up on the development and marketing of products developed by the Company.
- Payments will be made to the Company in stages: the first payment was made on the date the agreement was signed and others will be made when marketing approval of the treatments developed by the Company is granted and in levels according to the sales achieved by Orphan Europe. Consequently, if the Company does not achieve these objectives, this will have a significant material adverse effect on its activities, financial position, results or growth.
- A breach of agreement initiated by Orphan Europe could incur significant damages. However, the Company could also breach the said agreement in the event of serious misconduct on the part of Orphan Europe, and claim significant damages.
- The non-compliance of guarantees given by the Company could reduce the milestone payments.

# 4.1.8.Risk related to dependency on its most advanced product: ERY-ASP/GRASPA®

ERY-ASP/GRASPA® is the only product under clinical development, in the process of registration in Europe, and that may be placed on the market within the next 5 years.

 $ERY-ASP/GRASPA^{@}$  is, to date, the only company product under clinical development. In fact, the clinical development of  $ERY-ASP/GRASPA^{@}$  is not yet complete.

The development of ERY-ASP/GRASPA® has required and will continue to require the mobilization of numerous Company resources. The future of the Company depends on the successful development of its flagship product: ERY-ASP/GRASPA®. Indeed, if the Company does not successfully develop and market ERY-ASP/GRASPA®, and it does not, in parallel, reduce its dependence on this product, its activities, prospects, financial position, results, and growth could be significantly affected.

The Company considers its dependence on ERY-ASP/GRASPA® to be significant.

#### 4.1.9. Risks related to dependence on key scientific partnerships

#### The loss of certain scientific partnerships could hinder the growth of the Company

The Company depends on partnerships and expects to continue to depend on partnerships, namely with public and private research institutions, to conduct an important part of its discovery activities. If one of these partnerships breached or terminated its agreement with the Company or otherwise failed to work efficiently with the Company, the research, development or marketing of products planned as part of this partnership could be delayed or canceled. In the event a partnership agreement entered into by the Company is terminated or the Company is no longer in a position to renew the partnerships in question under acceptable conditions, the Company's activities may be delayed and even penalized.

#### 4.1.10. Risks of conflict of interest

#### A director or a member of the Scientific Board could be in conflict of interest and harm the Company

Directors (see also Sections 14 and 16 of the Reference Document) are subject to a regulatory and legal framework, including for conflicts of interest. However, no provision can replace the ethical conduct of a director. In addition, in the event of conflict of interest, a director risks losing his/her intellectual independence or objectivity. The occurrence of this risk could have a significant material adverse effect on the activities, financial position, results, reputation or growth of the Company.

Members of the scientific board (see also Section 16 of the Reference Document) contractually declare their interest(s). The Company consequently assesses the risks, but does not verify the truthfulness of these statements. In the event of omission or of false declaration, a member risks losing his/her intellectual independence or objectivity. The occurrence of this risk could have a significant material adverse effect on the activities, financial position, results, reputation or growth of the Company.

#### 4.1.11. Risks of dependence on subcontractors and key raw material suppliers

Access to raw materials and products required to complete clinical trials and to manufacture the Company's products is not guaranteed.

The Company is supplied in:

- Asparaginase (see also Section 22 of the Reference Document);
- Red Blood Cell (RBC) Concentrate.

EFS (Établissement Français du Sang [French national blood service]) is under contract with ERYTECH to supply the Company for its clinical trials in progress and as part of temporary approval for use. Blood collection and distribution is managed in France by EFS, a public institution with a monopoly position, the only blood transfusion authority responsible for meeting the national need in blood products, which it must supply in sufficient quantity with optimal quality. In the event of a major and/or international crisis impacting blood banks and the practice of blood donation, the Company may not be supplied sufficiently with RBC to satisfy clinical trials and/or the market.

The asparaginase market is a closed one with few international players and multiple marketing exclusivity rights between players and geographical areas. ERYTECH is exclusively supplied by a company with which it has signed a long-term contract to supply asparaginase.

# The Company is dependent on its subcontractors.

The Company outsources the following:

- The manufacturing of equipment required to operate its manufacturing process (see also Chapter 22 of the Reference Document);
- The management of its clinical trials to specialized companies (Contract Research Organizations or CROs);
- The completion of certain research and development studies;
- The shipping of its products.

In the event of failure, bankruptcy or shutdown of, or dispute with these subcontractors and/or key suppliers, the Company could then not be able to enter into new agreements with other contractors under commercially acceptable conditions and therefore could not be able to develop, test, manufacture and market its products in the expected time frame and at an acceptable cost. This could have a significant material adverse effect on the activities, financial position, results or growth of the Company.

In addition, the contracts that the Company entered into with these companies normally contain limitation of liability clauses in their favor meaning that the Company will not have recourse to full compensation of potential losses that it would risk incurring in the event of failure.

To reduce its dependence on these companies, the Company's contracts provide for, when possible, an extended notice period before any cancellation or shutdown of activity in order to have sufficient time to find a new qualified provider, if needed, that can meet the same need.

When possible, the Company also has alternate suppliers as part of its purchasing policy, and undergoes follow-up with its suppliers through audits managed by the Company Quality Assurance department. In addition, the Company suppliers are generally subjected to precise specifications. However, the Company cannot guarantee these suppliers will follow the Company's directives.

If third-party supplied and manufactured products do not comply with regulatory standards, penalties may be imposed on the Company. These penalties may include fines, injunctions, refusal by regulatory authorities to pursue our trials, delays, suspension or withdrawal of approvals, seizure or recall of our products and criminal prosecution, all measures which could have a considerable negative impact on the Company.

In the event the Company must change key suppliers or subcontractors, it will be asked to show that the change has had no impact on the quality of the manufactured products. This verification could be costly, time consuming and could require the attention of the most qualified personnel. In order to show absence of impact due to the change, the Company could be required to conduct animal studies or other clinical studies. Some changes are subject to approval by regulatory authorities. If the change is refused, the Company could be constrained in finding another supplier/subcontractor which could delay the production, development or marketing of products and increase the manufacturing costs of these products.

# 4.1.12. Risks relating to health, safety, and the environment

#### The Company is exposed to risks related to hazardous substance handling

The Company's research and development activities exposes it to chemical and biological risks and forces it to take and follow preventive measures according to current legislation.

During company preclinical research and development programs and tests, the Company uses hazardous materials, such as compressed gases, and biological material, blood from donors, but also from patients (see also the section Risk related to the particular nature of products from technology in the Reference Document), solvents and other chemical products that could be genotoxic.

There are therefore health risks related to the handling of these hazardous materials by the Company employees and/or subcontractors. Consequently, the Company is subject to environmental and safety legislation and regulations governing use, storage, handling, emission and hazardous materials disposal, including of chemical and biological products. While the Company considers that the safety measures meet the standards set out by current legislation and regulations and allow its employees and subcontractors to work under good conditions, the risk of accidental contamination or of occupational diseases related to hazardous material handling cannot be completely eliminated.

Although the Company doesn't identify major environmental risks related to its activity, as well as in the event of an accident, the company could be held responsible for all resulting damages and the incurred liability could exceed the limits of the insurances the Company subscribes to and even not be covered by them.

Moreover, conforming to environmental, health and safety regulations imposes on the Company additional costs, and it could have to incur significant expenses to conform to future environmental legislation and regulations.

# 4.2. Strategic risks

#### 4.2.1. Risk related to key personnel

# The Company may lose key employees and not be able to attract new qualified personnel.

The Company's success depends in large part on the actions and efforts by its executive officers and personnel in key positions. In the event that the Company is not able to retain its executive officers and scientists, its research and development (preclinical as well as clinical) could be delayed, and the implementation of its strategy could be negatively affected. As the Company progresses in its programs and extends the scope of its activities, it could have to recruit new employees with competencies in areas such as clinical trials, regulatory matters, reimbursement procedures, sales and marketing. As part of recruiting and retaining qualified personnel, the Company is confronted with intense competition from other companies in the sector, universities, public and private research institutions, as well as other organizations. Under these circumstances, the Company cannot guarantee its ability to recruit and/or retain its qualified personnel under conditions that are acceptable from an economic point of view. The delay in recruiting or the loss of a key employee could prevent the Company from reaching its overall objectives and consequently have a negative impact on its activities, results, financial position and its prospects.

Moreover, the loss or disability of one or more members of the board could lead to significant negative effects on activities, financial position and overall growth of the Company. While the Company benefits from a "*Key Persons*" insurance policy (described in Section 0 of the Reference Document) for Gil Beyen and Yann Godfrin, this policy could prove insufficient to compensate for any damages suffered.

# 4.2.2.Risks related to key objectives not being reached

The Company may not reach the objectives it has committed to as part of certain partnerships and partnership agreements.

The Company is bound to academic and commercial partnerships through financial agreements for research programs or by commercial development agreements. These agreements are contingent upon royalties, public funds, achievement of commercial, industrial, proof of concept or other objectives.

Consequently, if the Company does not reach these objectives, this will have a significant material adverse effect on its activities, financial position, results or growth.

#### 4.2.3. Risks related to the management of internal growth

### The growth of the Company will depend on its ability to manage its growth.

As part of its growth strategy, the Company will need to recruit additional personnel and develop its operational capabilities, which could excessively mobilize its internal resources. To do so, the Company will need:

- To create, generate, motivate and retain an increasing number of employees;
- To anticipate the expenses related to this growth and associated financing needs;
- To increase or transfer its production division and its premises;
- To forecast precisely demand for Company products and revenues that could be generated; and
- To develop information systems.

If the Company does not manage its growth or if it encounters unexpected difficulties during its growth, this could have a significant material adverse effect on its activities, financial situation, results or growth.

#### 4.2.4. Risks related to competition

Direct or indirect competitive solutions could halt the growth of the Company and render its products obsolete.

The markets in which the Company is involved in are well defined and very competitive and progress rapidly. The Company competes with larger companies that have more industrial and commercial experience and access to distinctly superior resources.

Consequently, the Company cannot guarantee that its drugs will:

- reach the target markets more rapidly than that of its competitors;
- be competitive compared to other developed products or products under development that turn out to be safer, more effective or less expensive;
- adapt rapidly enough to new emerging and developing technologies and scientific advancements;
- be accepted by medical centers, doctors and patients over existing treatments;
- be effectively competitive compared to other products for treating the same indications.

Finally, the Company cannot guarantee that its partners and/or employees will not choose, in the more or less long term, to join or work for competitors.

Such events could have a significant material adverse effect on the activity, results, financial position and growth prospects of the Company.

It is likely that new developments will continue in the pharmaceutical industry and in public and private research institutions. As well as developing safer, more effective and less expensive products than those developed by the Company, its competitors could manufacture and market their products under better conditions. As such, the Company cannot exclude the possibility that companies and other public and private organizations that are currently competing in the same space merge or enter into partnerships or other types of alliances, consequently becoming more aggressive competitors. In addition, rapid technological developments by these competitors could render the Company's drugs or its potential products obsolete before being able to recuperate the research, development and marketing costs for its products.

To the Company's knowledge, new forms of asparaginase are under development as well as other products that could be used in the treatment of acute leukemia (*see also Section 6.4, The L-asparaginase market*).

Even if the Company's products are marketed successfully, market recognition could be delayed and the Company could not be able to offset its costs with its potential revenues. In order to gain market acceptance for its products over existing ones, the Company will have to commit significant marketing as well as investment efforts. To date, the Company has not undertaken significant marketing activity and has few financial and human resources dedicated to this purpose.

#### 4.2.5. Risks related to confidentiality of Company information and knowledge

#### The Company may not be able to protect the confidentiality of its information and/or knowledge.

As part of partnership agreements, current and future, between the Company and natural persons as well as other public or private entities, subcontractors or third parties, information and/or products could be provided in order to conduct tests or other services. In these instances, the Company requires the signing of a confidentiality agreement. In fact, the proprietary non patented and/or non patentable technology, processes, knowledge and data are considered trade secrets that the Company attempts to protect through such confidentiality agreements.

It cannot be guaranteed that confidentiality agreements are not infringed or ensure the sought after protection, that the Company has appropriate solutions against such infringements, or that its trade secrets are not disclosed to or developed by its competitors.

More specifically, the Company has no control over the conditions under which third parties, with which it has agreements, have recourse themselves to third parties, and protect its confidential information.

The occurrence of this risk could have a significant material adverse effect on the activity, prospects, financial position, results and growth of the Company.

#### 4.2.6. Risks related to the use of information systems

#### ERYTECH could be the target of cyber attacks

In order to safeguard the information systems and their users, the Company standardized rules governing their use (information technology charter, internal control procedures) to outline the main precautions and guidelines of use that each user must follow when using Company information systems.

However, the Company cannot guarantee that the users will follow these rules and that these rules are sufficient to avoid cyber attacks, loss of sensitive data, discontinuity of operations and claims against the Company. These risks, should they occur, could have a material adverse effect on the activities, financial position, results, reputation or growth of the Company.

#### 4.2.7. Risk related to industrial espionage

#### ERYTECH could fall prey to industrial espionage

Given its highly technological and innovative activity and advanced research and development projects that could confer it a competitive advantage in its market, the Company is exposed to an industrial espionage risk.

Disclosure or theft of its scientific research content would deprive the Company of potential revenue sources and affect its activity.

Such a situation, should it occur, is susceptible to have a negative impact on the Company, its activity, financial position, results or growth.

# 4.2.8. Specific risks related to the use of technologies owned by third parties

# The Company cannot protect the intellectual property of technologies owned by third parties and that it uses

The Company has entered into agreements with researchers working for public and/or private entities (*see Section 22 of the Reference Document*). The agreements entered into with these entities contain specifications pertaining to intellectual property rights and confidentiality commitments.

It cannot be guaranteed that these agreements will ensure the protection sought or are followed by the Company's co-contracting parties. The Company also relies on the commercial licensing terms which it will obtain, if applicable, for the results of the experiments covered by such agreements.

Finally, the Company cannot guarantee that entities with which it has agreements have at their disposal all the rights to use the technologies and that they will be able to grant the Company licenses for such rights.

When the Company is granted a patent license from third parties (see Section 22 of the Reference Document), the Company undertakes to comply with certain conditions to maintain its rights on the patent. In addition, the Company relies on the patent being protected and enforced.

The conditions for maintaining rights on the technology could include elements such as carrying out development efforts to transform the patent into a commercial product, payment of licensing fees while carrying out predefined steps and payment of annual licensing fees based on sales revenue generated as a result of the patent.

Any failure on the part of the Company could lead to loss of patent exclusivity. If the Company loses its rights to the patent obtained under license or if it cannot obtain new similar rights under reasonable terms, this could constitute an obstacle to development, manufacture and sale of its products.

#### 4.2.9. Risks related to intellectual property

The protection offered by patents and other intellectual property rights is uncertain. The Company may not be able to maintain adequate protection of its intellectual property rights and thereby lose its technological and competitive advantage. Part of the Company's activity could depend on or infringe upon patents and/or other intellectual property rights owned by third parties. The exclusive nature conferred by intellectual property rights could be circumvented by the Company's third parties/competitors.

The Company's success depends on its ability to obtain, maintain and enforce its patents and other intellectual property rights. If one or more brands or patents covering a technology, the manufacturing process or a product were to be invalidated or found unenforceable, the development and marketing of such a technology or product could be directly affected or interrupted.

In the pharmaceutical industry in which the Company operates, patent law varies according to the country and is in constant evolution. There is therefore much uncertainty in this area. Consequently, the Company cannot guarantee that:

- its patents will be the basis for commercially viable products;
- its pending patent applications will lead to patent grants;
- its patent applications, even if they are granted, will not be challenged, invalidated or found unenforceable;
- the scope of protection offered by patents will be sufficient to protect the Company from its competitors;
- the products won't infringe on third party intellectual property rights or patents and that it won't be forced to defend itself against such accusations by third parties;
- third parties will not be granted patents or file patent applications for the Company's products before the Company is granted such patents or files such applications; or
- third parties will not be granted or will not file patent applications or use any other intellectual property rights that, even if they don't infringe on those of the Company, limit its growth.

Intellectual property litigation is often long, costly and complex. Some of the Company's competitors have access to greater resources and could be more able to conduct such proceedings. A court judgment against the Company could seriously affect its ability to continue its activity and, more particularly, could force the Company:

- to cease the sale or use of its products;
- to acquire the right to use the intellectual property licensing rights under costly terms; or
- to change the design, delay the launch or even abandon some of its products.

Patent applications in Europe and in the United States are not generally published until 18 months after the priority date on the application and, moreover, in the United States, some applications are not published before the patent is granted. In addition, in the United States, if the legislation has changed, the notion of the right to the patent for all patent applications before March 2013 is related to the notion of first-to-invent which is based on the date the invention was conceived, while in other countries, the right to the patent is attributed to the first to file the patent application. The new legislation in the United States provides that the right henceforth belongs to the first inventor to file under the new rules. As a result, the Company cannot guarantee that third parties will not be in a position to be considered as first inventor or first inventor to file an invention covered by its patents and its pending patent applications in the United States. In such circumstances, the Company could have to enter into licensing agreements with third parties (provided that these licenses are available), modify some of its activities or manufacturing processes, or develop or acquire different technologies.

The Company is confronted with similar risks for its trademarks.

The Company also relies on its technology, manufacturing processes, knowledge and non-patented confidential data that it protects through confidentiality agreements signed by its employees, consultants and some of its subcontractors. The Company cannot guarantee that these agreements will always be followed, that the Company has recourse in the event of a breach of such agreements or that the confidential information in question will not be disclosed to third parties or independently developed by competitors. The Company also cannot guarantee that, despite the implementation of measures, a consultant or employee will not claim rights on an invention discovered as part of a Company project.

The occurrence of any one of these situations regarding any patent or intellectual property right of the Company could have a significant negative effect on the activities, financial position, results or development of the Company.

#### 4.3. Legal risks

The liability of the Company and/or its subsidiary may be incurred where any harm is caused by one of its products.

The use or misuse of the Company's products during feasibility studies and clinical trials, as well as the sale, promotion, or use of future related products risk exposing the Company and/or its subsidiary to liability actions.

Complaints could be filed and legal action taken against the Company and/or its subsidiary by patients, regulatory authorities, pharmaceutical companies, or other third parties using or selling the Company's products. The Company cannot guarantee that its current insurance policies are sufficient to protect the Company and/or its subsidiary against such proceedings. If the Company and/or its subsidiary, its subcontractors, or its other partners are found liable (even in the case of proceedings that do not lead to conviction) or if it is impossible to obtain or maintain appropriate insurance policies at an acceptable price or to obtain other protection, this could significantly affect the development and, in the future, the marketing of the Company's products and have a significant negative effect on the activities, financial position, results, reputation, and growth of the Company.

#### 4.4. Regulatory risks

#### 4.4.1. Risks related to the regulatory environment

# Obtaining prior approvals for marketing is uncertain.

At this time, no Company product, including its most advanced product, ERY-ASP/GRASPA®, has received marketing approval from any regulatory authority. The Company cannot be assured that it will receive the necessary approvals to market any of its products. The Company as well as its products are subject to extensive and very stringent legislation and regulations and to controls by regulatory authorities such as the Agence Nationale de Sécurite du Médicament et des Produits de Santé [National Agency for the Safety of Drug and Healthcare Products] (ANSM) in France, the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe. The applicable regulatory requirements are known, but are subject to change. Any failure to comply with these requirements can lead to sanctions including fines, rulings, civil penalties, refusal of marketing approval, delays, suspension or withdrawal of approvals, seizure or recall of products, restriction of use and legal proceedings.

To obtain marketing approval for any of its products, the Company must show, through many long and costly clinical trials with uncertain outcomes, that use of its products is safe and effective in humans. If the Company was not in a position to follow its development schedule or if it cannot conduct clinical trials for its products within expected time limits, its activities, financial position, results and growth could be significantly negatively affected.

The Company's ability to obtain marketing approval for its products will depend on many factors, including the following:

- the opportunity to continue the development of its products that, with the exception of ERY-ASP/GRASPA®, are currently in early clinical stages, or to move products currently under pre-clinical development into a clinical stage;
- the Company alone or with its potential partners is able to successfully conduct clinical trials within stated time limits and with the resources and under the conditions originally outlined;
- the Company's trials show the safety and efficacy of its products as well as a positive risk/benefit for the patient;

- the Company obtains clinical results that are more promising that those of its competitors;
- the results of clinical trials, although positive, do not meet the applicable regulatory criteria;
- the Company cannot submit to the regulatory authority of a jurisdiction the results of clinical trials conducted in another jurisdiction or for other candidate drugs;
- the Company is forced to conduct additional clinical trials requested by regulatory authorities;
- the Company's competitors announce clinical trial results that causes the amendment of evaluation criteria used by relevant regulatory authorities;
- the ability of the Company to obtain the clinical trial approvals in relevant jurisdictions within the timelines outlined in the development plan; and:
- the ability of the Company to respond (notably within the required timelines) to questions by the competent authorities during the marketing approval process.

In addition, the Company's products that have already been approved could prove unsafe and be withdrawn from the market, or produce effects over time other than those expected, which could limit or render impossible their commercialization.

To obtain marketing approval for its products in a given jurisdiction, the Company must show that they meet the quality, safety and efficacy criteria defined by the relevant authorities for the intended indications.

If the Company is not granted marketing approval of a product in a given jurisdiction, it will not be able to sell the product in question for the intended indication in that jurisdiction. In addition, a refusal of marketing approval in one of the Company's key jurisdictions could have a negative influence on the authority in charge of granting marketing approvals in another key jurisdiction.

As such, if the Company is not granted marketing approval for its products in a given jurisdiction, this will have a significant material adverse effect on its activities, financial position, results or growth.

# 4.4.2. Risks related to regulations for the collection of human samples

# The collection of human samples is strictly regulated.

ERYTECH and its partners comply with the regulations on the collection of human samples. These regulations require, in some cases, patient consent, confidentiality of his/her identity, approval of clinical tests by (hospital) ethics boards and/or other supervisory boards and, in some cases, grant of certain regulatory approvals.

If ERYTECH and its partners failed in its obligation to comply with these regulations or if the regulations in question were to be amended unfavorably, research projects and activities and the growth at ERYTECH as well as its related schedule could be penalized.

#### 4.4.3. Risks related to changes in health care reimbursement policies

The conditions for determining the reimbursement price and rate of Company products constitute a key factor in the commercial success of the Company.

The commercial success of the Company will depend, in part, on the level of reimbursement of its products by public health associations, private insurers and managed healthcare organizations or any other organization.

No guarantee exists relative to the terms of reimbursement which will be applied on the Company's products or if the reimbursement will be sufficient.

If the Company's products are not granted a reasonable level of reimbursement, their market acceptance could be negatively affected.

Moreover, the legislative and regulatory measures to control or reduce health costs or to reform healthcare programs could mean lower sale prices for Company tests and products. A low price for the relevant products will limit the Company's ability to generate sales revenues in line with expectations, as currently estimated by the Company.

#### 4.4.4.Risks related to the regulatory status of the Company

#### Maintenance of the status required to manufacture and market Company products is uncertain.

To date, the Company holds the designation of "Pharmaceutical Manufacturing Facility" and of "Pharmaceutical Operating Facility." The Company cannot be assured that it or its partners will retain these statuses to manufacture and market any of its products. The Company as well as its products are subject to extensive and very stringent legislation and regulations and to controls from regulatory authorities such as the Agence Nationale de Sécurite du Médicament et des produits de santé (ANSM), the FDA, and the EMA. The applicable regulatory requirements are known, but are subject to change. The Company must show that it meets the quality and safety criteria defined by relevant authorities.

Any failure to comply with these requirements can lead to sanctions including fines, rulings, civil penalties, refusal of marketing approval, delays, suspension or withdrawal of approvals, seizure or recall of products, restriction of use and legal proceedings.

If the Company or its partners do not maintain these statuses, it or they will not be able to manufacture and/or sell the product in question in the jurisdiction concerned; this would have a significant material adverse effect on its activities, financial position, results or growth.

#### 4.5. Financial risks

#### 4.5.1. Risks related to historical and forecast losses

#### The Group has a history of operating losses, losses that could persist.

The Group has recorded accounting and fiscal losses since the start of its operations in 2004. At December 31, 2014, accumulated losses totaled 37.3 million Euros according to IFRS accounting standards. These operational losses are principally accounted to investments in research expenditures and development costs for conducting preclinical studies and clinical trials. The Group anticipates substantial new operating losses for the coming years as its research and development activities, pre-clinical studies, and clinical trials are pursued. At the time of filing of this Reference Document, neither ERY-ASP/GRASPA® nor any other of its products have generated sales revenue.

The Group's profitability will depend on its ability to successfully develop, produce, and market its products. The Group's own financial resources will come, in the near future, from the first sales of ERY-ASP/GRASPA® and from payments made by partners within the context of established distribution or licensing agreements related to the development of new products and/or use of the research platform.

Additional funding through public subsidies or from private associations are also possible. The Group does not anticipate revenue from the sale of products other than ERY-ASP/GRASPA® in the medium term. In the event of the absence or delay of marketing approval for this product, the Company may not sell any product in the short, medium or long term.

Refer to Section 20 of this Reference Document.

#### 4.5.2. Risks related uncertain additional funding

# The Group could need to strengthen its own funds or to make recourse to additional funding to ensure its growth.

As the final phases of product development in the biotechnology and biopharmaceutical industry require increasing investments, the financial needs of the Group will continue to increase as the Group invests in developing existing and new products. However, the Group considers that its internal financing capacities will be sufficient to cover its financial needs in the medium term, that is until 2016, at which point revenue from the Group will be sufficient to provide for its activities. These financial needs, other than structural costs, concern clinical trials that the Group has planned to conduct (please refer to Sections 6.5, 6.7, and 6.8) as well as expenses involved in research programs assisted by Oséo (please refer to Section 0). However, the Group may be required to raise additional funds sooner, by reason of various factors, such as:

- unexpected opportunities to develop new promising products or acquire technologies or other activities;
- higher costs and slower progress than anticipated by the Group for the development of new products and for obtaining the indispensable marketing approvals;
- costs incurred by the Group to file, maintain, and enforce patents and other intellectual property rights;
- costs incurred by the Group to respond to technological and market developments, to enter into and maintain partnership agreements, and to ensure the effective manufacturing and marketing of its products; and
- the inability of the Group to establish partnership agreements within the anticipated timelines.

The Group had a free cash flow of 37 million Euros at the end of December 2014, which will cover its needs for more than one year.

#### 4.5.3. Risk of major financial crisis

The Group could be linked to major events, in the background and external to its activity or existence. A systemic financial risk with a non negligible probability of major disruption can cause serious deterioration - if not paralysis - of the financial system as a whole for an entire economic sector, over a vast geographical area or even on a global scale.

A crisis of this magnitude would have a significant negative effect on its financial position, results, and growth.

#### 4.5.4. Risk of dilution

As part of its incentive policy for its executive officers, directors, and employees, the Group has issued or allocated share subscription warrants. In the future, the Group could proceed with the issue or allocation of new financial instruments giving access to Group capital.

Any additional allocation or issue of shares or other financial instruments giving access to capital would lead to potentially significant dilution for the Group's shareholders (See Section 21.1.5 herein).

#### 4.6. Social and fiscal risks

#### 4.6.1. Risks related to research tax credit

The Group benefits from public funding to which all innovative companies have access, in particular the research tax credit (crédit d'impôt-recherche - "CIR"). The research expenditures that are eligible for the

research tax credit include wages and salaries, consumer goods, services subcontracted to approved research organizations (public or private) and intellectual property costs.

The claim on the national treasury that the research tax credit represents is submitted during the first quarter of the next financial year.

Only the research projects (and related expenses) that meet the eligibility criteria for the research tax credit in accordance with provisions of Article 244c of the General Tax Code are entitled to the research tax credit scheme.

Due to its very nature, its corporate purpose, and its pipeline of pre-clinical and clinical projects, the Group is confident in its eligibility for the research tax credit program. Moreover, in 2013, the Group's authorization from the French Ministry of Research and Higher Education was renewed.

Lastly, the Group has been audited by the tax authorities with respect to the research tax credit for 2010, 2011, and 2012, the risk being thus extinguished for these years, as well as for previous years, due to lapse of the limitation period.

The Group considers that any financial consequences of future tax audits could jeopardize and/or halt the growth of the Group.

#### 4.6.2. Risks related to tax fluctuations for medicines

The deficit of certain national drug cost-sharing and coverage programs has lead to and could lead to governments in certain countries to impose taxes on drug company activities. The introduction of such taxes or their increase could have a negative impact on the activities and profitability of the Group.

#### 4.6.3. Risks related to changes in fiscal or labor legislation

There are multiple sources of fiscal risks. If the risk of deliberate violation of a tax law (legal or illegality risk) is ruled out, the risks could be current or long term; they could originate externally or internally, and could be related to persons, operating processes, technology, or business tax management procedures.

Taxation also constitutes an aspect of market risk as an element of cost and pricing.

# US risk

The French – US tax authorities and/or tax agreements could jeopardize the agreements between the Group and its subsidiary. The Group, however, is not specifically concerned by this risk, in the absence of any special new tax aspects existing at the present time.

#### Transaction risk

Each transaction is met with taxation. The more a transaction is complex, the more fiscal uncertainty it could generate and, consequently, fiscal risks. The more the transaction is uncommon or unusual, the more it exposes to specific risks.

The Group, however, is currently not specifically concerned by this risk with regard to the present situation.

#### Situation risk

Fiscal risk depends on its impact and its probability of occurrence. The probability of occurrence depends on the action or reaction of tax administration in response to a situation. As such, this probability is high when a company finds itself in certain situations attracting in its own right a tax audit such as a company generating VAT (Value-Added Tax) and CIT tax credits namely during the first requests for restitution.

The Group, however, is not specifically concerned by this risk, in the absence of any special new tax aspects existing at the present time.

#### Operational risk

Generally, repetitive operations do not tolerate uncertainty since uncertainty that relies on common activities can have consequences in terms of high risks. Operational risks involve all departments and persons concerned with tax aspects, and not only its corporate tax department (supply, transportation, inventory records, personnel, treasury and finances, commercial, invoicing, delivery, shipping, investment, accounting, etc.). The Group does not consider itself to be concerned by this risk, as it monitors the proper training of and documentation by persons involved and good communication between the parties involved in operations having a direct fiscal impact.

#### Risks related to retroactivity of the law

A good fiscal compliance strategy involves staying informed and taking into account the administrative doctrine or, even better, obtaining authorization or approval for fiscal administration on the chosen approach for the resolution of a tax problem. The risk is even greater since fiscal as well as social legislation could be retroactive and incur additional costs for the Group (for example, tax aspects relating to the BSPCEs).

The Group does not consider that its current tax situation is particularly subject to a risk of assessed back taxes.

#### Accounting risks

Accounting, as a consolidation, synthesis and tax base instrument, constitutes the main foundation for tax audits and, consequently, for tax litigation. Accounting also embodies the choices of the directors that have a fiscal consequence (allocation theory, tax credit, choice of accounting policies, etc...). Accounting therefore appears to be the tool for formalizing options deemed to offer business opportunities. Efficient processes for entry and allocation, analysis and cost accounting and accounting-tax alignment are to reduce fiscal accounting risks. The Group does not consider that its accounting structure bears any risk at the present time, aside from the work performed by the audit committee.

#### Management risks

Few companies document and formalize their management of fiscal risk. In this case, the main risk lies in the fact that fiscal risk management is the responsibility of the executive officers in charge of it. If these persons leave the Company, there is the risk of a difficult succession and especially loss of the ability to seize opportunities during the search for successors. Recourse to external advisers as well as internal expertise offer a certain level of stability and continuity and, at least, assistance for an easier succession.

However, the Group is not specifically concerned by this risk at the present time, in light of the stability of its management and its external advisors.

#### Reputation risk

A serious fiscal failure can affect the reputation of a company, its executive officers, its personnel and its auditors.

Given the aforementioned aspects of risk exposure, the Group does not believe that it is exposed to any particular risk to its reputation at the present time.

#### 4.7. Market risks

#### 4.7.1.Liquidity risk

The Group has been structurally loss-generating since its creation. The net cash flows associated with the Group's operating activities were respectively -6.5 million Euros at December 31, 2013 and -7.2 million Euros at December 31, 2014.

Historically, the Group has financed its growth by strengthening its shareholders' equity in the form of capital increases and the issue of convertible bonds. The increase in capital as a result of its stock market listing in May 2013 and the funds raised in October 2014 enable the Group to ensure its business continuity over a number of years. Likewise, the 2015 budget voted by the Board of Directors in January 2015 provides for an outlook over more than one year of activity.

The remaining contractual maturities of financial liabilities are broken down as follows (including interest payments):

in Euros		2014				
	Book value	Contra	Contractual cash flows			
	Dook value	Total	Less than 1	1 to 5 years		
Loans						
Conditional advances	549,161	(580,107)	(257,500)	(322,607)		
Financial debts related to						
lease agreements	220,376	(230,183)	(80,702)	(149,481)		
Convertible bonds						
Bank overdrafts						
Trade payables and related						
accounts	2,084,546	(2,084,546)	(2,084,546)			
Total	2,854,083	(2,894,836)	(2,422,748)	(472,088)		

in Euros		2013				
	Book value	Contractual cash flows				
	Dook value	Total	Less than 1	1 to 5 years		
Loans	15,000	(15,499)	(15,499)	-		
Conditional advances	693,669	(763,607)	(183,500)	(580,107)		
Debt associated with leases						
Convertible bonds	303,217	(319,826)	(89,643)	(230,183)		
Bank overdrafts	-	-	-	-		
Trade payables and related	-	-	-	-		
accounts						
	1,421,436	(1,421,436)	(1,421,436)			
Total	2,433,322	(2,520,368)	(1,710,078)	(810,290)		

The Company has conducted a specific review of its liquidity risk and considers that it is capable of meeting its upcoming payment deadlines. The net cash available at March 31, 2015 totals 33.5 million Euros.

# 4.7.2. Exchange rate risk

The Group uses the Euro as its reference currency within the context of its disclosures and financial communications. However, a significant portion, in the amount of 10% of its operating expenses, is denominated in US dollars (agency office in Philadelphia, collaborations relating to the production of clinical batches with the American Red Cross, business development consultants, consultants for the development of clinical trials in the United States, and various collaborations around tests and clinical projects in the United States).

To date, the Group has not opted to use active hedging techniques, and has not made recourse to derivative instruments to this end. Unfavorable exchange rate fluctuations between the Euro and the Dollar that are difficult to predict could affect the financial position of the Company.

This dependency will increase, as the Group will perform clinical trials in the USA and, in the longer term, sell on this market. The Group will opt to use exchange rate hedging techniques.

Expenses in US Dollars totaled \$949,232 during the 2014 financial year. The counter-values recorded in the accounts totaled  $\[Epsilon]$ 714,807 in relation to the receipt of invoices and price fluctuations. This represents an average annual rate of \$1.328 per  $\[Epsilon]$ 1 (\$1.324/ $\[Epsilon]$ 6 on average in 2013).

However, the EUR/USD rate fell considerably at the period end, reaching \$1.2141 per €1 at December 31, 2014.

The Group purchased 1 million dollars at the rate of \$1.2197 per €1 during December 2014.

The exchange rate differences are not significant for the periods presented.

#### 4.7.3.Interest rate risk

The Group's exposure to interest rate risk primarily involves cash equivalents and securities.

These are only comprised of term accounts. Interest rate variations have a direct impact on the remuneration rate of these investments at time of renewal, as well as on cash flow. These financial instruments are convertible at maturity of at most one month.

During the course of 2014, a variation of 10 basis points in interest rate would not have had a significant effect on the year's results.

# 4.8. Volatility risk

The price of the Company's shares could be affected by significant volatility. Aside from occurrence of the risks described in this section, the market price of the Company's shares could be significantly affected by a number of factors that would impact the Group, its competitors, or general economic conditions and the biotechnology sector.

The following factors could have a significant influence on the share price:

- negative changes in market conditions related to the Group's sector of activity;
- announcements by the Group, its competitors, or other companies with similar activities and/or announcements regarding the biotechnology market, including those concerning financial and operational performance or the scientific results of these companies;
- changes in the forecasts or outlook for the Group or its competitors from one period to another;
- changes in patents or intellectual property rights of the Group or those of its competitors;
- changes in international political, economic, and monetary context and notably unfavorable changes in the regulatory environment applicable in the countries or to the markets specific to the Group's sector of activity or to the Group itself;
- announcements regarding changes in Group's ownership structure;
- announcements regarding changes in the Group's management team; and
- announcements regarding the Group's asset perimeter (acquisitions, disposals, etc...).

Furthermore, stock markets have seen significant fluctuations that have not always been due to the results and outlook of the companies whose shares are traded on them. Such market fluctuations as well as economic environment could therefore also significantly affect the market price of the Company's shares.

# 4.9. Insurance and risk coverage

The Company has implemented a coverage policy of main insurable risks that it considers compatible with its cash flow requirements and activities.

The total premiums paid for all the Company's insurance policies amounted to 45,818 Euros for the financial year ended December 31, 2014 and 79,893 Euros for the financial year ended December 31, 2013.

The Company has subscribed to several insurance policies, including the following:

Policy	Insurer	Risks covered	Main characteristics	Expiry
Key person	April	Death, permanent total disability for Yann Godfrin Death for Gil Beyen.	Limit of liability of €500,000 per person.	Renewable by tacit agreement on January 1st of every year.
Premises and liability	Chubb	Insured activities: - Development of a new generation of drugs for serious diseases, orphan indications or patient sub-populations in areas	All damages including physical injury: €7,500,000 per claim with sub-limits outlined in the contract	Renewable by tacit agreement on January 1st of every year.
		of hematology, cancer and metabolic diseases.  - Encapsulation of therapeutic molecules in red blood cells  - Development of a therapeutic pipeline of innovative solutions based on its proprietary technology and its expertise in the physical properties of erythrocytes	Criminal Defense - Recourse: €30,000 per dispute	
Property and Casualty Business	COVEA RISKS	Address of risk: 60 Avenue Rockefeller 69008 Lyon	Fire and related risks Water damage: Equipment - furniture - personal belongings: guaranteed up to 2,016,198 Euros	Renewable by tacit agreement on January 1st of every year.
			Natural disasters Electrical damage Recovery by neighbors and third parties Broken glass Theft Equipment breakdown Computer and office automation all risks	
			Other events cover Automatic insurance on investment Resulting costs and losses Business interruption/material damage, equipment breakdown and electrical damage Inaccessibility	
Civil Liability for Executive Officers and	Chubb	Civil liability for executive officers.	Extensions: Claim of misconduct Claim against legal entity Crisis management costs	Renewable by tacit agreement on January 1st of every year.

Policy	Insurer	Risks covered	Main characteristics	Expiry
Corporate Officers			Maximum aggregate amount per insurance period: 5,000,000 euros with sub-limits set out in contract	
			Territory covered: Global coverage	
Transported Goods	Chubb	Merchandise consists of:  - ERY-ASP/GRASPA®  - ENHOXY®  Guaranteed worldwide Excluding shipments to/from the following countries: Afghanistan, Birma, Irak, Iran, Cuba, North Korea, Sudan and any country at war	Ground and air transport  Additional guarantees: Packing and packaging Loading and unloading Undelivered packages Merchandise return and reshipment Controlled temperature Disposal	Renewable by tacit agreement on January 1st of every year.
			Exclusions: rust, oxidation, various scratches, disturbed content	
Automobile	COVEA FLEET	All employees on assignments for a total of 3,000 km maximum per year.	Automobile liability Criminal defense and claim All accidental damages, theft and attempted theft, fire Broken glass Luggage and personal belongings Physical injury - driver	Renewable by tacit agreement on January 1st of every year.
Business travel	Chubb	Travel by 5 employees on behalf of the subscriber.	Personal injury Assistance Business travel Personal safety	Renewable by tacit agreement on January 1st of every year.
Clinical trials	HDI Gerling	Covers liability of the Company as a sponsor of biomedical research in the United States. The amount of guarantees subscribed for the trials depends on the number of trials, their location and the number of patients involved in the trial.	Fixed amount per patient and per protocol based on each clinical trial program.	_
Clinical trials	CHUBB	Covers liability of the Company as a sponsor of biomedical research in the United States	Maximum aggregate amount per insurance period: \$10,000,000	

Given that the Company has no sales revenues, it has not yet subscribed to insurance policies covering risks of operating losses.

The Company cannot guarantee that it will always be in a position to maintain, and in some cases, obtain similar insurance coverage at an acceptable price, which could lead it to accept more expensive insurance policies and to assume a higher level of risk particularly as the Company grows. Moreover, the occurrence of one or more important disasters, even if they are covered by these insurance policies, could seriously affect the activity of the Company and its financial position due to the interruption of its activities, which could result

from such a disaster, reimbursement delays from the insurance companies in the event policy limits are exceeded and finally due to increased premiums that would result.

The occurrence of one or more of these risks could have a significant material adverse effect on the activity, outlook, financial position, results or growth of the Company.

Given the Company's outlook, namely current and future activities in the United States, as described in Section 6.7 of the Reference Document, the Company anticipates that its insurance premiums could increase while remaining insignificant compared to its research and development expenses, its annual losses and the value of its assets.

# 4.10. Exceptional events and litigation

In the course of its normal activities, the Group is not involved in any legal proceedings.

To the Group's knowledge, there is no litigation or arbitration or pre-litigation having recently had or that will have in the future a significant influence on the financial position, results, activity and capital of the Group.

## 5. INFORMATION ABOUT THE COMPANY

# 5.1. History and evolution of the Company

# 5.1.1. Company name, trade name, and headquarters of the Company

The name of the Company is ERYTECH Pharma S.A.

The Company's headquarters are located at Bâtiment Adénine, 60 Avenue Rockefeller, 69008 LYON.

The Company's telephone number is 04.78.74.44.38.

The Company's website can be found at the following address: www.ERYTECH.com.

# 5.1.2.Location and registration number of the Company

The Company is registered with the Lyon Trade and Companies Register under number 479 560 013.

The Company's professional activity code (APE) is 7211Z and its computerized identification code (SIRET) is 479560013000 19.

## 5.1.3. Date of establishment, duration, and transformation of the Company

ERYTECH was established in the form of a French simplified limited company, pursuant to a private deed stipulated in Lyon on October 26, 2004. ERYTECH was transformed into a public limited company with an executive board and a supervisory board following a decision by the Company's extraordinary General Meeting of September 29, 2005. At the General Meeting of April 2, 2013 the Company amended its mode of governance, so as to implement a board of directors instead of the executive board and the supervisory board, subject to the condition precedent of the Company's initial public offering.

The term of the Company was set at 99 years from the date of its registration with the Trade and Companies Register, except in case of early dissolution or extension.

# 5.1.4.Legal form of the Company and applicable laws

The Company is a public limited company subject to the provisions of the French Code of Commerce.

#### 5.1.5. Financial year

The financial year has a duration of 12 months, and begins on January 1 and ends on December 31 of each year.

## **5.1.6. History**

ERYTECH's two co-founders, Dr. Yann Godfrin (Biomedical Engineer from the University of Compiègne, Doctorate in Life and Health Sciences from the University of Nantes, Master's degree in Strategy and Methods for Clinical Development – University of Lyon) and Pierre-Olivier Goineau (Master's and DEA [Advanced Studies Degree] in Management Sciences, Master's in Management for Pharmaceutical Industries – IAE Lyon), met in 2003, through the Lyon biotechnology entrepreneurs' network, BioTuesday.

At that time, Dr. Yann Godfrin was Chairman and R&D Director of Hemoxymed Europe, a subsidiary of Hemoxymed Inc based in the United States, a company developing technologies involving red blood cells. He had previously worked as a consultant with BioAlliance (FR0010095596 – BIO) and as a Development Engineer at Hémosystem (systems for detecting contamination in blood products).

Pierre-Olivier Goineau was, at the same time, a senior consultant for strategy at KPMG Enterprises, the national standard-setter in the "health and life sciences" sector. Previously, he had been the majority partner in his own finance and development consulting company targeting international projects.

Both wished to create a company specialized in the development of therapeutic profits for orphan indications.

Convinced of their complementary nature, they decided to combine their skills and abilities in biology, technology, preclinical and clinical development for Dr. Yann Godfrin, and management, strategic positioning and marketing, public and private finance for Pierre-Olivier.

#### 2004

ERYTECH began operating in March as part of the Créalys incubator, one of the best-known in the domain of life sciences in France, with the financial support of Conseil Régional Rhône-Alpes. An initial R&D collaboration was entered into with Centre Léon Bérard in Lyon, a reputable cancer-fighting research centre in Europe. The "ERYTECH Pharma" project was awarded a prize by the French Ministry of Research in the category of Creation and received a 40,000 Euro grant. In August, the Company filed its first patent involving encapsulation technology.

ERYTECH was established in October and started operations in the BioParc Lyon-Laennec business incubator. The co-founders made initial rounds with *Business Angels*. The Company also has surrounded itself with external scientific experts.

ERYTECH obtained the status of Young Innovative Company.

#### 2005

ERYTECH was a Laureate of the Prize from the Ministry of Research in the "Development" category and received a €450,000 stipend. Additionally, it obtained significant initial financial support from the Agence Nationale de la Recherche [National Research Agency] and from the Cancéropole Lyon Rhône-Alpes Auvergne [Cancer Center of Rhône-Alpes Auvergne].

In October, the AFSSAPS (which later became the ANSM - the French National Agency of Medicine and Health Product Safety) authorized the conducting of ERYTECH's first clinical trial: a Phase I/II trial involving the treatment of Acute Lymphoblastic Leukemia with GRASPA®.

Emboldened by this initial success, the Company raised €750,000 from its shareholders, Cap Décisif, Amorçage Rhône Alpes, and two new business angels from the health sector.

Two new patents associated with new candidate-products were filed.

#### 2006

ERYTECH began opening clinical investigation centers to conduct its first trial involving leukemia: more than 20 centers would be opened throughout France bringing together most of the French opinion makers treating children and adult patients suffering from acute lymphoblastic leukemia.

The European Medicines Agency (EMA) classified ERYTECH's medicinal product ("Medicinal Product") GRASPA® as its first Orphan Drug Designation (ODD) in the treatment of acute lymphoblastic leukemia and gave it "SME" status.

ERYTECH received a significant stipend of €450,000 from Oséo to finance the development of GRASPA®.

The Company accelerated its development by raising €12 million in funds from its historic shareholders, AGF Private Equity (which became IDInvest Partners), Auriga Partners, and Axa Private Equity.

#### 2007

2007 was a year of structuring, organization, and team building to prepare for future challenges:

The Company acquired space in a new building in the Bioparc Laennec site in Lyon and started work on its production unit in order to master its technology on an industrial scale and its production costs.

The team was enriched with a Medical Director, a Regulatory Director, a Quality Assurance Director, and increased its number of researchers; at the end of the year it would have 14 people.

The Belgian health authorities gave approval to treat patients in Belgium as part of the Phase I/II trial already authorized in France.

At the same time, the work by the R&D department was allowing new candidate products to be identified.

#### 2008

# Europe:

At the start of the year, ERYTECH included its last patient in the Phase I/II clinical trial started in 2006.

The Lyon production unit was completed at the end of the year and complete with the most demanding regulatory criteria. This unit is capable of production for both clinical trials and commercial uses.

The Company received new support from the Agence Nationale de la Recherche and the Cancéropôle Lyon Rhône Alpes (CLARA). Oséoalso confirmed its commitment to the company through a repayable aid of €735,000 to finance the clinical Phase I for GRASPA® in pancreatic cancer.

#### **United States:**

Very promising results from the study were presented orally at the American Society of Hematology's (ASH) Annual Meeting in San Francisco. ERYTECH presented its scientific results in New York and Las Vegas.

#### 2009

## Europe:

ERYTECH's production unit, after an audit and inspection by AFSSAPS (which became ANSM), the classification as a "Pharmaceutical Facility" validating its level of health safety in accordance with the EMA rules.

Shortly afterward, ISO 9001:2008 certification was delivered by SGS to ERYTECH, validating the quality control organization implemented in all departments in accordance with the policy of excellence sought by the executive officers.

The results from the Phase I/II clinical trial allowed ERYTECH to pursue its clinical development and obtain the authorizations to start to new clinical phases from the AFSSAPS (now the ANSM) for the treatment of acute lymphoblastic leukemia (ALL):

A Phase II clinical trial for first-line treatment of adult patients over 55 years of age,

A Phase II/III clinical trial for treatment of child and adult patients under 55 years of age who have relapsed.

ERYTECH also obtained authorization from the AFSSAPS to begin a Phase I clinical trial to test GRASPA® among patients suffering from pancreatic cancer. The European Medicines Agency granted a second Orphan Drug Designation to GRASPA® for pancreatic cancer.

The Ministry of Research granted new financial assistance to the Company in the form of a grant awarded by the ANR.

ERYTECH filed its 10<sup>th</sup> patent.

#### **United States:**

ERYTECH found space within the Philadelphia Science Center one of the largest health clusters in the United States. Shortly thereafter, the Company signed two agreements with the American Red Cross which is the largest blood bank in the world:

an agreement to provide Red Blood Cells coming from American donors;

A subcontracting agreement providing that premises of cGMP based in Philadelphia would be provided, in accordance with FDA regulations and personnel dedicated to produce GRASPA® in the United States.

This major step prepared the way for conducting clinical trials in the United States and considerably strengthened the visibility of ERYTECH's actions among American companies.

#### 2010

#### Europe:

ERYTECH continued its three clinical trials in parallel. The Company finished the year ahead of schedule, the recruitment of the last patient for its Phase II trial with treatment by GRASPA® of patients older than 55 years of age suffering from acute lymphoblastic leukemia.

The Company employed 36 people at the end of 2010.

#### **United States:**

The FDA granted Orphan Drug Designation status to GRASPA® for the treatment of acute lymphoblastic leukemia, offering advantages comparable to the European designation on American soil.

The Company signed an R&D partnership agreement with the MD Anderson Cancer Center in Houston to develop a companion test that would make it possible to detect patients suffering from cancer who could be treated with GRASPA®.

#### 2011

# Europe:

ERYTECH recruited its last Phase I patient for pancreatic cancer.

The Company formed a Joint Venture with the Teva Group (a NASDAQ-listed company as TLV:TEVA) to market GRASPA® in Israel (*see also Chapters 6 and 22 of the Reference Document*).

ERYTECH signed a long-term contract to provide aspariginase with the German pharmaceutical laboratory medac GmbH.

ERYTECH was selected by several international Conferences on Hematology to orally present promising preclinical results from a new proposed product for the treatment of sickle cell anemia.

## **United States:**

ERYTECH filed an IND application with the FDA to start a Phase I clinical trial with the GRASPA® to provide therapy as first-line treatment of adult patients, over 40 years of age, suffering from Acute Lymphoblastic Leukemia, in which the principal investigator was Professor Richard Larson (Chicago), Chairman of the Adult Leukemia group within the CALGB (the largest cooperative group treating leukemia and cancer in the United States).

## 2012

Gil Beyen became a consultant to the Company then Chairman of the Supervisory Board in August. Gil Beyen was the co-founder and CEO of TiGenix N.V. (NYSE Euronext Brussels: TIG), a European cellular therapy company with an approved product and advanced clinical trials.

#### Europe:

The Company has received assistance totaling 7 million Euros, including 4.9 million Euros in repayable advances and 2.1 million Euros in grants (refer to Section 22.1 for the terms of this contract), which shall be paid progressively between 2012 and 2019 in keeping with development within the context of the TEDAC

project, a research and development project focused on developing therapies for radiation/chemotherapy-resistant cancers, in association with other companies and entities (Diaxonhit, Inserm, University of Paris-Diderot, and the AP-HP [Public Assistance-Paris Hospitals]).

Over time, the goal is to offer a solution including a test predicting response to treatment, one or more suitable enzyme therapies, as well as a test to monitor therapeutic efficacy.

ERYTECH's production unit obtained the designation of "Operating Facility".

The Company received a favorable opinion from the Committee for Orphan Medicinal Products of the EMA (European Medicines Agency) concerning the orphan drug designation of its experimental product ENHOXY® for the treatment of sickle cell anemia.

The Company signed a partnership agreement with Orphan Europe (Recordati group) for the development and marketing of GRASPA® in 38 European countries for the treatment of children and adults suffering from acute lymphoblastic leukemia and acute myeloid leukemia (AML) (*see also Chapters 6 and 22 of the Reference Document*).

## **United States:**

Dialog with the FDA continued for the purpose of starting a clinical trial involving acute lymphoblastic leukemia and ERY-ASP.

#### 2013

On April 30, 2013, the Company became listed on the regulated market NYSE Euronext Paris, compartment C, raising €17.7 M.

On May 6, 2013, the Company changed its method of governance, with a view to establishing a board of directors in place of the executive board and supervisory board, and appointed Gil Beyen as Chief Executive Officer, formerly Chairman of the Supervisory Board.

#### Europe:

The committee of independent experts (the Data Safety Monitoring Board or DSMB) in charge of monitoring the Phase II/III clinical study of ERY-ASP/GRASPA® in adults and children experiencing a relapse of ALL met and delivered a favorable opinion concerning the conduct of this Phase III clinical trial following the original protocol with a total pool of 80 patients.

The European Union granted ERY-ASP/GRASPA® orphan drug designation for AML.

The ANSM (Agence nationale de sécurité du médicament et des produits de santé [French National Agency of Medicine and Health Product Safety]) granted ERYTECH the right to begin a Phase IIb in AML. ERYTECH recruited its first patient in March.

The DSMB in charge of monitoring the Phase IIb clinical study of ERY-ASP/GRASPA® in AML delivered a favorable opinion concerning the conduct of this clinical trial following an evaluation of the product's tolerance in 30 initial patients.

## **United States:**

The FDA granted ERYTECH the right to start a Phase Ib with ERY-ASP in ALL.

The USPTO (United States Patent and Trademark Office) delivered the patent protecting ERYTECH's technology, granting it exclusivity until 2029 with the potential for extension into 2034.

Internationally, the company filed two new patent applications.

## 2014

## Europe:

The Company launched a Phase II study of pancreatic cancer with its product ERY-ASP.

ERYTECH obtained the authorization of numerous European countries for its AML study, enabling it to broaden the recruitment of its patients, and obtained a second positive DSMB opinion.

The Company announced the addition of a new candidate drug to its oncology portfolio: "Affameur de tumeurs" [tumor starvation inducer] ERY-MET.

The Company announced the positive Phase III results on its clinical study with ERY-ASP/GRASPA® in the treatment of ALL.

The company received notice of the issue, by the European Patent Office, of a key patent covering the use of ERY-ASP in the treatment of pancreatic cancer.

#### USA:

The main centers for the recruitment of patients for the Phase I study opened (Chicago, Duke, Colombus), and the first patients were treated.

The Company has obtained the issue of a new patent in the United States, in the area of asparaginase.

## *International:*

The Company announced the issue, in India, of its main encapsulation patent entitled "Lysis/Resealing Process for Preparing Erythrocytes".

On the financial level, the Company:

- welcomed new shareholders following a reclassification operation with European institutional and American investors specialized in the field of healthcare;
- successfully raised thirty million Euros with a view to extending its therapeutic indications in oncology and to accelerating its clinical developments.

#### 2015

On January 9, 2015, the Company established a Level 1 American Depositary Receipt ("ADR") program on the American over-the-counter ("OTC") market, for which the Bank of New York Mellon is the custodian. Each American Depositary Share represents one ERYTECH Pharma share as traded on Euronext Paris.

The Company has strengthened its patent portfolio in the United States:

- with a newly issued patent protecting the use of ERY-ASP for the treatment of pancreatic cancer (currently in Phase II clinical trial); and
- extension of the protection duration by one and a half years on its active ingredient patent entitled "Lysis/Resealing Process for Preparing Erythrocytes".

The Company has announced the positive opinion of the DSMB relating to its Expanded Access Program in acute lymphoblastic leukemia.

The Company presented the complete results of the Phase III pivotal study of ERY-ASP/GRASPA® in ALL and a poster on the design of the Phase IIb study in progress on AML at the annual meeting of the American Society of Clinical Oncology ("ASCO") which took place from May 29 to June 2, 2015, and will do the same at the annual congress of the European Hematology Association ("EHA") taking place from June 11 to 14, 2015.

The Company will outline its activities for investors at the Jefferies 2015 HealthCare Conference, which will take place in New York on June 4, 2015 at 9:00 A.M. EST (3:00 P.M. CET).

#### **5.2.** Investments

# 5.2.1. Principal investments made since 2013

Because all clinical research and development costs are recorded in the accounts as expenses until obtaining marketing approval, the principal investments in the first two financial years essentially pertain to the current production site, the Pharmaceutical Facility, and the R&D laboratory, and to a lesser degree, office and computer equipment.

as of Dec. 31 in thousands of €	2 013	2 014
Purchase of fixed assets		
- Intangible assets	(9)	(26)
- Tangible fixed assets	(418)	(521)
- Investments	(3)	(0)
Disposal of fixed assets - Intangible assets - Tangible fixed assets - Investments	- 142 -	- 126 1
Grants cashed	-	-
Effects of changes in perimeter	-	-
Net cash flow generated by investment operations	(289)	(420)

# 5.2.2. Principal investments currently being made

Since the start of the 2015 financial year, investments performed have decreased by €10k, as compared to 2014.

## 5.2.3. Principal investments planned

The Company is not currently planning to make any significant investments in forthcoming years for which the Company's oversight bodies have made firm commitments.

#### 6. OVERVIEW OF BUSINESS ACTIVITIES

# 6.1. General presentation

ERYTECH was founded in 2004 to develop and market innovative therapies for acute leukemia and other cancers for which medical needs remain unmet. The innovative approach by ERYTECH consists of acting on the tumor's environment and "starving" it, so that the cancerous cells no longer have access to the growth factors that are necessary for them to live and proliferate.

The core product of ERYTECH, ERY-ASP/GRASPA<sup>®2</sup>, is used in the treatment of acute leukemias, a cancer of the blood and bone marrow that proliferates rapidly and requires urgent treatment. The two most common forms are acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), depending on the cells at the origin of the disease. Each year, approximately 50,000 patients are diagnosed with acute leukemia in Europe and the United States.

ERY-ASP/GRASPA® shows convincing clinical results obtained in several clinical trials and is in the final phase of clinical development in Europe with a view to obtaining a marketing authorization (AMM) in Europe for ALL. Based on these results, ERYTECH forged two distribution partnerships for the European and Israeli markets with international companies Orphan Europe (Recordati Group) and the Teva Group.

ERY-ASP/GRASPA®, developed based on ERYTECH proprietary technology, consists of an enzyme, L-asparaginase, encapsulated in the red blood cells. L-asparaginase is an essential weapon in the treatment of acute leukemia. This enzyme has the property of being able to remove the supply of asparagine, a naturally occurring substance in the blood that is essential for their growth, from leukemic cells. This L-asparaginase treatment, resulting in the death of cancer cells, has demonstrated efficacy in children with ALL, who almost all enter remission and have a high probability of full recovery. However, its usage is considerably limited by its significant side effects (allergic reactions and immune response, bleeding disorders, and pancreatitis, for example). Clinicians cannot administer it to most adult and senior patients, as they cannot tolerate free-form asparaginase.

Sales of existing treatments based on L-asparaginase are estimated at approximately  $\[ \le \] 250 \text{ M}^3 \]$  in Europe and in the United States, but represent only a fraction of a much larger market, still underdeveloped and which could represent a billion<sup>4</sup> Euros. Over 80% of current L-asparaginase sales are for children with ALL. Other leukemia patients, namely adults and seniors with ALL and all AML patients (more than 80% of patients with acute leukemia), have little or no access to these drugs because the patients are too fragile to tolerate them.

Through the encapsulation of asparaginase in the red blood cells using ERYTECH proprietary technology, ERY-ASP/GRASPA® is uniquely positioned to provide a solution to the significant unsatisfied medical needs of these fragile patients. The red cell membrane prevents interactions between the body and L-asparaginase, thereby protecting the body from the side effects of L-asparaginase and simultaneously preventing the immune system from eliminating L-asparaginase, thus reducing its efficacy. Encapsulated L-asparaginase fully achieves its goal of destroying asparagine circulating in the blood because it is absorbed inside the red blood cell through a natural phenomenon. The red blood cell acts as a bioreactor circulating in the blood and destroys asparagine, which could feed leukemic cells.

ERY-ASP/GRASPA® has the potential to become a reference medicine in the treatment of acute leukemias: ERY-ASP/GRASPA® allows fragile patients who currently do not have the possibility, due to their state of general health and side effects experienced, to be treated with L-asparaginase, and who have smaller chances of survival because of this. For patients who are unable to receive the current treatments based on L-asparaginase, ERY-ASP/GRASPA® offers an effective alternative with a considerably improved tolerance profile.

<sup>&</sup>lt;sup>2</sup> The GRASPA® brand has been licensed to Orphan Europe (Recordati Group) for placement of the product on the market in the treatment of ALL and AML in Europe; ERY-ASP is the code name used outside Europe and excluding acute leukemias.

<sup>&</sup>lt;sup>3</sup> Source: Jazz Pharmaceuticals and ERYTECH

<sup>&</sup>lt;sup>4</sup> Refer to the following sections:

<sup>-</sup> The pharmaceutical industry's strong and growing interest in orphan drugs

<sup>-</sup> ERY-ASP/GRASPA®: An innovative treatment entering the market

ERYTECH is in the final stages of clinical studies for GRASPA® for ALL and has compelling results in terms of efficacy and tolerance in: (a) the results of a Phase I/II study in children and adults with a relapse of ALL, (b) the results of a Phase II study performed on patients more than 55 years of age who are affected by ALL, and (c) the positive results of a Phase II/III study (in adults and children in relapse). In time, these studies will underpin the need for a Marketing Approval (MA) at the European level.

In November 2012, ERYTECH signed a marketing agreement with Orphan Europe, an orphan drug specialist subsidiary of the Recordati Group, a leading European pharmaceutical group, to distribute GRASPA® in 38 European countries. With the establishment of this partnership, GRASPA® may be sold efficiently as soon as the necessary approvals are obtained in all European countries and ERYTECH will receive a substantial part of the profits under the agreement. ERYTECH also signed a partnership agreement with the Teva Group, a world leading pharmaceutical company, to distribute GRASPA® in Israel.

The Company has a production unit based in Lyon with the qualifications of "Pharmaceutical Facility" and "Operating Facility", which makes it possible to serve the European and Israeli markets.

ERYTECH is developing possible new indications for ERY-ASP outside the area of leukemias. Initial preclinical and clinical results suggest that ERY-ASP could also be effective against certain solid tumors for which therapeutic options are currently reduced. ERYTECH launched a Phase II study of pancreatic cancer in 2014.

Further, the Company has a pipeline of potential products targeting orphan diseases that constitute medium and long-term sources of growth for the company and/or partnership options. In the longer term, the ERYTECH technology can encapsulate various molecules or active ingredients inside red blood cells and could help develop new drugs, particularly in cancer treatment, with much better efficacy and toxicity profiles, consequently improving the patients' survival and quality of life.

ERYTECH has what it takes to establish itself as a mature biotechnology company with revenues from partnership agreements for the distribution of a drug at the doors to the market and a pipeline of promising products and indications:

# • A unique therapeutic concept for the fight against cancer: "Starving tumors"

Treatments that affect the supply of oxygen or nutrients to tumor cells are one of the weapons to effectively fight cancer and are complementary to approaches that can potentially target cancer cells directly. These drugs cause tumor cells to die by asphyxiation or nutrient deprivation. ERYTECH develops innovative new enzyme therapies able to starve tumors and treat cancers that do not respond to radiation or chemotherapy. In particular, L-asparaginase treatment deprives leukemic cells of asparagine, an amino acid essential to their growth and survival. Removing this amino acid from the metabolic environment is a key issue in the fight against leukemia but also certain other cancers.

## • An initial target market with high potential: Acute leukemia

ERYTECH is positioned as a treatment for acute leukemia, which are most forms of leukemia, and it accounts for about 50,000 new cases diagnosed per year in Europe and the United States. Medical needs are considerable given this cancer's very poor prognosis for most patients. Children with ALL, which accounts for approximately 12% of new cases of acute leukemia, have over a 5-year survival rate of 90% due to L-asparaginase treatment. All other patients, adults and seniors, and relapsed patients typically cannot tolerate this treatment, despite efforts over dozens of years to adapt it. Adult and senior patients with ALL have a 5-year survival rate of between 10% and 30%, the lowest rate of all cancers combined. Existing asparaginase-based treatments generate sales estimated at approximately €250 M, largely relating to children, but the potential market is estimated at more than one billion Euros in Europe and the United States.

# • Compelling clinical results for GRASPA®: Efficacy and tolerance

ERYTECH anticipates filing an application for authorization with the European Medicines Agency (EMA) for the placement of GRASPA® on the market for ALL in mid-2015, based on three studies (including one Phase I/II and one Phase II/III study) in adult and pediatric patients with ALL in relapse and one study performed on

patients more than 55 years of age. The first study, in children and adults with ALL in relapse, demonstrated the safety of the product and identified the best dose. It also demonstrated that one injection of GRASPA® can result in the same depletion of asparagine as up to 8 injections of free-form L-asparaginase. It was followed by a Phase II/III study in the same type of patients. Analysis of the data from the GRASPIVOTALL clinical trial (GRASPALL 2009-06), after one year of monitoring, demonstrates that the study convincingly achieved its primary objectives, and its secondary objectives confirm a favorable profile for the clinical efficacy of GRASPA®. The study also shows favorable results in patients with histories of allergies to L-asparaginase. The third study is a Phase II study in patients greater than 55 years of age with ALL. This study showed that, in the category of fragile patients who often cannot be treated with L-asparaginase at induction, GRASPA® was well tolerated and resulted in complete remission for 77% of patients completing their induction.

In 2013, ERYTECH began a Phase IIb clinical study of AML, the results of which, if positive, will allow the indication of GRASPA® to be extended to these patients once the drug is on the market, an Expanded Access Program (EAP) for ALL in France, and a Phase Ib study, again on ALL, in the United States.

# • Strong marketing partnerships: Orphan Europe (Recordati Group) and the Teva Group

ERYTECH has entered into two major partnerships for the commercialization of GRASPA® in 38 European countries with Orphan Europe (Recordati Group) and in Israel with the Teva Group. Due to the innovative nature of GRASPA®, its ability to satisfy unmet medical needs, and its progress in clinical development, ERYTECH has been able to obtain favorable terms, particularly with regard to the sharing of future profits (representing up to 45% of the net sale price). Both partners have recognized trade capacities and can effectively promote GRASPA® in their respective territories. In particular, through its subsidiary Orphan Europe, Recordati is a specialist in orphan diseases and will work with ERYTECH on the regulatory approach to optimize the marketing of GRASPA®. The agreement with Orphan Europe (Recordati Group) notably provides for a payment of €5M upon signature, sharing in the development costs for GRASPA® in AML, and future payments of up to €37.5M, subject to achieving regulatory and commercial objectives. ERYTECH will receive a payment for product delivered, and royalties on the sales performed by Orphan Europe (Recordati Group) with GRASPA®, for a total of up to 45% of the net sale price.

Separately, another Recordati Group company has purchased bonds that were converted into an investment in ERYTECH equity worth €5 million at the time of the initial public offering.

# Favorable conditions for market access: The orphan drug designation, existing medical practice and expected medical needs

ERY-ASP/GRASPA® has obtained orphan drug status in ALL, AML, and pancreatic cancer in Europe and in the United States. ERYTECH can therefore benefit from a marketing procedure with shorter lead times and reduced costs, and benefit from exclusive marketing after obtaining the marketing authorization for the product for 7 and 10 years, in the United States and Europe respectively. L-asparaginase treatment has been included in almost all European and American chemotherapy protocols since the 1970s for pediatric ALL patients. ERYASPTM/GRASPA® will be incorporated in or be added to the existing medical practice. Therefore, ERYTECH anticipates a rapid adoption of ERY-ASP/GRASPA®. Moreover, they are the same clinicians who treat AML patients and, for this indication, ERY-ASP/GRASPA® will capitalize on the clinical experience of these prescribers. The placement of ERY-ASP/GRASPA® on the market will require reasonable promotional and commercial resources, given the specialized position of the drug (clearly identified and relatively few prescribers, hospital treatment or specialist care center).

# • Proprietary and industrialized technology: Pharmaceutical Operating Facility Status

ERYTECH's encapsulation technology is internationally protected by 12 patent families filed both on the processes and on the products. ERYTECH has successfully developed a process to produce loaded erythrocytes in a reproducible, reliable and economical way on a large scale, regardless of the initial characteristic and origin of the red cells used. More than 400 bags of ERY-ASP/GRASPA® have already been produced and transfused in five clinical trials conducted by ERYTECH. ERYTECH's production unit operates according to the highest standards of pharmaceutical production, quality and traceability. The Company has obtained the status of "Pharmaceutical Facility" and "Operating Facility" from ANSM to produce GRASPA® for the European and Israeli markets. The current production capacity is sufficient to meet the needs of the various

clinical trials scheduled and the initial years of sales. The gross margin for ERY-ASP/GRASPA® is in line with pharmaceutical industry standards.

# • Opportunity to develop ERY-ASP in the United States: Launch of the clinical program

The US market is virtually equivalent to that of Europe in terms of number of patients with acute leukemia and is the natural progression in the development of ERY-ASP. A Phase Ib clinical trial in adult patients greater than 40 years of age with ALL is in progress, after obtaining authorization for a Phase Ib study from the "Food and Drug Administration" (FDA). The Company is relying on studies already underway in Europe. ERYTECH believes that the development of ERY-ASP in the United States could allow it to anticipate placement on the market within the 2019 horizon, and it will evaluate partnership opportunities at various key stages of the clinical development program for ALL and AML. ERYTECH has established a close partnership with the American Red Cross of Pennsylvania (Philadelphia, USA) to produce, under the Company's supervision, the lots needed for clinical studies.

## A promising pipeline: Solid tumors

Asparagine has been shown to also be a growth factor for several other types of cancer. In partnership with the MD Anderson Cancer Center (Houston, USA), one of the most recognized hospitals in the world for the treatment of cancer, ERYTECH analyzed various types of solid tumors and determined that asparaginase could effectively help combat solid tumors. The first milestone for developing ERY-ASP for solid tumors was achieved with a positive Phase I study, which demonstrated good tolerance of the product even at high doses. The next step is the initiation of a Phase II study, for which the first patients were recruited in 2014. In addition, ERYTECH's technology platform is versatile and opens up many possibilities for developing new drugs. The effectiveness of the technology has been demonstrated mainly with L-asparaginase, but it is possible to encapsulate other enzymes, molecules or proteins in red blood cells. The TEDAC program has made it possible to identify a new drug candidate: ERY-MET.

## • Strong scientific and medical support: 7 leading world experts

With its scientific and medical board, ERYTECH is surrounded by world-renowned American and European experts, particularly in the fields of oncology and leukemia. In addition to their active role in optimizing ERYTECH's strategy, their opinion in the scientific and medical communities will help promote the adoption of ERY-ASP/GRASPA® in hospitals and specialized care centers.

## An experienced and highly complementary team

ERYTECH is directed by Gil Beyen, Chief Executive Officer of the Company, with strong expertise in international development and pharmaceutical partnerships, and by one of his co-founders, Yann Godfrin, Delegated Managing Director, Scientific Director, biologist and scientific expert in the development of health products and the industrialization of processes. The Company relies on a talented team of 45 professionals with diverse, complementary backgrounds and skills totally in line with the ERYTECH's development objectives.

## • The pharmaceutical industry's strong and growing interest in orphan drugs

The interest of pharmaceutical companies in orphan and rare diseases has grown steadily since the mid-2000s and the last decade has been the most productive for the development of these drugs. Several major international pharmaceutical companies such as Pfizer, GSK and Sanofi, and many mid-size pharmaceutical groups such as, Recordati, Swedish Orphan Biovitrum and Shire have created specialized divisions for orphan and rare diseases and/or made them a major strategic focus. Consequently, transactions in this area, in the form of acquisitions or partnership agreements have multiplied. In particular, there were 3 operations in the L-asparaginase market: the acquisition of OPI (France) by EUSA (UK) for €100 million in 2007, the acquisition of a portfolio of products from Enzon (US) by Sigma Tau (Italy) for \$327 million in 2009, and the acquisition of EUSA by Jazz Pharmaceuticals (US) for \$700 million in 2012. In this context, ERYTECH has created significant strategic value with ERY-ASP/GRASPA® and its technology platform.

#### • Project pipeline

Product	Indication	Pre- clinical	Phase I	Phase II	Pivot	Registration	Market
	Acute lymphoblastic leukemia EU						
GRASPA®/	Acute lymphoblastic leukemia US						
ERY-ASP	Acute myeloid leukemia EU						
	Non-Hodgkins lymphoma			>			
	Pancreatic cancer						
ERY-MET	Tumor starvation						
ERY-VAX	Cancer immunotherapy						
ERY-TOL	Tolerance induction						

#### **6.2.** Introduction to cancer treatment

Cancer treatment is mainly based on surgery, radiotherapy and medical treatment, including chemotherapy. Each cancer is unique and the techniques used depend on the type of cancer, the stage at which it was discovered and the patient and his/her general health. They can also be combined to yield better results.

Surgery and radiation are effective as local treatment and loco-regional treatment. Medical treatments can reduce the volume of the primitive tumor and/or tackle the cells spread throughout the body but also reduce the risk of relapse after loco-regional treatment.

Chemotherapy is a mainstay cancer treatment and involves the use of a set of several drugs with different mechanisms of action that are combined and managed in a coordinated manner to effectively fight cancer cells. The drugs and doses used depend on a number of parameters including the type of cancer and the patient profile.

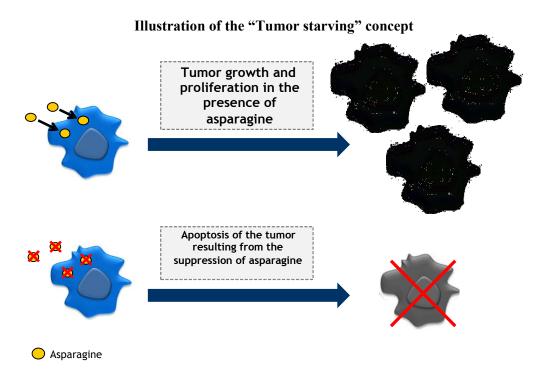
These drugs act by altering the reproductive mechanism of the cancer cell. Indeed, cancer cells reproduce continuously and uncontrollably and can be destroyed by selective medications, acting at different stages of the cells' reproductive cycle. However, in a course of chemotherapy, some normal cells (skin cells, mucous membranes, blood, etc.) which are also reproducing, are affected. This is the reason these treatments are associated with significant side effects.

In chemotherapy cocktails, "targeted" therapies, developed thanks to advances in research, particularly in understanding the operating mechanisms of the cancer cell, have played an increasingly significant role. These drugs produce a targeted action that saves healthy cells and are therefore potentially more effective and less toxic. They can be classified into 3 main categories:

- Drugs acting at a specific stage of the tumor cell's development, for example in the transduction of the signals telling the cell to multiply or by ordering the death of cancer cell (apoptosis);
- Treatments that stimulate and direct the body's immune response against cancer cells to destroy them (e.g., "therapeutic" vaccines);
- Treatments that act on the tumor cells' supply of oxygen or nutrients. These drugs suffocate or starve tumors.

ERYTECH is positioned in the last treatment category and is developing innovative new enzyme therapies able to starve tumors and treat cancers that do not respond to radiation or chemotherapy. In particular, L-

asparaginase treatment deprives leukemic cells of asparagine, an amino acid essential to their growth and survival. Removing this amino acid from the metabolic environment is a key issue in the fight against leukemia but also certain other cancers.



# 6.3. Acute leukemia: A significant unmet medical need

#### 6.3.1.Bone marrow cancer

Leukemia is a cancer of the bone marrow cells, sometimes called cancer of the blood. Leukemia is characterized by an abnormal and excessive proliferation of white blood cell precursors which, in the absence of treatment, invade the bone marrow and then the blood.

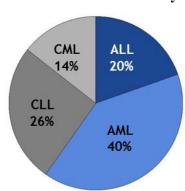
Leukemias are categorized according to their speed of development and the type of cells that proliferate:

- Acute leukemia (AL) is characterized by a rapid proliferation of abnormal cells in bone marrow and requires urgent treatment. Chronic leukemia (CL) has a slow proliferation with a clinical tolerance of cancer cells and a development that may take place over months or years.
- The cancer cell lineage can be either lymphoid precursors (which, in their normal state, participate in the defense of the body and form white blood cells) at the onset of lymphoblastic leukemia or it can be myeloid cells for myeloid leukemia.

By combining these two criteria as shown in the diagram below, there are four types of leukemia and ERYTECH is focused exclusively on acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), which are quickly life-threatening for patients.

# The 4 categories of leukemia Rapidity of development Chronic (slow myeloid Chronic lymphoblastic leukemiahronic leukemia progression) (CLL) (CML) Acute (rapid Acute myeloid leukemia (AML) lymphoblastic leukemia Acute progression) (ALL) type Lymphocytic Myeloid

Acute leukemias account for about 60% of cases of leukemia and 40% of chronic leukemia as shown in the following chart.



Breakdown of cases of leukemia by cell type

Source: PETRI Study

## 6.3.2.An increasing number of patients worldwide

Each year, approximately 50,000 patients are diagnosed with acute leukemia in Europe and the United States.

Approximately 10,000 new cases of patients suffering from ALL are diagnosed in Europe<sup>5</sup> (EU27) per year and 6,000 in the United States<sup>6</sup>, which corresponds to an age-adjusted incidence estimated to be approximately 2 new cases per year out of 100,000 persons<sup>7</sup>.

AML has an age-adjusted incidence approximately twice as high, with about 4 new cases per year per 100,000 people, representing approximately 19,000 new cases in Europe<sup>8</sup> and 15,000 in the United States<sup>9</sup>.

As shown in the following diagram, the majority of ALL patients are children. The remaining ALL patients are divided evenly between adults (18-55 years old) and seniors (> 55 years old).

<sup>&</sup>lt;sup>5</sup> Rodrigues-Abreu et al., Annals of Oncology, 2007

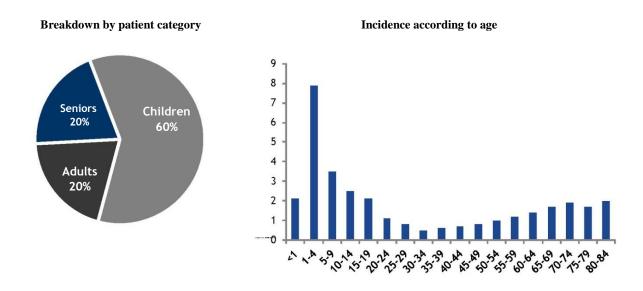
<sup>&</sup>lt;sup>6</sup> Siegel et al., CA Cancer J Clin, 2013

<sup>&</sup>lt;sup>7</sup> Dores et al, Blood 2010; SEER Cancer Statistics

<sup>&</sup>lt;sup>8</sup> Rodrigues-Abreu et al., Annals of Oncology, 2007

<sup>&</sup>lt;sup>9</sup> Siegel et al., CA Cancer J Clin, 2013

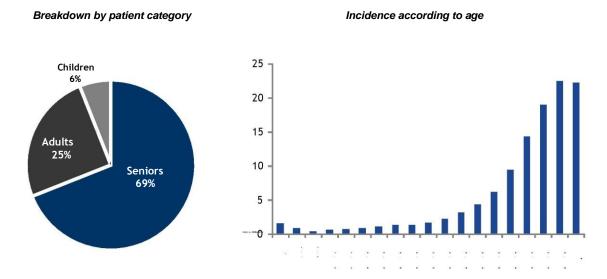
# Breakdown of ALL patients by age and disease incidence according to age



Source: U.S. NIH – NCI - SEER Cancer Statistics Source: SEER Cancer Statistics 1975-2007

AML is, however, a form of leukemia that affects mainly adults and seniors, and marginally children as shown in the following chart. The median age at diagnosis is 67. Because of their age and often multiple pathologies, these patients are particularly difficult for clinicians to treat.

# Breakdown of AML patients by age and disease incidence according to age



Source: SEER-17, 2001 to 2007 Source: SEER (Surveillance, Epidemiology and End Results) Cancer Statistics Review, 1975-2008. National Cancer Institute; 2011.

The exact causes of leukemia have not been completely identified, but various studies have shown<sup>10</sup> that the following conditions increase the risks for it:

- Radiation
- Benzene, formaldehyde and dioxins
- Tobacco
- Anticancer chemotherapy

<sup>&</sup>lt;sup>10</sup> Rodriguez-Abreu et al., Annals of Oncology, 2007

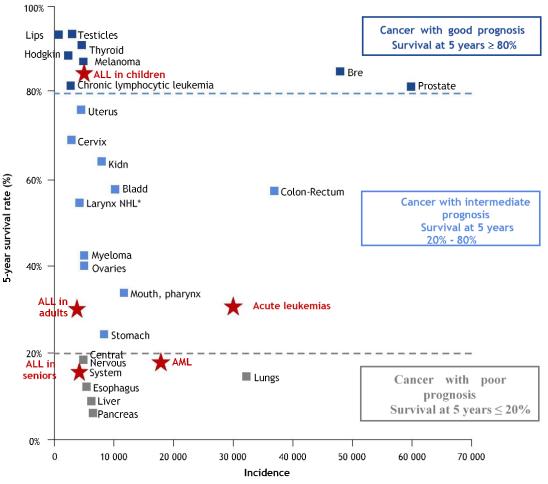
#### Some genetic disorders.

The incidence of the disease is relatively stable and tends to increase with the aging of the population.

## 6.3.3.A lower 5-year survival rate for adults and seniors

With the development of new drugs and new therapies, the prognosis for some of these cancers has dramatically improved, such as breast and prostate cancer, as well as ALL in children or thyroid cancer. There is still a large number of cancers with a poor prognosis, such as pancreatic, liver, esophageal or even lung cancer. Among the cancers with the worst prognoses are ALL and AML in adults and seniors.

# Major cancers in terms of incidence and 5-year survival rate in Europe



<sup>\*</sup> NHML: Non-Hodgkin malignant lymphoma Source: INCA 2012 & ERYTECH

The 5-year survival rate for ALL varies considerably between young subjects (children and young adults), who currently have about a 90% 5-year survival rate<sup>11</sup> and older subjects (adults and seniors) who have a low 5year survival rate (10 to 30%).

The evolution of treatment protocols and new drugs has led to steady improvement in the remission rate and chance of long-term survival. The protocols and drugs used successfully in children, in particular Lasparaginase, are often not transposable in older subjects due to their difficulty tolerating intensive chemotherapy because of their general health. For these priority patients, clinicians have a great need for new treatments with a better safety profile. ERYTECH is developing a new product, ERY-ASP/GRASPA® to meet this need.

<sup>&</sup>lt;sup>11</sup> Source: Cancer Statistics Review 1975–2005

For AML, without effective treatment, the 5-year survival rate is estimated at 23% and around 13% <sup>12</sup> for patients over 50 years of age suffering from AML.

# 6.4. L-asparaginase: a decisive drug in the treatment of acute leukemias

# 6.4.1. Current treatment of patients with acute leukemia

The current treatment of patients with leukemia is based on chemotherapy combining several drugs according to various regimens as is the case for the vast majority of cancers.

Treatment protocols for ALL are clearly established in all European countries and the United States depending on the patient's age, medical history and the specific characteristics of the disease. For AML, despite a generally similar approach, treatment protocols may differ considerably from one country to another and may also change depending on clinical or scientific advances.

Generally, after a diagnosis and preparation stage, chemotherapy protocols include several phases: induction of complete remission, remission consolidation, delayed intensification to prevent recurrence of leukemia and maintenance treatment:

- Induction: This step requires one or more months of treatment and is based on the administration of
  chemotherapy including several drugs whose goal is to achieve remission, i.e., the disappearance of
  signs of the disease.
- Consolidation: This phase comprises chemotherapies administered repeatedly over several days to one
  month, in order to prevent a relapse. Depending on the treatment's efficacy, the characteristics of the
  disease and age of the patient, hematopoietic stem cells may be required.
- Delayed intensification: Intensive chemotherapy may be necessary for one to two additional months.
   This Phase Is also called re-induction and is a repeat of the initial induction treatment about 3 to 4 months after the induction of remission. Delayed intensification helps prevent the recurrence of leukemia.
- *Maintenance:* This treatment is for patients for whom transplantation is not being considered. It is chemotherapy, essentially taken orally for about two to three years.

# 6.4.2.L-asparaginase's crucial role in the remission of patients

Asparagine is an amino acid naturally produced by healthy cells for their own use in protein synthesis. Too much of this amino acid produced by healthy cells is found in the bloodstream. Cancer cells also need it to grow and survive but they do not produce it. Therefore they use circulating asparagine.

The principle of the treatment is to remove circulating asparagine using a specific enzyme: L-asparaginase. This enzyme is capable of destroying asparagine and deprives cancer cells of a key nutrient, causing them to die.

The history of L-asparaginase as an antitumor agent began with the first observations of a cytotoxic effect in 1953 and the confirmation of these results in the early 1960s. A bit later, L-asparaginase was purified from bacteria (E. coli) and it was demonstrated to have an effect on acute leukemia.

Introduction of L-asparaginase to standard ALL treatment in the 1970s. Its use has revolutionized pediatric protocols by improving complete remission rates and the duration thereof. It experienced a significant therapeutic decline both with regard to its efficacy and its tolerance<sup>13</sup>

Asparaginase gradually established itself as a pillar of anti-leukemia chemotherapy. Clinicians place it at the center of the therapy, along with other cytotoxic molecules and have extended its use to young adults and adults when they can tolerate this therapy.

The objective of clinicians is for the patient to go into complete remission of the disease (i.e., disappearance of the tumor cells) for as long as possible. Their current clinical practices are based on systems of intensive use of L-asparaginase (the more doses given, the sooner and longer the remission). Indeed, it has been shown

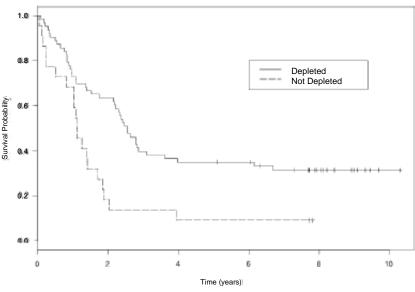
<sup>&</sup>lt;sup>12</sup> Source: SEER (2004 data; US)

<sup>&</sup>lt;sup>13</sup> Stock et al., Leukemia & Lymphoma, 2011)

that the longer the deprivation of asparagine, the higher the chances of complete remission, maintaining this remission, and having it remain sustainable<sup>14</sup>.

As the study presented below shows, the patients in whom the level of asparagine was reduced have considerably higher chances of remission and survival than those in whom it was not possible. The graph shows the survival of 63 adult patients with ALL who obtained a good level of asparaginase activity following treatment with asparaginase, as compared to a group of 22 patients for whom asparaginase activity was not sufficiently suppressed (depleted) during treatment.

# Survival rates for ALL by the level of asparagine deprivation



Source: Wetzler M et al. CALGB. Blood 2007;109: 4164

For AML, L-asparaginase is currently only partially used. It has received a marketing authorization for AML in some countries only (e.g., Canada), and is used in certain treatment protocols.

As illustrated in the diagram below, the relevance of L-asparaginase treatment and its efficacy for AML have been demonstrated. In 1988, a study of 195 patients with AML demonstrated the efficacy of L-asparaginase<sup>15</sup> as adjunct therapy to the standard cytarabine-based therapy.

The significant risk of side effects for this population of often elderly patients in fragile health is a major obstacle to the use of L-asparaginase.

Complete remission rate in adults according to age and response to treatment (relapsed or refractory)

	Refrac	ctory	Relapsed		
Age	High-dose cytarabine and asparaginase	High-dose cytarabine	High-dose cytarabine and asparaginase	High-dose cytarabine	
< 60 years old	54%	18%	37%	33%	
> 60 years	31%	0%	43%	21%	

Source: Capizzi & White, The Yale Journal of Biology and Medicine, 1988

In addition, in vitro experiments have demonstrated the efficacy of L-asparaginase on over 70% of several biological samples from different AML subtypes (M0, M1, M4 and M5), comparable to the results obtained

<sup>&</sup>lt;sup>14</sup> Silverman et al. Blood 2001

<sup>&</sup>lt;sup>15</sup> Capizzi & White, The Yale Journal of Biology and Medicine, 1988

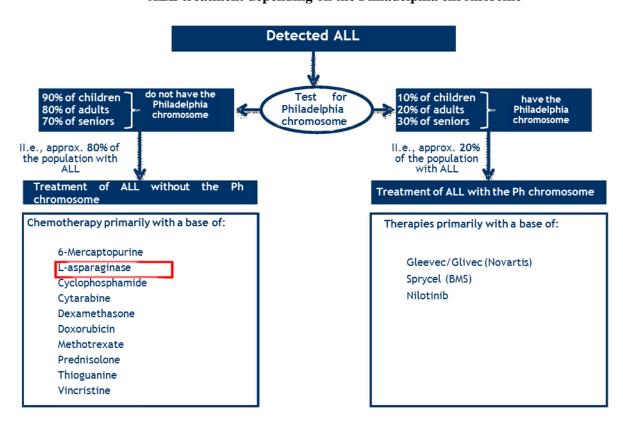
on biological samples of ALL. Approximately 50%-60% of patients are estimated to be potential responders to L-asparaginase treatment<sup>16</sup>.

## 6.4.2.1. ALL treatment

In the case of ALL, the choice of drugs involved in the successive phases of chemotherapy depends on a genetic specificity, the presence or absence of the Philadelphia chromosome. This anomaly is present in approximately 10% of ALL cases in children and about 20% to 40% of ALL cases in adults. Its frequency increases with age.

ALL patients with the Philadelphia chromosome (called Ph+ "Phi positive") are primarily treated with monoclonal antibodies and in particular tyrosine kinase inhibitors (BCR-ABL) such as imatinib, marketed by Novartis under the name Gleevec®/Glivec®, and dasitinib marketed by BMS under the name Sprycel®. However, clinical trials have demonstrated the lack of efficacy of imatinib and dasitinib on ALL patients without the Philadelphia chromosome.

The remaining ALL patients, i.e., the majority of patients (~80%) do not have the Philadelphia chromosome (called Ph- "Phi-negative"). These patients' lymphoblasts respond to L-asparaginase. Therefore, L-asparaginase treatment has been included in almost all European and American chemotherapy protocols since the 1970s for this type of patient.



ALL treatment depending on the Philadelphia chromosome

The following diagram provides an overview of the key molecules that can be used in chemotherapy cocktails depending on the different phases of treatment.

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<sup>&</sup>lt;sup>16</sup> Okada et al., Br J Hematology, 2003

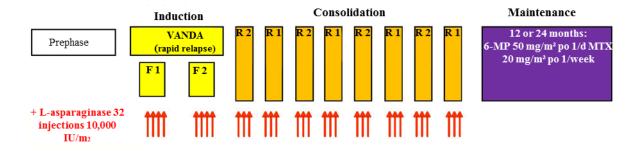
# Overview of the substances used in chemotherapy for ALL patients without the Philadelphia chromosome in the COPRALL protocol

	Induction	Consolidation	Intensification	Maintenance
Possible treatments	Cytarabine Methotrexate (MTX) Prednisolone Vincristine (VCR) Doxorubicin Dexamenthasone Asparaginase	Cytarabine VCR Cyclophosphamide 6-Mercaptopturine(6- MP) Asparaginase	Cytarabine MTX VCR Dexamethasone Doxorubicin Cyclophosphamide Thioguanine Asparaginase	MTX VCR Dexamethasone Cyclophosphamide 6-MP Thioguanine
Duration of treatment	~ 1 to 2 months	3 to 9 months	~ 1 to 2 months	2 - 3 years

L-asparaginase is the only drug of those used for treating ALL without the Philadelphia chromosome to affect asparagine and thus to be able to deprive tumor cells of this demonstrated growth factor.

The following figure shows an example of a treatment protocol for relapsed patients (COPRALL protocol - France). After a preparation phase, the patient receives intensive treatment with up to 32 injections of L-asparaginase in the induction and consolidation phases.

## Example of a protocol for the treatment of ALL (COPRALL protocol)



## 6.4.2.2. <u>AML treatment</u>

Acute myelogenous leukemia (AML) is a form of cancer that affects bone marrow cells that produce the blood components (red cells, white cells and platelets). Without treatment, it is rapidly fatal because of the risk of infection and bleeding. It is potentially curable with intensive chemotherapy courses, and the risk of relapse is lower if a bone marrow transplantation can be done, but at the cost of transplant-related mortality that increases with age. The chances of remission and relapse risks vary according to age and abnormalities of the karyotypes of leukemic cells.

There are several categories of AML based on the appearance of leukemic cells viewed by microscope (cytology) and the analysis of leukemic cell chromosomes.

Numerous treatment protocols have been developed taking this variety of subtypes into account.

FAB (French-American-British) international classification is the most commonly used and the following table provides the frequency and particular aspects of each.

## **Different categories of AML**

Type of AML	Particular aspects	Frequency
AML0-M2	Myeloid, very little differentiation	50%
AML3	Promyelocytic (bundles of Auer Rods), with bleeding disorders	
AML4	Myelomonocytic: dystrophic monocytes in the blood, bone marrow myeloblasts	25%
AML5A and B	Monoblasts somewhat differentiated	frequency of dermal and gingival involvement) 10%
AML6	Erythroblastic	4%
AML7	Megakaryocytic	1%

Classification of M0 to M7 does not reflect the severity of the disease. Treatment is essentially the same for all leukemia subtypes except for AML-M3, which has an effective treatment of transretinoic acid.

Without treatment, AML causes rapid death by infection, bleeding or respiratory and brain disorders by significant increase in white blood cells. The goal of treatment is for abnormal blasts to disappear from bone marrow and increase neutrophils, platelets and hemoglobin in the blood. This condition is called "complete remission." Without further treatment, relapse (recurrence of blasts in bone marrow) is most often observed.

Apart from a minority subtype (AML3) requiring a more specific drug, the molecule *all-trans retinoic acid* or ATRA which is proven to be effective for this subtype, the treatment is essentially the same for all types of AML.

The choice of treatment depends on the patient's pre-treatment assessment (cardiac, kidney, liver function) and the physiological age of the patient. AML in children is differentiated from that in subjects under 60 years old and that in subjects > 60 years old.

For AML in children, the therapeutic strategy after obtaining complete remission is a bone marrow allograft from an intra-family donor (75% disease-free 5-year survival rate) or treatment intensification with high-dose cytarabine and maintenance treatment with subcutaneous cytarabine and 6-thioguanine (55% disease-free survival).

For AML patients 18 to 60 years old, intensive chemotherapy may be offered with several phases: an induction phase, a consolidation phase and finally maintenance treatment including either autograft, marrow allograft or further courses of chemotherapy.

- *Induction*. Its objective is to achieve remission. The standard used is based on an infusion of cytarabine for 7 days in combination with anthracycline (daunorubicin or idarubicin) for 3 doses ("7+3").
- Consolidation. This treatment aims to maintain remission. It consists of administering high doses of chemotherapy. Several consolidation rounds are usually needed, requiring new and somewhat long hospitalizations. The treatment consists of high-dose cytarabine (HIDAC) in repeated courses (1 to 4 courses) or hematopoietic stem cell transplantation. In the latter case, it may involve a graft made from a donor (allograft) or stem cells from the patient collected at the end of consolidation treatment (autograft). Stem cells are cells from bone marrow (which are also present in cord blood) from which all blood cells are produced
- Intensification. This type of treatment is available and tailored to the risk of leukemia relapse and varies from one subject to another in order to obtain long-term remission and recovery. It is based on several courses of chemotherapy similar or identical to that administered during consolidation, i.e., based on a hematopoietic stem cell transplantation. Intensification can only be considered for patients under 60-70 years old because, beyond this age, the body is no longer able to tolerate the adverse effects of this type of treatment.

Remission maintenance treatment (4-12 months) can then be given as appropriate.

#### INDUCTION $10^{12}$ leukemia cells Chemotherapy inducing a long aplasia stage requiring a long hospitalization and significant NEUROMENINGEAI PROPHYLAXIS support allowing for complete remission to be achieved CATCH-UP in the event of a setback POST-INDUCTION TREATMENT 10<sup>9</sup> leukemia Depends on initial prognosis factors and response to inducti cells if complete remission after induction CONSOLIDATION RE-INDUCTION INTENSIFICATION MAINTENA $< 10^5 \text{ cells}$ Autologous transplant Allogenic transplant if cured

## Approach to the treatment of AML

In patients over the age of 60, there is no standard treatment. Intensive chemotherapy treatments cannot be given and conventional bone marrow allografts are not possible. Induction treatment will consist of a treatment similar to that for young subjects but with a lower dose of cytarabine. Post-induction treatment may involve a sequence of high-dose cytarabine if the patient's physiological condition permits. It is similar to the case for young subjects associated with anthracycline that is different from that used in induction, novantrone or the use of another interposing treatment such amsacrine. Hematopoietic growth factors could reduce the toxicity of the treatment. Maintenance treatment following completion of consolidation treatment. Patients not eligible for intensive chemotherapy may also be offered supportive care by transfusions, anti-infectious agents and palliative chemotherapy, with the goal being quality of life, and/or participation in a clinical trial.

Principles of treatment protocols for AML

	INDUCTION	CONSOLIDATION	INTENSIFICATION	MAINTENANC E (RESERVED FOR AML 3)
SUBJECT < 18 YEARS OLD	ARACYTINE MITOXANTRONE	HIGH DOSE ARACYTINE AMSACRINE VP16 DAUNORUBICIN ASPARAGINASE ALLOGENIC TRANSPLANT	OR HIGH DOSE CYTARABINE (HIDAC)	
SUBJECT 18-60 YEARS OLD	STANDARD 7+3 CYTARABINE + IDARBUCIN OR DAUNORUBICIN	HIGH DOSE CYTARABINE (HIDAC) STEM CELL TRANSPLANT	-	
SUBJECT > 60 YEARS OLD	LOW DOSE 7+3	HIGH DOSE CYTARABINE (HIDAC) NOVANTRONE AMSACRINE	-	
DURATION OF TREATMENT	~ 1 MONTH	6-9 MONTHS	~1-2 MONTHS	4-12 MONTHS

Like lymphoblasts for ALL cases, most myeloblasts need circulating asparagine to grow and multiply. The medical rationale for the use of L-asparaginase for the AML is therefore identical.

L-asparaginase is used in some pediatric treatment protocols: for example, in France in the ELAM 02 protocol, in the USA in the COG or St. Jude protocols), or in Canada, where it has marketing approval.

However, its toxicity profile prevents its widespread use in fragile children and especially in adult patients, or it is rarely used.

# 6.4.3. Limitations of direct administration of L-asparaginase

In clinical practice, ERYTECH estimates that one third of ALL patients – mostly elderly and relapsed patients – and the majority of adult AML patients are intolerant to L-asparaginase treatment. These patients are considered fragile.

Other patients, mostly children and young adults with ALL, receive L-asparaginase treatment which enables them to achieve remission of the disease and improves survival. Nevertheless, the use of L-asparaginase in these patients may also cause severe side effects including hypersensitivity reactions (anaphylactic shock), pancreatitis and bleeding disorders.

Severe toxic effects of L-asparaginase include:

- Allergic reactions, including anaphylactic shock and hypersensitivity.
- A decrease in coagulation factors. Coagulation problems may be responsible for severe thrombosis or bleeding. L-asparaginase interferes with the liver's production of both procoagulant and anticoagulant proteins.
- Pancreatic toxicity with acute pancreatitis and diabetes. Acute pancreatitis is seen in less than 15% of cases, but can sometimes progress to hemorrhagic or necrotizing pancreatitis, which is usually fatal.
- Liver damage from elevated liver enzymes that requires regular monitoring.
- Brain damage resulting in a state of confusion or clear coma.

Clinicians consider that the risk of serious intolerance has been identified in adult and senior patients with ALL and in patients in relapse. There is indeed an increased risk of liver, pancreatic, and nervous system toxicity, as well as hypersensitivity and bleeding disorders in these fragile patients.

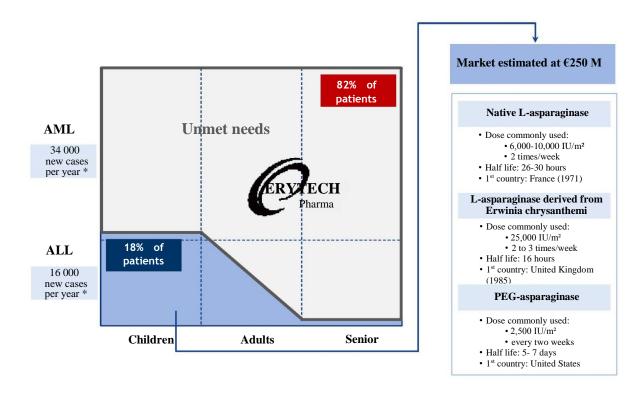
Relapsed ALL patients representing approximately 15% of children and 40% of adults with the illness (totaling approximately 20% of these patient groups) have a demonstrated risk of severe intolerance.

#### 6.4.4. The current market for L-asparaginase

ERYTECH believes that the current market for the various forms of aspariginase is approximately 250 million Euros <sup>17</sup>for Europe and the United States, and that less than 20% of patients suffering from acute leukemia are treated with aspariginase. The potential market for other patients, including adult and elderly patients with ALL and all AML patients is not being exploited and could represent more than one billion Euros.

<sup>&</sup>lt;sup>17</sup> Source: Jazz Pharmaceuticals and Erytech

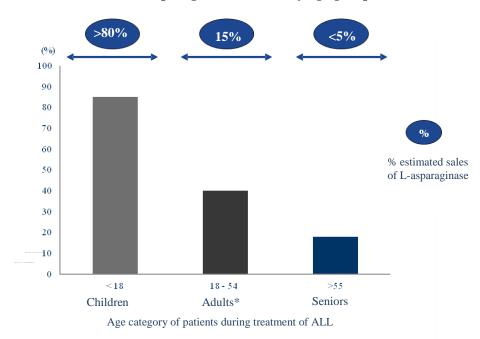
## The current and potential market for L-asparaginase



<sup>\*</sup> Europe and the United States Source: Company

The diagram below shows that over 80% of current sales of L-asparaginase are from children with ALL and approximately 15% from adults and primarily young adults (under 40 years old) with ALL who are still able to tolerate it. However, older patients are only marginally treated with L-asparaginase.

Use of L-asparaginase for ALL by age group



<sup>\*</sup> The survival rate 5 years after diagnosis varies depending on the patient's age. For example, patients under 29 years old have a 5-year survival rate of 54% and patients 30 to 54 years old have a 5-year survival rate of 28%.

The current market for L-asparaginase mainly includes 3 products, "native" L-asparaginase (Kidrolase<sup>®</sup>, Leunase<sup>®</sup>, Asparaginase Medac<sup>®</sup>), Oncaspar<sup>®</sup>, and Erwinase<sup>®</sup>, which correspond to different formulations and/or different production processes. As a result, these products have separate profiles, particularly in terms of activity duration, frequency of injections, and side effects.

The native form (Kidrolase®, Leunase®, or Asparaginase Medac®) is the first L-asparaginase. Sales of it began in France in 1971. Erwinase® and Oncaspar® were sold for the first time in 1985 and 1994 respectively. These products are indicated for the treatment of ALL, but are not or are very rarely used in patients with AML.

Themain L-asparaginase drugs are described briefly below:

# • Native L-asparaginase

The introduction of native L-asparaginase to the standard treatment of ALL in children and then adults dates back to the 1970s. This L-asparaginase was purified from *E. coli* bacteria.

Native L-asparaginase remains the first-line treatment for ALL in children in many European countries. Because of its general toxicity, this native form is rarely or not used in fragile patients. Its market is in steady decline, faced with competition from other more recent formulations.

Native L-asparaginase is mainly produced by the Japanese company Kyowa and distributed in Europe by Jazz Pharmaceuticals (following the acquisition of Eusa Pharma, formerly OPI, in June 2012) under the brand Kidrolase<sup>®</sup> and by the German company medac under the brand asparaginase medac<sup>®</sup>.

In the United States, the native form (Elspar®) was recently taken off the market because of production problems and the competition of the pegylated form (Oncaspar®).

#### • PEG-asparaginase

PEG-asparaginase is an L-asparaginase from *E. coli*, pegylated (attachment of a polyethylene glycol group to the enzyme) so as to reduce its toxicity, including immune and allergic reactions, and to prolong its duration of action (half-life).

PEG-asparaginase is typically administered in patients with an allergic reaction to native L-asparaginase. In some countries (United States, United Kingdom), it has almost completely replaced native L-asparaginase in children. PEG-asparaginase has been the subject of numerous publications in pediatrics but comparatively few studies in relapsed patients or adults. In practice, incorporating PEG-asparaginase in chemotherapy for adults is still uncommon because of the side effects feared by clinicians.

The only form of PEG-asparaginase allowed on the market is Oncaspar<sup>®</sup>. This injectable drug is registered in the United States, Germany, and Poland, and is available in other countries through special approvals. It was developed by Enzon, a company acquired by Sigma Tau in November 2009. Oncaspar<sup>®</sup> was previously distributed in Europe by medac; Sigma Tau resumed direct sales in August 2012.

ERYTECH estimates that about one third of current sales of L-asparaginase are related to the use of PEG-asparaginase.

## • L-asparaginase derived from Erwinia chrysanthemi

L-asparaginase produced by *E. chrysanthemi* bacteria is marketed by Jazz Pharmaceuticals (previously by EUSA Pharma) in Europe and in the United States under the brands Erwinase® and Erwinaze® respectively. The product has been present in some European countries since 1985 and in the United States where it was approved again in November 2011.

Worldwide sales revenue of Erwinase® published by Jazz Pharmaceuticals for 2014 was \$199.7 million.

This product is positioned as second-line treatment in cases of hypersensitivity reactions to L-asparaginase derived from *E. coli* (the native form or the pegylated form). Immune reactions (allergies and antibodies) that a patient develops against the form produced with E. coli are specific to that form in particular, and do not

target L-asparaginase derived from *Erwinia chrysanthemi*. However, treatment with Erwinase<sup>®</sup> can generate a specific immune reaction with the development of antibodies against Erwinase.

The differences between the half-life for the various preparations were therefore that Erwinase® is administered more frequently than the form derived from E. coli.

The following table shows the use of each L-asparaginase according to patient category. For ALL, the strategy adopted by clinicians' over time has been to attempt to adapt treatment protocols that have achieved high remission rates in children for use in older subjects (adolescents and young adults). L-asparaginase treatment is not used for ALL patients over about 55 years old and AML patients too fragile to receive it.

Use of L-asparaginase treatments according to acute leukemia and patient category

- ✓✓ Commonly used
- ✓ Rarely used
- X Not used

To the Company's knowledge, the following new forms of asparaginase are under development:

- Medac, a German company based in Hamburg, is developing a recombinant L-asparaginase. This is currently in the registration Phase In Europe. Phases II and III results have shown efficacy, a life span, and a side-effect profile quite similar to native L-asparaginase<sup>18</sup>.
- Medac is also developing a pegylated form currently in Phase I.
- Jazz Pharmaceuticals is developing a pegylated recombinant form of its Erwinia L-asaparaginase currently in Phase I.

There have been three major transactions in the market for L-asparaginase that are part of a broader trend in the interest of pharmaceutical groups in rare and orphan diseases. ERYTECH believes that these transactions were performed based on particularly attractive valuations:

- In June 2012, Jazz Pharmaceuticals acquired EUSA for \$650 million in cash, plus a \$50 million earn-out based on certain deferred sales goals. The transaction values EUSA at about 3x the sales expected by the company for 2013 (\$210 million to \$230 million). Erwinaze® is EUSA's main product, representing approximately two-thirds of sales (approximately \$125 million expected at the time of acquisition; \$131.9 million earned in 2012, the year after marketing approval in the United States; \$200 million earned in 2014).
- In November 2009, Sigma Tau acquired Enzon's specialty drug business activities for \$300 million, plus an earn-out of up to \$27 million contingent upon reaching certain goals. This transaction involved 4

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<sup>&</sup>lt;sup>18</sup> Borghorst et al., Pediatric Hematology and Oncology, 2012

marketed drugs, Oncaspar®, Adagen®, DepoCyt®, and Abelcet®, as well as a site in the United States. These 4 products totaled \$116.5 million in sales in 2009, including \$52.4 million for Oncaspar®.

In March 2007, EUSA acquired the French company OPi specializing in rare and orphan diseases for €110 million. OPi had a portfolio of specialty products including Kidrolase<sup>®</sup> (L-asparaginase derived from Escherichia coli) and Erwinase<sup>®</sup> (crisantaspase, L-asparaginase derived from Erwinia chrysanthemi) and monoclonal antibodies in various stages of preclinical and clinical development. OPi posted sales revenue of €18 million in 2006 and was profitable for the second consecutive year.

To the Company's knowledge, the more advanced products under development that may be able to treat ALL without the Philadelphia chromosome or AML are:

- Amgen is developing blinatunomab, a product under development acquired with the company Micromet in January 2012, in an ALL sub-category called B lineage. This drug candidate is in Phase 2 in B-lineage ALL adults who have relapsed or refractory to existing treatment, in Phase 2 in adult patients with minimal residual ALL B-precursors, in Phase 1/2 for pediatric relapsed or refractory B-lineage ALL patients, and in Phase 1/2 in relapsed or refractory adult patients with diffuse large B-cell lymphoma. Blinatumab has received drug designation for various indications, including ALL in Europe and the United States.
- Pfizer is developing inotuzumab ozogamicin for B-lineage ALL. The drug candidate is currently in Phase 3 in patients with B-lineage ALL who have relapsed or refractory to existing treatments, and in Phase 1/2 in senior patients with B-lineage ALL. Inotuzumab ozogamicin has received orphan drug designation from the FDA for ALL in the United States.
- Marquibo<sup>®</sup>, a new formulation of Vincristine, developed by the American company Talon Therapeutics was approved in the U.S. in 2012. Vincristine is a product used with GRASPA<sup>®</sup>. Talon was acquired by Spectrum Pharmaceuticals in 2013.
- New approaches based on modified T-cells under development by companies such as Juno Therapeutics and Novartis have shown promising Phase I results.

ERYTECH believes that these products can be used with GRASPA®.

# 6.5. ERY-ASP/GRASPA®: An innovative treatment entering the market in ALL

Recognizing a real need for a new L-asparaginase drug, ERYTECH developed the product ERY-ASP/GRASPA®. ERY-ASP/GRASPA® consists of an L-asparaginase encapsulated in a red blood cell. Encapsulation allows L-asparaginase to destroy asparagine within the red blood cell, without causing allergic reactions and reducing other side effects. ERY-ASP/GRASPA® offers a treatment with extended efficacy relative to the other forms and a significantly improved safety profile, making it possible to treat fragile patients.

Since 2006, ERYTECH has conducted 5 clinical trials, including 4 involving ALL, to establish the safety and efficacy of ERY-ASP/GRASPA®. The following table summarizes the main findings of these ALL studies. The results of the Phase I pancreatic cancer study are presented in Section 3.4.6 on solid tumors.

Synopsis of ALL clinical data

Indication	Study	N	Status	Key findings
	Phase I/II	24	Completed	GRASPA® is well tolerated even at the highest dose and shows depletion similar to 8 injections of Kidrolase®
Relapsed ALL in children and adults	Phase II/III	80	Completed	Primary objectives achieved and secondary objectives confirm a favorable profile for the clinical efficacy of GRASPA®; the study also shows favorable results in patients with histories of allergies to L-asparaginase.
ALL patients > 55 years old	Phase II	30	Completed	GRASPA® is well tolerated in this highly fragile population and has shown a remission rate of approximately 70%

Based on completed or ongoing clinical studies, ERYTECH expects to be able to file an application for marketing approval through the centralized procedure for Europe in 2015 for ALL.

In the meantime, ERYTECH has launched a study within the Expanded Access Program (EAP), treating patients who are allergic to all current forms of asparaginase; within this program, the 1<sup>st</sup> DSMB recommended continuing the recruitment of patients into the program, with no modifications to the study.

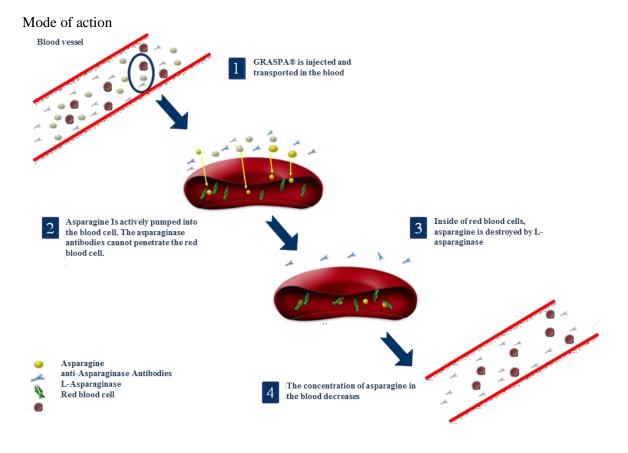
The European Medicines Agency (EMA) and the American Food and Drug Administration (FDA) have granted ERY-ASP/GRASPA® orphan drug designation for ALL, offering it exclusive marketing upon obtaining marketing approval for the product for 7 and 10 years in the United States and Europe respectively.

## 6.5.1.L-asparaginase encapsulated for greater efficacy and improved safety

ERY-ASP/GRASPA® involves the encapsulation of the enzyme L-asparaginase. The red cell membrane protects the L-asparaginase from the antibodies that are present in patients' blood and would likely substantially lessen or completely neutralize the enzyme activity or cause a hypersensitivity reaction. Thus, L-asparaginase remains active within the red blood cell without causing immune or allergic reactions in the patient. The enzyme can remain active and effective in the red blood cell as long as it is in the bloodstream and it has been demonstrated that the encapsulation process does not significantly alter the red blood cell's life span (29 days on average).

The encapsulation of L-asparaginase therefore not only significantly improves the drug's safety profile but also maintains the therapeutic efficacy of the enzyme over a long period compared to directly administering it to the patient. For this reason,, ERY-ASP/GRASPA® may be administered to fragile patients who cannot receive current forms of L-asparaginase and offer all patients an effective treatment with fewer injections and fewer side effects.

As illustrated in the following diagram, asparagine is an amino acid that naturally enters the red blood cell and ERYTECH's technology does not interfere with this natural mechanism. <sup>19</sup> The enzyme encapsulated in the cell, L-asparaginase, can then break down asparagine into L-aspartic acid and ammonia. The concentration of asparagine in the patient's blood decreases and leukemic and cancer cells are deprived of the asparagine they need to live, grow and develop.



<sup>19</sup> Ataullakhanov, 1985

## 6.5.2. Clinical results and ongoing clinical programs for acute leukemia

Clinical development program for acute leukemias

#### At April 20, 2015:

Clinical study	Status	Number of patients included in the study
Phase I/II study in adults and children with relapsed ALL (Europe)	Completed	24
Phase II study in patients over the age of 55 for first-line treatment (Europe)	Completed	30
Phase II/III study in adults and children with relapsed ALL (Europe)	Completed	80
Phase I/II study in adults over the age of 40 with ALL (in the United States)	Ongoing	12
Phase IIb study in patients over the age of 65 with AML (Europe)	Ongoing	123
Expanded Access Program for ALL in children and adults not eligible for other forms of asparaginase (France)	Ongoing	N/A
Total		269

This section presents the protocols for these completed and ongoing clinical studies, and provides a breakdown of the results:

#### Phase I/II clinical trial in adults and children with relapsed ALL

Between 2006 and 2009, ERYTECH performed a Phase I/II multicenter, randomized clinical trial (in France and Belgium) of GRASPA®, comparing it to the standard treatment (free L-asparaginase - Kidrolase®) in adults and children with relapsed ALL. The study has demonstrated the safety of GRASPA®, its efficacy over time in reducing the level of plasma asparagine in a single injection by an amount equivalent to that observed after 8 injections of free L-asparaginase (standard treatment), as well as fewer side effects associated with L-asparaginase (high-grade allergic reaction and cases of reduced coagulation disorders).

## Study protocol:

The main objective of this comparative study was to determine the relationship between the dose of GRASPA® (three doses tested: 50, 100 and 150 IU/kg) administered and the period during which plasma asparagine was reduced (depletion) in the sick patient. The trial was also designed to evaluate the efficacy of GRASPA® compared to the standard treatment through the duration of plasma asparaginase depletion, and the tolerance of the product by examining the side effects associated with GRASPA® encapsulated L-asparaginase.

The protocol for the clinical trial involved treating some adult or pediatric patients with relapsed ALL, according to the standard treatment, namely chemotherapy in combination with Kidrolase® free asparaginase, and the remaining patients with chemotherapy in combination with GRASPA®. Patients were randomly distributed into 4 groups of 6 people: 3 groups received three gradual doses of GRASPA® (50, 100 and 150) in parallel and on a double-blind basis in addition to chemotherapy; the 4th control group received only the free asparaginase standard treatment (Kidrolase®) in combination with chemotherapy.

## Results:

This Phase I/II study showed that GRASPA® produced an average asparagine plasma depletion duration of 18.6 days after the first injection of a 150 dose, a period equivalent to the average depletion observed in the control group treated with Kidrolase® (which has an average depletion duration of 20.6 days after 8 injections of a 10,000 IU/m² dose administered every three days).

A reduction in side effects was also observed for GRASPA®, particularly with regard to the occurrence of allergies, pancreatitis or coagulation disorders regardless of the dose of the product administered.

The table below presents the main clinical results of the Phase I/II study in adults and children with relapsed ALL during the first treatment cycle.

Clinical results of the Phase I/II study in adults and children with relapsed ALL

	Kidrolase® (standard L- asparaginase) (n=6)	GRASPA® (n=18)
	N (%)	N (%)
Allergic reaction	3 (50%)	0 (0%)
including high grade (3 or 4)	2 (33%)	0 (0%)
Clinical pancreatitis	0 (0%)	0 (0%)
Pancreatic enzyme elevation	1 (17%)	3 (16%)
Liver problems	3 (50%)	7 (38%)
Hypoalbuminemia	2 (33%)	0 (0%)
Coagulation disorder	4 (67%)	3 (16%)
including clinical thrombosis	1 (17%)	0 (0%)

Source: Domenech e.a. BJH 2010

#### Phase II clinical study in patients over the age of 55 with ALL as first-line treatment

In 2008, ERYTECH conducted a Phase II, dose-escalation clinical trial on GRASPA® as first-line treatment in 30 patients over the age of 55 with ALL and without the Philadelphia chromosome (Ph- ALL). These clinical trials confirmed a favorable tolerance profile for GRASPA® in a particularly fragile population of senior patients, and an absence of clinical allergies and absence of pancreatitis. Moreover, this trial showed that GRASPA® (100 IU/kg) resulted in complete remission for 77% of patients with a median survival improved by 6 months compared to historical data.

# Study protocol:

The study's main objective was to determine the maximum tolerated and effective dose of GRASPA® (among the three doses of 50, 100 and 150) in combination with chemotherapy, in the population studied. This clinical trial also aimed to evaluate the side effects related to the investigational drug in combination with chemotherapy, its pharmacokinetic and pharmacodynamic parameters and the rate of complete remission after treatment.

The study was open-label with a 3-patient cohort and included escalating doses of GRASPA® (50 IU/kg, 100 IU/kg and 150 IU/kg). After administration and review of the clinical response of the first cohort to the lower dose of GRASPA®, an independent monitoring board approved the transition to the higher dose. Patients were monitored every 3 to 4 weeks and then every 2 to 3 months to collect data pertaining to patient survival.

#### Study results:

The following table presents the main results of the Phase II clinical trial by dose of GRASPA® administered:

Clinical results of the Phase II study in patients over the age of 55 with ALL as first-line treatment

	GRASPA® 50 (n=3)	GRASPA® 100 (n=13)	GRASPA® 150 (n=14)
	N (%)	N (%)	N (%)
Clinical allergies	0 (0%)	0 (0%)	0 (0%)
Clinical pancreatitis	0 (0%)	0 (0%)	0 (0%)
Pancreatic enzyme elevation	1 (33%)	2 (15%)	3 (21%)
Thrombosis / attack	1 (33%)	1 (8%)	2 (14%)
Reduction of ATIII	2 (67%)	3 (23%)	7 (50%)
Complete remission	2/3 (67%)	10/13 (77%)	9/14 (64%)
Median survival	-	15.6 months	9.5 months

Source: Hunault – Berger e.a., ASH abstract #1473, 2012

## Phase II/III clinical trial in adults and children with relapsed ALL

The GRASPIVOTALL study (GRASPALL 2009-06) is a controlled, multi-center Phase II/III clinical study performed on 80 children and adults with relapsed or refractory acute lymphoblastic leukemia (ALL). This study is broken down into three arms. The first two compare GRASPA® with native E. Coli L-asparaginase, both in association with standard chemotherapy (COOPRALL), in a randomized study with a proportion of one to one in patients without a history of allergy to L-asparaginase. The third arm is an open study evaluating GRASPA® in patients who have had allergic reactions to L-asparaginase during first-line treatments.

Analysis of the data from the GRASPIVOTALL clinical trial, after one year of monitoring, demonstrates that the study convincingly achieved its primary objectives, and its secondary objectives confirm a favorable profile for the clinical efficacy of GRASPA®. The study also shows favorable results in patients with histories of allergies to L-asparaginase.

The main evaluation criteria for this study involves two objectives, in accordance with the opinion of the CHMP<sup>20</sup>: a) a higher tolerance, seen in a significant reduction in the incidence of allergic reactions to GRASPA® as compared to the control group, and b) a duration not less than that of the asparaginase activity, beyond the threshold of 100 IU/l, during the induction Phase In non-allergic patients. The two criteria needed to be satisfied for the study to be considered positive. The main secondary objectives of efficacy involved complete remission (CR), minimal residual disease (MRD), progression-free survival (PFS), and overall survival (OS).

The primary objectives achieved are as follows:

- Statistically significant reduction in allergic reactions: none of the 26 (0%) patients treated with GRASPA® had an allergic reaction, as compared to 12 patients out of 28 (43%) treated with native L-asparaginase in the control group (p<0.001).
- Statistically significant increase in the duration of activity of the circulating asparaginase: in the GRASPA® group, the asparaginase levels were maintained below 100 IU/l for 20.5 days on average, with at most 2 injections during the first month of treatment (induction phase), as compared to 9.6 days in the control group (p<0.001).

The secondary objectives confirm a favorable profile for the clinical efficacy of GRASPA<sup>®</sup>. At the end of the induction phase, 15 patients (65%) in the GRASPA arm showed complete remission, as compared to 11 patients (39%) in the control arm.

<sup>20</sup> Based on the scientific opinion obtained by the Scientific Advice Working Party (SAWP)/Commission for Human Medicinal Products (CHMP) at the European Medicines Agency (EMA)

Equally promising results were seen in patients with histories of allergies to L-asparaginase. A favorable clinical profile was found in patients with histories of allergies to L-asparaginase. Only three patients had slight allergic reactions.

These results confirm the previous observations obtained with GRASPA® in a Phase I/II randomized, dose-escalating study of 24 patients with a relapse of ALL, and a Phase II study in patients older than 55 years of age with ALL and receiving first-line treatment.

Table summarizing the results of the Phase III clinical study of GRASPIVOTALL with ERY-ASP/GRASPA®:

	Randomized arms			HypSen arm
	ERY001 N=26	L-ASP N=28		<b>ERY001</b> N=26
Primary objectives				
Duration with asparaginase				
activity > 100 IU/l (days)*	$20.5 \pm 5.2$	$9.4 \pm 7.4$	p < 0.001	$18.6 \pm 6.3$
Hypersensitivity to asparaginase				
All grades	0 (0%)	12 (43%)		3 (12%)
			p < 0.001	
Grade ≥ 3	0 (0%)	7 (25%)		0 (0%)
Main secondary objectives				
Complete remission**	17 (65%)	11 (39%)	p < 0.05	14 (54%)
MRD < 10-3**	9 (35%)	7 (25%)		6 (23%)
Overall Survival at 6 months	92.3%	78.6%		73.1%
Overall Survival at 12 months	76.9%	67.9%		50.0%
Event Free Survival at 6 months	75.7%	60.7%		60.4%
Event Free Survival at 12 months	64.9%	48.6%		50.3%

<sup>\*</sup>measured in whole blood \*\*at the end of induction

On May 30, 2015, the Company presented the complete results of its Phase III pivot study of GRASPA® in acute lymphoblastic leukemia (ALL) at the 51<sup>st</sup> annual meeting of the American Society of Clinical Oncology (ASCO).

The presentation was entitled:

"Clinical activity of ERY001 (erythrocyte encapsulated l-asparaginase) and native l-asparaginase (L-ASP) in combination with COOPRALL regimen in Phase III randomized trial in patients with relapsed acute lymphoblastic leukemia (ALL)".

GRASPIVOTALL is a controlled, multi-center Phase II/III randomized study comparing GRASPA® (development code: ERY001) with native l-asparaginase (L-ASP) in children and adults with relapsed or refractory acute lymphoblastic leukemia. The first positive results of the study were published at the end of last year, demonstrating that the two primary objectives had been achieved.

The main findings of the study are as follows:

• GRASPA, combined with chemotherapy, demonstrated maintenance of asparaginase activity for longer than with L-ASP in the treatment of patients with ALL. The duration of the asparaginase activity at levels greater than 100 IU/l was 20.5 days in the GRASPA group, as compared to 9.4 days in the L-ASP control arm (p<0.001).

- GRASPA has demonstrated a significant reduction in the risk of a hypersensitivity reaction, as compared to L-ASP. No hypersensitivity reactions of any nature were observed in the group treated with GRASPA, as compared to 46% in the L-ASP control arm (p<0.001).
- The prolonged asparaginase activity led to an improvement in the rate of complete remission. 65% of patients in the GRASPA group were thus in complete remission after the induction phase, as compared to 39% of patients in the control arm (p=0.026).
- The treatment was generally well tolerated, with a low risk of major incidents such as coagulation disorders (35% as compared to 82%<sup>21</sup>), pancreatic toxicity (27% as compared to 50%<sup>21</sup>), and liver toxicity (19% as compared to 43%<sup>21</sup>).
- The favorable safety and efficacy profile of GRASPA offers effective alternative options for patients who have previously been treated with asparaginase, notably those who have already developed a hypersensitivity to *E-coli* derived asparaginase.
- The plenary session ended on a positive note, with the commentator concluding by considering GRASPA as an "advance". The commentator notably has the role of providing the medical oncology community with constructive criticism on research, matters addressed, results presented, or on the ability of publications to provide new perspectives in this field of medicine.

## Phase IIb clinical trial in patients over the age of 65 with AML

A Phase IIb, multi-center clinical study is currently under way in newly diagnosed patients with AML over 65 years of age and unable to receive intensive chemotherapy. Generally, L-asparaginase is very rarely used for this indication. Although the efficacy of this treatment has been demonstrated for AML, the risk of side effects for this fragile population of often elderly patients is too great to justify the administration. The primary objective of this study is to evaluate the efficacy of GRASPA® when added to the standard product (low-dose cytarabine). To accomplish this, progression-free survival will be analyzed between patients receiving GRASPA® in combination with low-dose cytarabine, and patients receiving only low-dose cytarabine. This study plans to recruit 123 patients, 2/3 of whom will be treated with GRASPA®. The study protocol includes monitoring patients for 24 months, an analysis of the first 30 and 60 patients to analyze tolerance by a Data Safety Monitoring Board (DSMB), and a third interim analysis where sixty patients have experienced a progression of their disease.

The first analysis by the DSMB was performed in November 2013, and the second in August 2014. The committee of independent experts has issued two favorable opinions with regard to the continuation of this clinical trial after evaluation of the product's safety in the first 30 and 60 patients treated. The results at one year from the study are expected in the first half of 2017.

On May 31, 2015, the Company presented a poster on the design of the Phase IIb study in progress on acute myeloid leukemia, entitled:

"GRASPA-AML 2012-01 study: A multicenter, open, randomized Phase 2b trial evaluating ERY001 (L-asparaginase encapsulated in red blood cells) plus low-dose cytarabine vs low-dose cytaragine alone, in treatment with newly diagnosed acute myeloid leukemia (AML) elderly patients, unfit for intensive chemotherapy".

The GRASPA-AML study was launched in mid-2013. On June 1<sup>st</sup>, 2015, nearly three-quarters of the 123 patients scheduled for recruitment into the study had been treated. Two reviews have been performed by the DSMB (committee of independent experts) on 30 and 60 patients respectively. A third DSMB review, accompanied by a futility analysis, was initially planned when 60 patients had experienced an incident (progression of the illness or death). This 60-incidences review trigger recently occurred, later than anticipated. Considering the now considerably advanced recruitment of patients into the study, and to retain statistical strength for final analysis of the study ('α-spending' limit), it was decided that the futility analysis would not be performed. Futility analyses are generally performed at the start of a study to avoid useless treatments for

patients and costs for the company conducting the study. A study of the tolerance data is nevertheless planned, the results of which are expected toward the end of Q3 2015. Full recruitment to the study, in turn, should be completed by the end of this year.

## 6.5.3. Obtaining orphan drug designation and its benefits

Regulatory authorities in Europe and the United States have established marketing approval and specific reimbursement procedures for drugs to treat orphan diseases in order to encourage development efforts and innovation in connection with these diseases that affect very few patients. In particular, requirements for the necessary clinical studies are adjusted to take into account the small patient population and procedures for obtaining Marketing Approval (MA) are often facilitated and accelerated to meet public health needs.

The major advantage of this legislation is to allow manufacturing pharmaceutical companies selling products with orphan drug designation to take advantage of exclusive marketing after obtaining an MA for the product for 7 and 10 years, in the United States and Europe respectively.

The EMA and the FDA have granted Orphan Drug Designation to ERY-ASP/GRASPA® for ALL, AML, and pancreatic cancer.

## 6.5.4.Marketing GRASPA®

Based on the results from the Phase II/III clinical study in adults and children with relapsed ALL, and based on previous studies, ERYTECH will be able to file an AMM marketing approval application through the European centralized procedure in 2015.

The Company will request, from the health authorities, the broadest possible indication for its AMM. It will then be up to these authorities to accept or not, and to specify whether additional studies are necessary in order to obtain the AMM (see Section 4.4.1 and Chapter 6.1).

#### Indicative timetable

ALL: Phase II/III results in relapsed adult or pediatric patients	Q3 2014
ALL: Submission of the MA application to the EMA	2015
ALL: European MA through the centralized procedure	2016
AML: Results at one year from the Phase IIb study	S1 2017

## 6.5.5.Positioning of GRASPA® on the market

GRASPA® will be marketed by Orphan Europe (Recordati Group) in 38 European countries and by the Teva Group in Israel. The product's positioning in terms of marketing strategy will be developed in consultation with ERYTECH.

For ALL, ERYTECH anticipates that the dynamics of adopting the product will begin with the fragile populations, first with senior and older adult patients who cannot receive the current forms of L-asparaginase, and then with relapsed or refractory adult and pediatric patients who also cannot be treated with L-asparaginase. GRASPA®'s use can naturally be extended to other patients with the clinical experience acquired by oncologist-hematologists by capitalizing on GRASPA®'s proven safety.

Based on the advantages that GRASPA® could have compared to other forms of L-asparaginase and unmet medical needs, ERYTECH believes that GRASPA® could potentially be the preferred L-asparaginase treatment for one in three ALL patients or approximately 5,000 newly diagnosed patients per year (3,000 in Europe and 2,000 in the United States).

The lack of an L-asparaginase treatment that is approved and/or used in AML may allow GRASPA® to be positioned as the first-line treatment for these patients. Clinicians have expressed a strong interest in using L-asparaginase to treat AML, and ERYTECH intends to meet this demand with GRASPA®. GRASPA®'s primary target for AML represents more than 11,000 patients with AML (more than a third of new cases each year in Europe and the United States). These are patients whose type of AML is particularly sensitive to the removal of asparaginase (about 70%) and whose general health is particularly fragile (about 2 in 3 patients).

The following table illustrates the treatment costs associated with the major L-asparaginase drugs currently on the market for one round of chemotherapy (about 1 month) – considering that a given patient usually requires several. Taking into account the innovative nature of GRASPA®, its medical value and its target position in the treatment of acute leukemia, ERYTECH expects to target a price position similar to Erwinase®. It is important to remember that the pricing and reimbursement of GRASPA® will need to be determined according to the regulations and practices in force in the various countries and the health and drug delisting policies will gradually become more rigorous.

The estimated cost of treatment with the major L-asparaginase drugs

Product	One-month treatment cycle	
Troduct	Injections	Cost
Oncaspar <sup>®</sup>	2	Europe price: 2,400 – 4,800 Euros US Price <sup>21</sup> : \$11,200 – 23,000
Erwinase <sup>®</sup>	12	Europe price: 17,000 – 42,000 Euros US Price <sup>7</sup> : \$86,400 – 216,000

Source: ERYTECH

#### 6.6. Marketing GRASPA® in Europe and Israel

ERYTECH has entered into two major partnerships for the commercialization of GRASPA® in 38 European countries with Orphan Europe (Recordati Group) and in Israel with the Teva Group. Thanks to the innovative

<sup>&</sup>lt;sup>21</sup> Based on the last price per vial

nature of GRASPA®, its ability to satisfy unmet medical needs and its progress in clinical development, ERYTECH was able to obtain favorable terms, particularly with regard to the sharing of future profits. Both partners have recognized trade capacities and can effectively promote GRASPA® in their respective territories.

Furthermore, it should be noted that there are relatively few potential prescribers of GRASPA® in each country, mainly hematologist-oncologists, who are clearly identified. Therefore, awareness of specialized products such as GRASPA® and adoption of the drug can occur very quickly. In addition, GRASPA® does not require existing ALL treatment protocols to be modified since L-asparaginase is already included in them. For specialty products like GRASPA®, the commercial and promotional resources required are modest compared to other drugs in general practice for example, thereby making high margins possible.

## European partnership with Orphan Europe (Recordati Group) for placement on the market in Europe:

On November 23, 2012, ERYTECH signed a marketing agreement with Orphan Europe, a company specialized in the development, production, and marketing of drugs for orphan diseases. Orphan Europe is a subsidiary of Recordati, a major pharmaceutical group in Europe.

Orphan Europe holds a portfolio of orphan drugs already on the market in different areas, such as neonatology, pediatrics, and metabolic disorders. Orphan Europe is a leading player in the field of orphan diseases and has the medical, clinical, regulatory and commercial expertise to market and effectively sell GRASPA<sup>®</sup> in Europe. Orphan Europe is a strategic business for Recordati, which acquired the company in 2007 for €135 million and built it up further with the acquisition of a portfolio of rare and orphan disease drugs in the United States for \$100 million.

Orphan Europe will market GRASPA® in 38 European countries, including all the countries in the European Union for the treatment of ALL and AML. The parties have the opportunity to discuss the extension of this agreement to other areas around Europe and other indications.

ERYTECH is keeping the production of GRASPA® at its Lyon site and will supply Orphan Europe in the various European countries where the drug will be sold.

Under this agreement, Orphan Europe contributed €5 million upon signing. Orphan Europe will have to pay ERYTECH up to €37.5 million in future payments based on various clinical, regulatory and sales events, and Orphan Europe will participate in the costs of the clinical development of GRASPA® in AML. ERYTECH will receive a price for product delivered, and royalties on the sales performed by Orphan Europe with GRASPA®, for a total of up to 45% of the net sale price.

Separately, another Recordati Group company has purchased bonds that were converted into an investment in ERYTECH equity worth €5 million at the time of the initial public offering in April 2013.

#### Partnership with the Teva Group for placement on the market in Israel:

On March 28, 2011, ERYTECH signed a partnership agreement with the Teva Group, a global player in the pharmaceutical industry based in Israel, to distribute GRASPA® in that country. The Teva Group is a diversified pharmaceutical group with a strong strategy in innovative specialized products and particularly in therapeutic areas such as the central nervous and respiratory systems, women's health, oncology, and pain.

In accordance with the terms of the agreement, the Teva Group will submit the request for approval of the drug for ALL in Israel and ensure marketing and distribution in the long term in this country. The Teva Group will pay interim payments and share net earnings of product sales in Israel.

#### Other partnerships under consideration for other countries:

ERYTECH retains all rights to ERY-ASP outside the 38 European countries covered by the partnership with Orphan Europe (Recordati Group) for ALL and AML, and in Israel with the Teva Group for ALL. In particular, ERYTECH owns all rights for ERY-ASP in the United States and for other indications such as, for example, solid tumors.

ERYTECH aims to secure distribution agreements in countries surrounding Europe, and particularly key markets such as Russia and Turkey. In some of these countries, Orphan Europe (Recordati Group) has a right of first negotiation.

## Commercial scale industrial process and secure supply

The Company has a production unit with enough capacity to cover the needs of the European market for 2-3 years after initial placement on the market. This unit meets the highest requirements of ANSM and has "Operating Pharmaceutical Facility" status.

The company has secured its supply for the main raw materials needed to manufacture ERY-ASP/ GRASPA®:

L-asparaginase: ERYTECH Pharma and Medac have signed two worldwide exclusive long-term agreements according to which Medac supplies ERYTECH with two forms of asparaginase that ERYTECH uses for the production of ERY-ASP/GRASPA®, for clinical trials and for the sale of ERY-ASP/GRASPA®, for the therapeutic indications defined by ERYTECH. Medac is a German pharmaceutical company based near Hamburg and selling L-asparaginase (*see also Chapter 22 of the Reference Document*).

Red blood cells: ERYTECH signed two supply contracts with the Établissement Français du Sang [French Blood Facility] and the American Red Cross, two well-known blood banks, for transfusion quality human red blood cells.

## 6.7. Development of ERY-ASP for leukemia in the United States

ERYTECH's goal is to develop ERY-ASP in the United States, which represents a significant potential market for ALL and AML.

ERYTECH plans to capitalize on the clinical studies already completed or underway in Europe and replicate the clinical development of ERY-ASP in the United States. On March 21, 2013 ERYTECH obtained approval from the FDA (Investigational New Drug or IND) to begin a Phase Ib clinical trial in ALL, and began recruiting its first patients in the third quarter of 2014. The estimated cost of this Phase Ib clinical study is approximately 4 million Euros, and the Group intends to finance it with funds raised from the initial public offering. This study will also make it possible to pursue clinical development for ALL and AML alone or in a partnership. Further clinical development may include Phase II/III studies for ALL and AML and could make it possible to file an authorization for placement on the market within the 2018/2019 horizon.

ERYTECH has established a close partnership with the American Red Cross in Philadelphia. Under this agreement, the American Red Cross will provide red blood cells, a classified production area and staff trained by ERYTECH, under the supervision of an ERYTECH representative sent to Philadelphia.

In April 2014, ERYTECH created a subsidiary in the United States (Cambridge) under the name of ERYTECH Pharma Inc., 100% held by the parent company, ERYTECH Pharma.

## **Development plan in the United States**



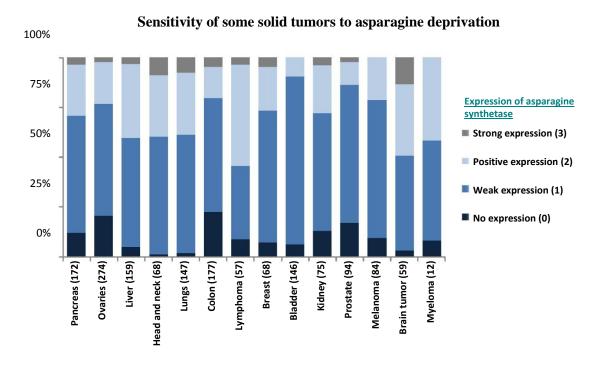
Phase Ib clinical study in patients over the age of 40 for the first-line treatment of ALL

In 2013, ERYTECH launched a Phase Ib clinical study in the United States for patients greater than 40 years of age without the Philadelphia chromosome as first-line treatment in ALL, in combination with the standard chemotherapy (CALGB chemotherapy in the United States), in a sample of 12 to 18 patients with escalating doses (50 to 150 IU/kg).

This multicenter, non-randomized clinical trial strictly in the United States aims primarily to validate the toxicity, safety and efficacy profile of ERY-ASP, in combination with standard chemotherapy. This Phase Ib study is the first clinical trial conducted by ERYTECH in the United States. As a toxicity study, the results will also be used in the Phase I AML study.

#### 6.8. Potential new indications for ERY-ASP: Solid tumors

As for leukemia, the rationale for treating tumor cells deprived of asparagine synthetase (see figure 1 in Section 6. Illustration of the "Starving tumor" concept) is also applicable to solid tumors as long as they do not produce asparagine synthetase and need to consume asparagine contained in plasma. Thus, ERYTECH conducted a study in collaboration with the MD Anderson Cancer Center to assess the proportion of tumors potentially sensitive to asparaginase, i.e., tumors that produce little or no asparagine synthetase.



Source: Dufour et al., "Pancreatic Tumor Sensitivity to Plasma L-Asparagine Starvation," Pancreas, 2012

ERYTECH also validated an immunohistochemistry test using tumor tissue to detect whether the tumor produces asparagine synthetase and therefore whether it is resistant or sensitive to asparaginase.

Moreover, the Company entered into an exclusive license agreement with the NIH to develop a companion test to determine tumor sensitivity to asparaginase. This test could be used in clinical studies and be commercially developed with an industrial partner.

ERYTECH has conducted a Phase I study on pancreatic cancer to demonstrate the safety of ERY-ASP. This clinical trial demonstrated that ERY-ASP was well tolerated even at high doses. With these initial clinical results for solid tumors, ERYTECH plans to continue to develop ERY-ASP for pancreatic cancer and expand this development to other solid tumors of interest.

ERYTECH is developing possible new indications for ERY-ASP outside the area of leukemias and pancreatic cancer. Initial pre-clinical and clinical results suggest that ERY-ASP could also be effective against certain solid tumors for which therapeutic options are currently reduced. ERYTECH is preparing for the launch of a Phase II study on non-Hodgkin lymphoma.

## Phase I and Phase II clinical studies on pancreatic cancer

From 2009 to 2010 (12 months), ERYTECH conducted a Phase I, non-randomized, dose-escalation clinical trial on 12 patients in France. This clinical trial demonstrated that ERY-ASP is well tolerated in this highly fragile population, even at the highest dose (150 IU/kg).

Based on these initial clinical results with solid tumors, ERYTECH has continued the development of ERY-ASP in pancreatic cancer in a Phase II study in patients as a second-line treatment.

The Phase II study involves a total of 90 patients randomized 2 to 1 between the standard treatment (Gemcitabine or Folfox) with or without ERY-ASP.

Clinical study	Status	Number of patients included in the study
Phase I study on pancreatic cancer (France)	Completed	12
Phase II study on pancreatic cancer (France)	Ongoing	90
TOTAL		102

## **6.9. ERYTECH's encapsulation technology**

## 6.9.1. The innovative approach to encapsulate therapeutic enzymes

ERYTECH's proprietary technology is based on the encapsulation of therapeutic molecules in red blood cells also called erythrocytes. The administration of red blood cells is completely managed and controlled by the hospital staff. In addition, it is a biocompatible carrier with a long half-life in the body of about one month and its elimination by the cells of the reticuloendothelial system is well known.

Because the red cell membrane protects its contents from the external environment, i.e., the body, and vice versa:

- The encapsulated molecule is protected from the body's defense reactions or interactions with it, which can lead to inactivation, degradation or to its rapid elimination,
- The body is protected against attack from the contents and as a result, side effects are reduced.

This results in an increase of the therapeutic index (toxicity offset by efficacy). For example, in the case of asparaginase, for a given level of efficacy, patients receive a dose 10 times lower when it is encapsulated using ERYTECH's technology.

ERYTECH's technology can transform the red blood cell into a cellular bioreactor. The red blood cell has the natural property of being able to absorb certain amino acids freely circulating in the blood. The therapeutic enzyme encapsulated in the red blood cell can interact and break down the amino acid in question.

# 6.9.2. Automated and strong industrialized encapsulation process

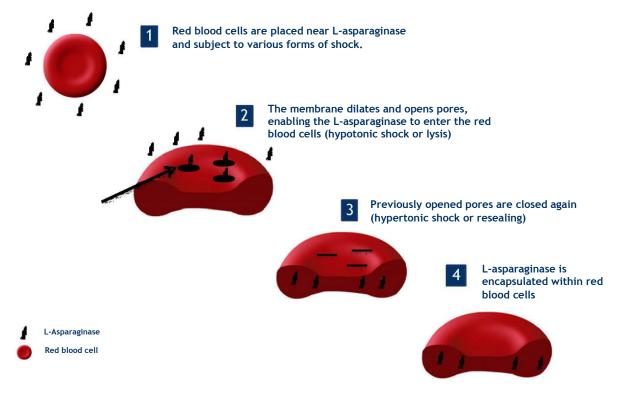
The process of encapsulation inside red blood cells is based on a concept of reversible hypotonic lysis as shown in the diagram below:

Red blood cells are subjected to a low-ionic strength medium (hypotonic medium) and swell until they reach a critical volume when the membrane is distended to the point of becoming permeable to macromolecules.

Pores form on the surface of the membrane allowing molecules to enter the erythrocyte.

Restoration of the isotonicity of the suspension medium results in the closing of the pores, rendering the membrane impermeable to macromolecules. Only permeability to very small elements (less than 200 Daltons) is retained. The molecule is thus permanently encapsulated.

Principle of the encapsulation process



The osmotic fragility of one sample of red blood cells to another varies. Thus, the membrane distension capacity and therefore the encapsulation capacity varies. However, osmotic fragility variation may be offset by hypotonic lysis parameters. Thus, variations in the amount of the product encapsulated are reduced. This is the heart of ERYTECH's process patent (*see Section 11 on Intellectual Property*).

ERYTECH has successfully developed this encapsulation process to produce loaded erythrocytes in a reproducible, reliable and economical way on a large scale, regardless of the initial characteristic and origin of the red cells used. More than 300 bags of ERY-ASP/GRASPA® have already been produced and transfused in five clinical trials conducted by ERYTECH.

An automated and industrialized encapsulation process



Specifically, the major competitive advantages of the production process are:

- its speed: the fully automated preparation of the product requires only 3 hours,
- its stability: 72 hours to deliver the drug (at a temperature of 2-8°C),
- reproducibility: consistent quality loaded erythrocytes are produced, regardless of the initial characteristics and the origin of the red blood cells used. Various control steps ensure the quality of the product before release by the chief pharmacist,
- its safety: supply of transfusion-quality red blood cells from blood banks operating in accordance with the highest quality standards and quality control processes strengthened at each stage of production.

ERYTECH's production unit is based in Lyon and the production staff includes 6 people. Production meets the highest pharmaceutical production standards (cGMP) and is ISO 9001 certified. In particular, product batches are fully traceable from blood collection and separation of red blood cells performed by the blood banks that supply ERYTECH to the patient. The Company has "Pharmaceutical Company" and "Operating Company" status, which allows it to operate on the European market.

## 6.9.3. Organized production in the United States for future clinical trials

In anticipation of clinical trials in the United States, ERYTECH deployed a qualified production unit in Philadelphia in partnership with the American Red Cross (ARC). The American Red Cross (ARC) is the leading blood bank in the world. It is a federal agency located in all states in the United States of America and its primary activity is collecting, classifying and distributing bags of red blood cells for transfusion.

The ARC is the service provider for the production of GMP (Good Manufacturing Practice) batches of ERY-ASP for clinical trials. The ARC also provides the raw material, the bag of red blood cells. Since ERYTECH's analytical method and process were the subject of an industrial transfer, the operations performed at the U.S. site are similar to those at the French site in compliance with FDA regulations. ERYTECH oversees production and controls for this unit jointly with the ARC.

This agreement with the ARC does not include any transfer of rights to technology or to ERY-ASP, and allows ERYTECH to produce the quantities needed for clinical trials planned in the United States.

#### 6.10. TEDAC and other projects under development

ERYTECH's technology platform is versatile and opens up many possibilities for developing new drugs. The efficacy of the technology has been demonstrated mainly with L-asparaginase, but it is possible to encapsulate other enzymes, molecules or proteins in red blood cells.

#### **TEDAC/ERY-MET**

TEDAC is a research and development project meant to treat cancers resistant to radiation/chemotherapy conducted by ERYTECH in association with other companies and organizations: Diaxonhit, Inserm, Université Paris-Diderot [Paris-Diderot University] and AP-HP [Public Assistance - Hospitals of Paris].

The purpose of this project is to develop innovative enzyme therapies targeting the metabolic environment of tumors, provide individual care to patients with chemotherapy or radiation-resistant cancer thanks to the development of screening, and monitoring tests. This project will also enable the Group to develop a new range of therapeutic solutions by combining anti-cancer enzymes efficiently and safely by acting on the complete metabolic environment of the tumor. Over time, the goal is to offer a solution including a test predicting response to treatment, one or more suitable enzyme therapies, as well as a test to monitor therapeutic efficacy.

This project has a total cost of 22.6 million Euros (14.3 million Euros for which ERYTECH shall be responsible) and will take place over 8 years; €10.7 million is being provided by Oséo (BPI) to fund it under the "Strategic and Industrial Innovation" program, of which €7 million will be paid to ERYTECH (i.e., 48% of the project amount for which ERYTECH is responsible). €2.1 million in grants and €4.9 million in repayable advances.

This made it possible to identify a new drug candidate, ERY-MET, composed of methionine-γ-lyase (MGL) encapsulated in red blood cells. MGL breaks down methionine, an amino acid, and may thus starve very many types of tumors sensitive to the elimination of this amino acid.

In its natural form, MGL has a very short half-life and is highly dependent on a co-factor to be effective. However, this co-factor has the special characteristic of being naturally present within red blood cells. With its exclusive encapsulation technology, ERYTECH demonstrated good stability of MGL in red blood cells, and the increase in its half-life to several days compared to some hours in its free-form.

On the basis of these promising pre-clinical results, the Company is continuing its pre-clinical development for the purpose of performing a clinical trial. The production industrialization phase has been launched with a view to providing for the launch of a Phase I study in humans at the end of 2015/start of 2016.

#### Vaccin'ERY System®

This is the development of a new anti-tumor vaccine using the Vaccin'ERY System® technology by intraerythrocyte encapsulation of tumor antigens and adjuvant(s) to enable in situ activation of immune cells and generate an immune response.

The use of red blood cells as tumor-specific antigen carriers makes it possible for them to be delivered specifically and simultaneously to dendritic cells, immune cells. Red blood cells are processed to direct themselves toward dendritic cells which will capture them, the phagocytes, and thus incorporating the antigens associated with the tumor cells. This results in a classic immune response, i.e., the immune cells introduce these antigens to lymphocytes which are stimulated to specifically become cells responsible for destroying the tumor.

Furthermore, this technology also makes it possible to consider the encapsulation of adjuvants in order to optimize the efficacy of the vaccination.

#### Tol'ERY

Red blood cells can be modified to more specifically target "tolerogenic" cells, i.e., that induce tolerance such as Kupffer cells in the liver. Thus, the tolerogenic cells phagocytose the loaded red blood cells in one immunogenic protein and will generate a tolerogenic response vis-à-vis the immunogenic protein. The purpose is to give the body the ability to make proteins normally not well tolerated tolerable and can induce immune reactions (allergy). ERYTECH Pharma has already achieved very encouraging results for its innovative strategy of inducing immune tolerance (patent pending). This technology is also applicable to autoimmune diseases.

#### **ENHOXY**

ENHOXY® could be a product able to quickly and effectively improve tissue oxygenation to avoid or significantly reduce sickle deformation, and thus heal and prevent the crisis. It consists in the encapsulation of a molecule that will make it possible to allow a greater salting out of oxygen in the presence of the hypoxic cells or tissues, compared to a normal red blood cell. Preclinical results in the study were presented at different international conferences and resulted in strong interest.

However, and due to its prioritization decisions, the Company has decided to suspend this research program for an undetermined period.

## 6.11. The pharmaceutical industry's interest in orphan drugs

The market for orphan disease therapies was estimated at \$50 billion in 2011, or about 6% of the global pharmaceutical market. Over the 2001-2010 period, this market grew rapidly with an estimated 26% CAGR, compared to 20% for other drugs (source: Thomson Reuters).

Rare or orphan diseases are characterized by having a low incidence rate. In the United States, the definition used by the FDA includes diseases affecting fewer than 200,000 people and in Europe, those affecting fewer than 5 patients per 10,000 persons (EMA definition). Approximately 6,800 orphan diseases have been identified<sup>22</sup> and each year, several hundred new orphan diseases are discovered.

Although the orphan drug designation has been established since 1983 by the FDA in the United States (Orphan Drug Act) and since 2000 by the EMEA [sic: EMA] in Europe, only in the last decade have applications for orphan drug designation and the interest in this market segment increased sharply. The number of drugs that have obtained orphan drug designation in the United States has more than doubled over the past 10 years, from 208 in 2000-2002 to 425 in 2006-2008. (Source: Tufts Center for the Study of Drug Development study). Since 1983, more than 2,000 drugs have received this designation and 350 were approved. These figures confirm clear success in the implementation of this specific regulation, which has since been adopted in Japan, South Korea, China and Singapore.

The interest of large pharmaceutical groups has grown steadily since the mid-2000s and the last decade has been the most productive for the development of orphan drugs. The number of transactions, in the form of acquisitions or partnership agreements involving pharmaceutical groups, has clearly increased since 2010. For example, following a licensing agreement with Protalix Therapeutics on a treatment for Gaucher's disease signed in December 2009, Pfizer decided to make orphan drugs one of the group's development focus points and created an R&D division specialized in the study of rare diseases in June 2010. Similarly, after signing a strategic agreement with Isis Pharmaceuticals in April 2010 and an exclusive partnership agreement with Prosensa, including the marketing of a treatment for Duchenne muscular dystrophy in October 2009, GlaxoSmithKline created a dedicated division called GSK Rare Diseases. Finally, Sanofi accessed this market in February 2011 with the acquisition of Genzyme, one of the first companies to have organized its business model around orphan diseases, selling in particular Cerezyme and Fabrazyme.

## Examples of transactions in the field of orphan diseases

Date	Purchaser	Target	Amount
Dec. 2007	Recordati	Orphan Europe	\$193 million
Jan. 2010	Sigma-Tau	Enzon Pharmaceuticals	\$327 million
Jan. 2010	Biovitrum	Swedish Orphan	\$500 million
Sept. 2010	Pfizer	FoldRx	\$200 million
Oct. 2010	GSK	Amicus Therapeutics (20%)	\$260 million
April 2011	Sanofi	Genzyme	\$19.5 billion

22 Source: Cliff Mintz, PhD, "Orphan Drugs: Big Pharma's Next Act?" Life Science Leader, October 2010

Mar. 2012	Shire	FerroKin Biosciences	\$325 million
June 2012	Jazz Pharmaceuticals	EUSA Pharma	\$700 million
Dec. 2012	Recordati	Portfolio of 10 Lundbeck U.S. products	\$100 million
August 2013	Amgen	Onyx Pharmaceuticals	\$10.4 billion
Nov. 2013	Shire	ViroPharma	\$4.2 billion
Jan. 2014	Jazz Pharmaceuticals	Gentium	\$1.0 billion
March 2015	Teva Pharmaceuticals Industry	Auspex Pharmaceuticals Inc	\$3.5 billion

**ERYTECH** 

Source: Mergermarket, press

Orphan diseases represent a promising segment of the pharmaceutical industry given the significant unmet medical needs. In addition, the business model for these drugs has strong appeal for pharmaceutical companies of all sizes, particularly thanks to easy market access, a period of market exclusivity and data protection, high prices and reduced sales and promotional efforts. A number of biotechnology companies such as Genzyme have also successfully developed around this orphan disease model.

## 6.12. Environmental, social and corporate responsibility policy

See appendix 2 of the Reference Document

#### 7. ORGANIZATION CHART

As of the date of this document, the Company does not have any branches or secondary facilities. It wholly owns the subsidiary "ERYTECH Pharma, Inc.", created in Delaware (US) on April 9, 2014. The purpose of the subsidiary is:

- the research, manufacture, import, distribution, and marketing of experimental drugs, drugs, devices, and equipment;
- the provision of all advisory services associated therewith;
- and generally, all financial, commercial, industrial, civil, property, or security-related transactions, such as may directly or indirectly relate to one of the purposes specified or such as may facilitate their fulfillment.

Its directors are Gil BEYEN (President) and Pierre-Olivier GOINEAU (Treasurer and Secretary).

Its share capital is one dollar.

The Group's consolidation perimeter is presented in the IFRS consolidated financial statements under Chapter 20.1, Section 5.5.

## 8. REAL ESTATE PROPERTY, MANUFACTURING PLANTS AND EQUIPMENT

#### 8.1. Real property

The Company leases the premises located at Bâtiment Adénine -60 avenue Rockefeller -69008 Lyon. It does not own any real estate.

The items pertaining to these leases are summarized in the table below:

Address	Nature of the premises	Lease date of effect	Term	Rent
Bâtiment Adénine 60 Avenue Rockefeller 69008 Lyon	Commercial (Laboratories and Offices)	24/09/2007	23/09/2016	€396,292 excluding tax, for rent and rental charges
France				Re-invoicing share of property tax

In addition, the Company owns the following significant assets:

type of equipment	year ofacquisition	Before-tax value
Electronic document management	2010	50,587.53
Electronic document management	2014	8,000.00
	2004	19,000.00
	2006	22,125.00
Equipment dedicated to production	2007	39,535.00
Equipment dedicated to production	2008	63,589.60
	2009	28,000.00
	2014	372,264.00
General systems & layout	2007	42,599.92
General systems & layout	2008	47,098.01
Contains to an local and the	2008	615,413.56
Systems at production sites	2009	130,329.70
IT systems	2013	47,298.42
	Total	1,485,840.74

The Company also uses a significant amount of equipment located at the production or pre-clinical research site financed through leasing-purchase agreements or "lease-backs":

type of equipment	year of acquisition	Before-tax value
	2010	110,104.49
Equipment dedicated to production	2011	40,000.00
	2013	240,413.00
	Total	390,517.49

# 8.2. Environmental constraints that may affect the use of assets

With the exception of the risks described in Section 4.2 "Risks related to health, safety and the environment", the Company has no environmental impact that could affect the use of its tangible assets (see also Annex 2 of the Reference Document "Environmental, Social, and Corporate Responsibility Policy").

# 9. EXAMINATION OF THE RESULTS AND FINANCIAL POSITION

#### 9.1. Overview

The Group's main activity is research and development in the areas of treatment of acute leukemias and other orphan diseases.

Since its creation, the Group has concentrated its efforts:

- On the development of a patented technology based on the encapsulation of molecules in the red blood cells, offering an innovative approach to the treatment of acute leukemias and other solid tumors. Development of the main product, ERY-ASP, initiated upon creation of the Group, has led to the issue of 10 patent families held by the Company. The Group has likewise established a patented industrial process capable of producing clinical batches of ERY-ASP, and capable of responding to demand upon the product's placement on the market.
- The implementation of clinical study programs intended initially to validate Graspa® in terms of safety of usage and toxicology through a Phase I clinical study on ALL in adult and pediatric patients with a relapse of ALL. Based on the results obtained, the Group performed a Phase II clinical study that likewise demonstrated the safety of the product's use and its efficacy in patients older than 55 years of age with ALL. The Group has completed a Phase II/III clinical study, at the end of which Erytech intends to file an application, in 2015, for approval for the placement of Graspa® on the European market for the treatment of ALL. The Group has likewise initiated a Phase IIb study on acute myeloid leukemia (AML), as well as a Phase II study on pancreatic cancer.

The Group's business model is to develop its products up to the point of obtaining authorization for their placement on the market in Europe and then in the United States. Commercial partnerships established by Erytech will allow for the distribution of ERY-ASP to be ensured first in Europe and then in the United States and in the rest of the world. Erytech has the capacity to ensure the supply of Graspa® for the first years of its sale in Europe, through its production unit in Lyon.

# 9.2. Comparison of the last two years

The comparison of the last two financial years below concerns the financial statements presented in accordance with IFRS standards. The financial statements prepared in accordance with French standards are commented on in Chapter 20.

## 9.2.1. Operating profit breakdown

## 9.2.1.1. Sales revenue and other income from activity

The other income from activities is composed of the following elements:

as of Dec. 31 in thousands of €	2013	2014
Sales revenue	-	-
Other earnings	1,802	2,026
Research tax credit	1,367	1,524
Earnings from ongoing activities	1,802	2,026

The other income was primarily generated by the research tax credit and the grants associated with the preclinical research programs in partnership with BPI France.

The "Other income" totaled €230,769 in 2014, representing the sum of the internal costs sustained by the Group within the scope of the AML study, and re-invoiced to the company Orphan Europe to this end. The other external costs associated with this clinical trial were re-invoiced to Orphan Europe with no margin, and do not appear under income from activities, but rather deducted from the associated expenses.

## 9.2.1.2. <u>Operating expenses</u>

#### Cost of sales

At December 31, 2014, no cost of sales existed relative to the manufacture of batches of GRASPA<sup>®</sup>. Costs related to the manufacture of ERY-ASP within the context of pre-clinical studies or clinical trials are included in the fees for R&D and clinical studies.

#### Expenditures for research and development

In accordance with IAS 38, "Intangible Assets," research expenditures are accounted for in the period during which they are incurred.

An intangible asset internally generated relating to a development project is booked as an asset if, and only if, the following criteria are met:

- Technical feasibility required to complete the development project;
- Intention to complete the project, use or sell it;
- Demonstration of the probability of future economic benefits related to the asset;
- Availability of appropriate resources (technical, financial and other) to complete the project;
- Ability to reliably assess the expenditures attributable to the development project underway.

The initial assessment of the development asset is the sum of expenditures incurred from the date on which the development project meets the criteria above. When these criteria are not met, development expenditures are accounted for in the period in which they are incurred.

According to IAS 38, "Intangible Assets," development costs must be accounted for as intangible assets when specific conditions relating to technical feasibility, marketability and profitability are met. Considering the strong uncertainty associated with the development projects performed by the Group, these conditions will only be met when the regulatory procedures necessary for placement of the products on the market have been finalized. Most of the expenditures being incurred before that stage, the development costs, are accounted for in the period in which they are incurred.

Over the periods presented, the total amount of expenditures for research and development increased sharply from €5,328 k in 2013 to €6,613 k in 2014. Research and development efforts have focused primarily on the TEDAC program, Phase II/III clinical studies on ALL in pediatric and adult patients, the launching of a Phase II study on ALL in the USA, as well as a Phase II study on solid tumors in France.

Research and development expenses during the periods presented are listed by type as follows:

as of Dec. 31 in thousands of €	2013	2014
R&D costs personnel costs	2,503 1,332	2,244 1,351
Clinical studies personnel costs	2,462 <i>815</i>	3,875 1,017
Intellectual property costs  personnel costs	363 98	493 <i>75</i>
Total research costs	5,328	6,613

R&D costs mainly include costs related to preclinical studies and fees for consultants and scientists. These costs fell considerably in 2014, due to a general refocusing of the department on the TEDAC program.

Costs related to clinical studies primarily include costs of raw materials related to the purchase of supplies necessary for the production of clinical batches of GRASPA®, the staff dedicated to ERYTECH's clinical studies, as well as the outsourcing of monitoring and other services.

This table shows the significant increase in the clinical trials item from 2013 to 2014, due to the high level of clinical activity as mentioned above.

Costs associated with intellectual property likewise experienced a significant increase from 2013 to 2014, due to an increase in subcontracting through Cabinet Lavoix for the protection of its intellectual property.

# General expenses

General expenses primarily include the costs of administrative staff, overhead costs for the head office, external expenses such as accounting, legal, human resources, marketing and communications expenses, as well as travel expenses (excluding scientific conferences).

They totaled €3,587 k and €4,361 k for the financial years ending December 31, 2013 and 2014.

as of Dec. 31 in thousands of $\epsilon$	2013	2014
Overhead and general costs	3,587	4,361
personnel costs	1,840	2,368

The Company recorded a significant increase in its structural costs and general expenses, notably associated with the development of its strategy in the USA, as well as the performance of its capital increase on Euronext in October 2014.

#### Personnel costs – Share subscription warrants (BSA) and Founder Subscription Warrants (BSPCE)

Share options were allocated to the directors, to certain employees, as well as to members of the board of directors in the form of Share Subscription Warrants ("BSA") or Founder Subscription Warrants ("BSPCE") during the extraordinary general meeting of 05/21/2012. The exercise price for the warrants allocated is equal to the market price of the shares at the date of authorization to issue the warrants.

These warrants may only be effectively exercised where a triggering event occurs (such as a M&A or IPO). Since the Company has been listed on NYSE Euronext since May 6, 2013, the warrants may, in fact, be exercised at any time.

The BSAs and BSPCEs allocated in 2014 are acquired immediately, hence the accounting treatment representing their full market value posted as an expense for the financial year (no spreading out over an acquisition period).

On January 22, 2014, the Board of Directors moreover used the delegation granted by the combined general shareholders' meeting of April 2, 2013, in its twenty-fifth resolution, to decide on a plan for the free allocation of 22,500 founder subscription warrants (hereinafter entitled BSPCE<sub>2014</sub>) to the benefit of Erytech directors (12,000 warrants) and to a category of "employees with management status" not yet identified by name (10,500 warrants).

Concerning the directors and in accordance with IFRS 2, it was considered that the entirety of the 12,000 warrants were assigned on January 22, 2014. The fact that the directors can only subscribe to one third of these warrants each year constitutes a condition of service. In other words, these warrants form the object of a gradual 3-year acquisition period.

Moreover, the board of directors' meeting of December 4, 2014 transformed 3,000 BSPCE $_{2014}$  into 3,000 BSA $_{2014}$  for a Medical Director at the subsidiary ERYECH PHARMA INC., in accordance with Annex IV-BSA $_{2014}$  Regulations, as recorded in the minutes. This allocation is conditional upon the recruitment of a person to this position. As this suspensive clause has not yet been lifted, these BSA $_{2014}$  had no accounting effect on the 2014 financial year.

## 9.2.1.3. Net income breakdown

#### Earnings and expenses

The net financial results showed a profit of 668 k for 2014, as compared to a loss of 61,100 k in 2013.

Net cost of debt includes interest charges on financial liabilities (cost of gross financial liabilities integrating financial costs, issue costs on financial liabilities) consisting of loans and other financial liabilities (including overdrafts and liabilities on finance leases), less income from cash and cash equivalents. Other financial income and expenses consist of other fees paid to banks for financial transactions, and the impact on the income from marketable securities.

The breakdown of the item is shown in the table below:

as of Dec. 31 in thousands of €	2013	2014
Interest on leasing	(5)	(7)
Interest on bonds	(1,059)	
Financial charges	(56)	(43)
Net cost of debt	(1,120)	(50)
Earnings (losses) from disposal of VMP	20	141
Other Financial Income	3	1
Other Financial Charges	(3)	(23)
Other income & financial charges	20	118
Total Income (Loss)	(1,100)	68

This table primarily shows that, for the periods presented:

- Interest on leases slightly increased from 2013 to 2014, due to a new lease financing agreement;
- Interest on bonds sharply decreased due to the conversion of bonds in May 2013;
- This resulted in an downward shift in the net cost of debt, which decreased from €1,120 k in 2013 to €50 k in 2014;
- Earnings on investment securities correspond to interest on term deposits.

#### Corporate taxes

Given the deficits over the past 3 financial years, the Company has not recorded corporate tax expenses, nor taxable income associated with activation of the loss that can be carried forward.

## 9.2.1.4. Net income and net income per share

The loss per share issued (weighted average number of shares in circulation during the financial year) amounted respectively to 1.74 Euros for the financial year ending in 2013 (taking into account the division of the nominal value of shares decided in the general meeting of April 2, 2013) and 1.51 Euros for the financial year ending in 2014.

## 9.3. Non-deductible expenses

The Company has made the following tax add-backs to its earnings:

- tax on company passenger vehicles, for 5,310 Euros,
- excess depreciation on passenger vehicles rented, for 13,545 Euros.

## 9.4. Balance sheet analysis

#### **9.4.1** Assets

#### 9.4.1.1. Non-current assets

Net non-current assets amounted to €910 k at December 31, 2013 and €1,080 k at December 31, 2014 respectively.

Non-current assets include tangible and intangible assets (concessions, patents, licenses, software), non-current financial assets (deposits and sureties), and deferred taxes.

as of Dec. 31 in thousands of €	2013	2014
NON-CURRENT ASSETS		
intangible assets	14	31
tangible fixed assets	813	967
non-current financial assets	83	82
deferred tax assets	-	-
TOTAL NON-CURRENT ASSETS	910	1,080

In 2014, there was an increase in tangible assets, primarily dedicated to the production site.

Moreover, non-current financial assets primarily consisting of deposits and sureties have remained relatively stable over the last two financial years.

Loss carry forwards were capitalized only up to the amount of deferred tax liabilities; the amounts capitalized were not significant.

#### 9.4.1.2. Current assets

Net current assets amounted to €17,039 k and €39,526 k in 2013 and 2014 respectively.

In 2014, the amount of net current assets increased significantly due to the fact that the capital increase strengthened the Group's cash flow, and due to the increase in the research tax credit as a result of the very significant increase in research activity.

as of Dec. 31 in thousands of $\epsilon$	2013	2014
CURRENT ASSETS		
Inventories	138	198
Clients & associated accounts	87	105
Other current assets	1,701	2,235
research tax credit	1,367	1,524
tax receivables & other receivables	204	494
prepaid expenses	101	217
other grants receivable	29	-

Cash & cash equivalents	15,113	36,988
TOTAL CURRENT ASSETS	17,039	39,526

#### 9.4.2 Liabilities

## 9.4.2.1 Equity

Equity was mainly affected by:

- the capital increase in October 2014,
- the exercise of share subscription warrants,
- as well as the period results, recording a loss of €6,479 k.

#### 9.4.2.2 <u>Non-current liaiblities</u>

This is essentially the non-current portion of lease commitments, repayable advances received and, to a lesser degree, pension commitments in accordance with IAS 19.

as of Dec. 31 in thousands of €	2 013	2 014	
NON-CURRENT LIABILITIES			
Provisions, portion at greater than one year	117	89	
Financial liabilities - Non-current portion	731	436	
repayable advances	511	292	
leases	220	144	
Deferred tax liabilities	-	-	
Other non-current liabilities	-	-	
TOTAL NON-CURRENT LIABILITIES	848	525	

## 9.4.2.3 <u>Current liaiblities</u>

This balance sheet item primarily includes short-term liabilities relating to supplier debts, tax and social security debts (employees and social security entities), the non-current portion of sums related to repayable advances granted by OSEO (see point 7.9.1 of the annex, section 20.1) and, lastly, deferred income.

as of Dec. 31 in thousands of $\epsilon$	2013	2014	
CURRENT LIABILITIES			
Provisions, portion at less than one year	-	-	
Financial liabilities - Current portion	281	334	
Trade payables & related accounts	1,421	2,085	
Other current liabilities	1,812	1,840	
tax & social security debts	816	971	
deferred income	649	368	
TOTAL CURRENT LIABILITIES	3,514	4,258	

Total current liabilities increased significantly from 2013 to 2014, essentially due to the increase in supplier debts.

#### 10. CAPITAL RESOURCES AND CASH

# 10.1. Information on the Company's capital, liquidity and capital resources

Also refer to the notes accompanying the financial statements prepared according to the IFRS standards contained in Chapter 0 of the Reference Document. At December 31, 2014, the amount of cash and cash equivalents held by the Group amounted to €36,988 k, as compared to €15,113 k at December 31, 2013.

Cash and cash equivalents include liquid assets and current financial instruments held by the Group (exclusively money-market mutual funds and non-interest bearing short-term bank deposits). These liquid assets will serve to fund the Group's business activities, notably its expenses for research and development and clinical study programs.

Moreover, the Group also retains the potential use of the liquidity contract, for which the management envelope totaled  $\in$ 200 k at December 31, 2014.

Between its establishment in 2004 and December 31, 2014, the Company has received the following sources of funding:

- several rounds of financing by issuing new shares in several categories: ordinary shares, Class P, U and A preferred shares for total gross proceeds of €18 million as of December 31, 2012,
- initial public offer of the Company for total gross proceeds of €16.6 million,
- a second round of funds raised on the stock market in 2014, for 30.7 million Euros,
- the granting of repayable advances by Oséo for a total of €5,711 k, of which €878 k had been received at December 31, 2014,
- reimbursement of the research tax credit, in the total amount of €5,575 k.

The financial status is presented below:

as of Dec. 31 in thousands of €	2013	2014
Cash and cash equivalents (a)	15,113	36,988
Current financial liabilities (b)	281	334
Non-current financial liabilities (b)	731	436
Financial debt (b+c)	1,012	770
Net financial debt $(b) + (c) - (a)$	(14,101)	(36,219)
Net financial position	14,101	36,219

# Capital financing

At December 31, 2014, the Company had received a total of 64 million Euros during successive rounds of financing and following the Company's initial public offering.

## Financing by repayable advances

The Group did not undertake any bank loans in the 2 financial years presented. However, during 2011, 2012, and 2013, it received €878 k out of a total of €5,711 k granted as conditional advances forming the object of three contracts relating to repayable advances for innovation projects with Oséo/BPI France.

The Group received no new payments in the year 2014: only one contract is still ongoing (TEDAC) and thus in a phase of assistance payments, but the corresponding expenses allowing for new drawdowns on funds have not been reached. However, the Group is clearly within the anticipated schedule with regard to the scientific progress of the TEDAC project. The expenses incurred are lesser than planned in the initially submitted budget, as, in the end it was not necessary to go beyond that in order to achieve the initial steps of the project.

## Financing by research tax credit

The Group benefits from the provisions of Articles 244 quater B and 49 septies F of the French General Tax Code pertaining to the research tax credit (French CIR). Since the Group has not initiated any R&D expenditures up to granting of the marketing approval for treatments identified through clinical developments, the CIR is fully accounted for under other operating income.

#### 10.2. Cash flow

Cash consumption associated with operating activities for the financial years ending December 31, 2013 and 2014 amounted to a negative flow of  $\in$ 6,473 k and a negative flow of  $\in$ 7,239 k respectively.

The table below shows the net cash flows generated by Group activities over the past two financial years:

as of Dec. 31 in thousands of $\epsilon$	2013	2014	
Net income	(8,145)	(8,860)	
Expenses (income) not affecting cash		-	
- Depreciation (write backs) and provisions of non-current assets	287	277	
- Depreciation (write backs) and provisions of current assets	(107)	-	
- Expenses (income) as share-based payments	581	1,236	
- Investment grants written back to income	-	-	
- Gains and losses on disposals	-	-	
Operating subsidies	(1,661)	(1,795)	
Cost of net financial debt	1,120	50	
Income tax expense (current and deferred)	(40)	(20)	
Internal financing capacity before financial results and tax	(7,965)	(9,113)	
Taxes paid	-	-	
Changes in working capital needs related to business activities	1,492	1,874	
Net cash flow generated by business activities	(6,473)	(7,239)	

The working capital requirements for business activities increased significantly in 2014 due to the Group's increased activity in both pre-clinical and clinical research.

Cash consumption associated with investment activities for the financial years ended December 31, 2013 and 2014 amounted respectively to €289 k in 2013 and €420 k in 2014.

The table below shows the net cash flows over the past two financial years:

as of Dec. 31 in thousands of $\epsilon$	2013	2014
Purchase of fixed assets		
- Intangible assets	(9)	(26)
- Tangible fixed assets	(418)	(521)
- Investments	(3)	(0)
Disposal of fixed assets		
- Intangible assets	-	-
- Tangible fixed assets	142	126
- Investments	-	1
Grants cashed	-	-
Effects of changes in perimeter	-	-
Net cash flow generated by investment operations	(289)	(420)

Cash consumption associated with financing activities for the financial years ending December 31, 2013 and 2014 amounted respectively to a positive flow of €13,999 k in 2013 and a negative flow of €29,535 k in 2014.

The table below shows the net cash flows over the past two financial years:

as of Dec. 31 in thousands of €	2013	2014
Increase in cash capital	16,551	30,731
Costs of cash capital increase	(2,014)	(1,558)
Loan issue	193	-
Costs of loan issue	-	-
Bond redemptions	(130)	(281)
Treasury shares	(600)	651
Interest paid	(2)	(7)
Net cash flow generated by financing operations	13,999	29,535

The net flows associated with financing activities result from the introduction of the Company on the stock market in 2013, as well as the new round of fund raising on the market in 2014.

#### 10.3. Information on the borrowing requirements and funding structure

The structure of financing received by the Group between its establishment and December 31, 2014 is summarized in Section 10.1 above.

The main conditions of the repayable advances that had been granted to the Group at December 31, 2014 are described in the annex to the IFRS financial statements inserted under Chapter 20, Part I of the Prospectus.

#### 10.4. Restriction on the use of capital

The Group faces no restrictions on the availability of its capital.

## 10.5. Sources of financing needed for the future

The Group had a free cash flow of 33.5 million Euros at the end of March 2015, which will cover its needs for more than one year. Other than the anticipated 2015 payments relative to reimbursement of the 2014 CIR, which should represent an additional resource of €1.5 million, the Company has not received any new funding.

## 11. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

# 11.1. Research and development activity

See Sections 6.5 and 6.7 of the Reference Document for clinical development.

See Sections 6.5 and 6.10 for Research & Development (R&D) activity.

See Section 5.7 of the IFRS annexes for the R&D costs.

# 11.2. Intellectual property

Patents and other intellectual property rights are of the utmost importance in the Group's business sector and constitute the main barrier to entry for competitors. The Group also relies on industrial secrets, and confidentiality agreements are signed to protect its products, technologies, and manufacturing process. Without prejudice to the statements made in Section 4.2 (Risks related to intellectual property), the Group's intellectual property is not, to its knowledge at the date of this Reference Document, subject to any challenge by a third party.

#### 11.2.1. Patents

## 11.2.1.1. <u>In its own name</u>

At April 20, 2015, ERYTECH Pharma's patent portfolio consisted of 12 patent families held in its own name.

Technology/products	Family	Title	Filing date	Status
		Lysis/resealing process and device for incorporating an active ingredient in erythrocytes	08/05/2004	Issued in Japan Issued in Europe Issued in Australia Issued in China Issued in the United States Issued in Korea Issued in India Issued in Canada
Production process	2	Process for stabilizing suspensions of erythrocytes encapsulating the active ingredient, suspensions obtained	05/07/2013	PCT application filed National applications filed
ERY-ASP/GRASPA®	3	Medication for the treatment of pancreatic cancer	12/24/2007	Issued in Europe Issued in the United States Issued in Israel Issued in Australia Issued in Singapore National/regional phases for other territories
		Test for predicting neutralization of asparaginase activity	11/07/2008	Issued in Europe Issued in the United States Issued in Australia Issued in Singapore National/regional phases for other territories

Technology/products	Family	Title	Filing date	Status
	•	Medication for the treatment of acute myeloid leukemia	03/21/2012	National/regional phases initiated
		Erythrocytes containing Arginine deiminase	04/25/2005	Issued in Europe, Japan, China, Canada, Korea, and Australia Review phase under way in the United States
TEDAC	2	Pharmaceutical composition comprising erythrocytes encapsulating an enzyme	02/12/2014	PCT application filed National applications filed
		Composition to induce specific Immune Tolerance	10/27/2009	Issued in Australia Issued in Singapore National/regional phases for other territories
Immune modulation platform	2	Composition and therapeutic anti-tumor vaccine	08/08/2007	Issued in France Issued in China Issued in Australia Issued in Singapore Issued in Israel National/regional phases for other territories
		Formulation and method for the prevention and treatment of skeletal manifestation of Gaucher's disease	02/13/2008	Issued in Europe Issued in Israel Other national/regional phases
Other earnings	3	Formulation and method for the prevention and treatment of bone metastases and other bone diseases	03/10/2008	Issued in France Issued in China Issued in Australia Issued in Hong Kong National/regional phases for other territories
		Composition of erythrocytes encapsulating phenylalanine hydroxylase and therapeutic use thereof	02/10/2013	PCT application filed

The Company's intellectual property strategy aims to secure and perpetuate its exclusive use by filing and obtaining patents on its production process, its products and/or their therapeutic uses as well as diagnostic tests or assay methods directly related to the use of its products.

Prior to each filing, a detailed analysis of the prior art is done in order to satisfy the patentability criteria while seeking a robust and broad scope, in connection with the proposed use.

So-called "main" patents are those that protect the Company's key products and technologies, while the others are considered "secondary."

The "main" patents and the current stage of their process are discussed below:

## Patents on the production process

• Process patent entitled "Lysis/resealing process and device for incorporating an active ingredient in erythrocytes":

This is the Company's main patent covering its technology for the encapsulation of therapeutic molecules. The innovation developed by ERYTECH is based on taking into account key physiological parameters of erythrocytes to obtain a reproducible product. The initial application covers both the production process, the device for its implementation as well as all directly resulting products.

This patent was issued in France, Japan, Australia, South Korea, India, and China without any significant changes being made to the claims. In Europe, the process claims had to be separated from the device claims due to inventive unit reasons. An initial European patent was thus issued for the claims covering the production process and the directly resulting products. It currently covers more than 20 countries of the European Patent Organization. The claims covering the device for the implementation of the process were included in a divisional application currently under review by the European Patent Office.

In the United States, the process claims also had to be separated from the device claims. An initial American patent has been issued for claims covering the production process, in accordance with American law and the Patent Term Adjustment. The term of this patent has been extended by an additional five years, which means that it is protected in the United States until April 2030. The claims covering the device for the implementation of the process were included in a divisional application currently under review by the United States Patent Office.

In Canada, a patent has also been issued for claims covering the process.

This patent was licensed by the Company to Orphan Europe as part of an exclusive license and distribution contract (*see also chapter 22 of the Reference Document*) for the development and distribution of GRASPA® in the EU-27. This contract covers the indications of ALL and AML.

The European patent issued formed the object of opposition proceedings with the European Patent Office. Following withdrawal by the adverse claimant, the European Patent Office concluded the opposition proceedings and upheld the patent in force without any changes to the claims (See also Section 4.2(9) of the Reference Document). This decision was made known to ERYTECH on February 7, 2014.

• Process patent entitled, "Process for stabilizing a suspension of erythrocytes encapsulating the active ingredient, suspensions obtained":

This patent application covers an improvement in ERYTECH Pharma's encapsulation process to improve the stability of the erythrocytes suspensions obtained. The application was extended through the PCT process in addition to several direct national filings.

# Patents on products and/or their therapeutic uses.

• Patent entitled "Erythrocytes containing Arginine deiminase":

This patent covers erythrocytes encapsulating the enzyme arginine deiminase and any related pharmaceutical compositions. Arginine deiminase encapsulated in erythrocytes is an enzyme therapy developed under the TEDAC project. This enzyme is capable of breaking down arginine and thus acting on the metabolism of certain tumor cells by depriving them of a nutrient that is essential for them.

This patent was issued in Europe, Japan, China, Canada, Korea, and Australia without significant changes to the claims. The scope obtained is therefore broad, since product claims not restricted to a particular therapeutic use are included in the claims issued. This patent is under review in the United States.

# Patent pertaining to a pharmaceutical composition comprising erythrocytes encapsulating an enzyme:

This patent, filed within the context of the TEDAC project, formed the object of a priority filing in France on 02/10/2014 and has been extended internationally by the PCT and various direct national filings.

## • Patent entitled "Medication for the treatment of pancreatic cancer":

This patent covers the use of ERY-ASP for the treatment of pancreatic cancer. This patent has been issued in Europe, the United States, Israel, Australia, and Singapore, and is under review in other territories (Japan and Canada in particular).

## • Patent entitled "Medication for the treatment of Acute Myeloid Leukemia":

This patent covers the use of GRASPA® for the treatment of acute myeloid leukemia. It was the subject of a priority application filed in the United States and it was extended by the PCT, plus some direct national filings.

This patent was licensed by the Company to Orphan Europe as part of an exclusive license and distribution contract (*see also Chapter 22 of the Reference Document*) for the development and distribution of GRASPA® in the EU-27. This contract covers the particular indication of AML.

# • Patent entitled "Composition to induce specific immune tolerance":

This patent application covers the technology to induce a specific immune tolerance developed by ERYTECH. The proposed scope is broad, because the application covers both a composition capable of inducing immune tolerance with respect to a therapeutic protein or peptide and a composition capable of inducing immune tolerance with respect to an autoantigen. This patent has been issued in Australia and Singapore; the application is in national/regional phases for other territories.

## • Patent entitled "Composition and therapeutic anti-tumor vaccine":

This patent covers a composition of erythrocytes incorporating a tumor antigen and/or adjuvant and its use as a therapeutic cancer vaccine. The proposed scope is broad because it is not limited by the nature of the antigen, the adjuvant, or their combination.

This patent has been issued in France, Australia, Israel, China, and Singapore, and is under review in other territories (Europe, Japan, USA, and Canada in particular).

\* \* \*

The duration of a patent is 20 years from its filing date. However, in the pharmaceutical field, supplementary protection certificates may be granted in the major industrialized countries, generally extending protection for a non-renewable term of up to five years.

The Company has a policy of regularly filing patent applications to protect its technologies, products and production process.

The Company's strategy is, in fact, to systematically file priority applications in France and/or the United States. For other countries, the Company uses a procedure known as "Patent Cooperation Treaty" (PCT) that makes it possible to validly file for more than 100 countries: PCT filing is done one year after the priority filing. This PCT application is subsequently converted into national or regional filings to cover countries or groups of countries selected according to the desired geographic coverage. Some countries not accessible by PCT may be subject to direct national filings.

With regard to intellectual property, the objective of the Company's strategy is to strengthen its leading position in the use of red blood cells for therapeutic purposes. Its portfolio of filed patents covers 12 different patent families. Of these 12 patent families, 8 are already protected by at least one issued patent.

The inventions of the Company's employees are governed by employment contracts. Upon discovery of a patentable invention, each employee agrees to reveal and recognize that this invention or discovery, as part of its mission, is the property of ERYTECH, which holds all rights. A supplemental remuneration policy for each additional invention was implemented and a confidentiality clause is contained in the employment contracts. Inventions of non-salaried consultants are governed by specific contractual provisions, as the consultants are systematically bound by confidentiality clauses and generally include waiving all rights they might have to the inventions in which they may participate.

An internal procedure ensures the proper use of laboratory notebooks so that ERYTECH's intellectual property rights can be justified if necessary and in the event there is an invention. These laboratory notebooks are regularly signed and dated by a bailiff, then stored on the Company's premises.

Scientific and technological monitoring has also been implemented at ERYTECH in order to monitor:

- scientific programs that could influence the Group's R&D programs and that could identify new opportunities;
- the emergence and development of technologies complementary to or competitive with Group technologies.

## 11.2.1.2. Licenses

The NIH (National Institutes of Health) has granted an exclusive license to ERYTECH on intellectual property covering a diagnostic method for predicting the efficacy of L-asparaginase in a patient (*see also Chapter 22 on major contracts in the Reference Document*). This intellectual property based on developments of the National Cancer Institute includes an issued U.S. patent (U.S. 7,985,548) and a patent application under review at the USPTO.

#### 11.2.2 Trademarks

The Company filed the following trademarks:

TRADEMARK	DESIGNATED COUNTRIES	No.	DATE	
	France 03 3 264 900		December 26, 2003 (Renewed)	
	European Community	00 3 921 319	July 5, 2004	
	Albania	_		
	Bosnia and Herzegovina	_		
	China	_		
	Croatia	_		
	Former Yugoslav Republic of Macedonia	_	November 26, 2007	
1 ERYtech Pharma	Liechtenstein	_		
1 EK Hech I harma	Monaco	_		
	Serbia	947 762		
	Switzerland	_		
	Australia	_		
	United States	- - -		
	Iceland			
	Japan			
	Turkey			
	Singapore		May 14, 2008	

2014 – Reference Document \_\_\_\_\_\_ ERYTECH

	TRADEMARK	DESIGNATED COUNTRIES	No.	DATE
		Belarus		
		Algeria		
		Egypt	•	
		Georgia	•	
		Russia	•	
		Ukraine	•	December 18, 2013
		Montenegro	•	
		Norway	•	
		Iran	•	
		Republic of Korea	•	
		Morocco	•	
		Israel	226 985	February 3, 2010
		Canada	1 387 023	March 12, 2008
		Kosovo	KS/M/2013/ 1211	December 17, 2013
		France	39 11 751	April 10, 2012
		European Union		
		Australia		
		South Korea		
		United States	1127934	June 20, 2012
	ERYTECH Pharma	Israel		
•		Iceland		
2		Monaco		
		Russia		
		Singapore		
		Switzerland		
		Turkey		
		Montenegro		0 1 04 0010
		Norway		October 26, 2012
		France	06 3 421 435	April 6, 2006
		Albania		
		Bosnia and Herzegovina		November 26, 2007
		China		
		Croatia		
3	GRASPA	Former Yugoslav Republic of		
		Macedonia		
		Liechtenstein		
		Monaco		
		Serbia		
		Switzerland		
		Australia		

	TRADEMARK	DESIGNATED COUNTRIES	No.	DATE
		European Community		
		United States		
		Iceland		
		Japan		
		Republic of Korea		
		Turkey		
		Singapore		May 14, 2008
		Russia		June 20, 2012
		Montenegro		0 1 04 0040
		Norway		October 26, 2012
		Belarus		
		Egypt		
		Georgia		December 18, 2013
		Morocco		
		Ukraine		
		Israel	226992 226993 226994	February 3, 2010
		Canada	1 387 024	March 12, 2008
		Kosovo	KS/M/2013/ 1212	December 17, 2013
4	ERYASP	France	13 397 6584	January 23, 2013
		France	06 3 402 981	January 12, 2006
_	Class/EDV Creators	European Community		November 26, 2007
5	Cleav'ERY System	Switzerland	947760	
		United States		
		France	06 3 402 941	January 12, 2006
_	O JEDY C	European Community		
6	Oxygen'ERY System	Switzerland	947 761	November 26, 2007
		United States		
		France	07 3 533 090	October 22, 2007
_	T. India	European Community		
7	Vaccin'ERY System	Switzerland	967450	May 14, 2008
		U.S.		
	ERYCAPS	France	07 3 546 157	December 21, 2007
		European Community	972 047	
8		Switzerland		July 8, 2008
		United States		, ,
9	Deliv'ERY System	France	06 3 402 968	January 12, 2006
10	EryDexone	France	06 3 459 689	October 26, 2006

	TRADEMARK	DESIGNATED COUNTRIES	No.	DATE
11	ERYTECH Pharma Deliv'ERY System	France	07 3 543 340	December 10, 2007
		France	11 3 819 125	March 23, 2011
		European Union		
		United States		
		China		
		Switzerland		
		Australia		
12	ENHOXY	Iceland		10 February 2012
1,2	ENHOXI	Japan	1,110,463	
		Republic of Korea		
		Turkey	]	
		Israel	]	
		Singapore		
		Russia		June 20, 2012
		Monaco		June 20, 2012
13	KYTASPAR	France	14 4 103 802	July 8, 2014
		France	14 4 103 800	July 8, 2014
		European Union	013 466 123	November 17, 2014
14	ASPACELL	International:  - Albania - Armenia - Azerbaijan - Belarus - Bosnia and Herzegovina - Iceland - Kazakhstan - Kyrgyzstan - Liechtenstein - Macedonia - Moldova - Montenegro - Norway - Uzbekistan - Russia - Serbia - Switzerland - Tajikistan - Turkmenistan - Turkey - Ukraine	1 235 383	December 3, 2014
		Kosovo	KS/M/2014 109	November 19, 2014

None of the Company's trademarks above are subject to a third party trademark license, except under distribution agreements with the Teva Group and Orphan Europe, for the trademark GRASPA® (see also Chapter 22 "Major Contracts" of the Reference Document).

The Company has established global monitoring of its main trademarks, namely ERYTECH Pharma<sup>®</sup> and GRASPA<sup>®</sup>.

#### 11.2.3 Domain Names

The Company filed the following domain names:

Domain Name	Expiry
erytech.com	July 20, 2017
erytech.fr	May 5, 2017
erytech.eu	September 30, 2015
graspa.fr	September 23, 2015
graspa.bio	September 23, 2015
graspa.biz	September 23, 2015
graspa.eu	September 23, 2015
graspa.de	September 23, 2015
graspa.uk	September 23, 2015
graspa.info	September 23, 2015

#### 12 TREND INFORMATION

## 12.1 Main trends since the end of the last financial year

See the year 2015 in Section 5.1 of the Reference Document.

It should be noted that, as of March 31, 2015, cash and cash equivalents totaled 33.5 million Euros, as compared to 37 million Euros at the end of 2014. This increase in expenses is the result of an acceleration of activities following the capital increase performed in October 2014 and activities associated with submission of the file to obtain marketing approval, notably related to the use of consultants.

During the first quarter of 2015, ERYTECH did not record any revenue from activities.

# 12.2 Known trends, uncertainties, requests for commitments or reasonable events that could affect the Company's prospects

None.

## 13 FORECASTS OR ESTIMATES OF EARNINGS

The Company does not wish to report on forecasts of earnings because the assumptions on which these forecasts would be built would include elements that are too vague as of the preparation date of this document.

#### 14 ADMINISTRATIVE AND MANAGEMENT BODIES

A summary description of the primary stipulations of the Company's articles of incorporation and rules of procedure concerning specialized committees is found respectively in Sections 21.2 and 16.5 of the Reference Document.

Please note that the Company was established in the form of a limited liability company with an Executive Board and a Supervisory Board on September 29, 2005. In a general meeting of April 2, 2013, the Company modified its mode of governance to the current one, that being a public limited company with a Board of Directors.

#### 14.1 Executive Officers and Directors

# 14.1.1 Composition of the Board of Directors

The Company has the following directors:

Last name, first name, age	Term of office	Position
Gil Beyen 53 years old	1st appointed: The General meeting of April 2, 2013 (he had been chairman of the Supervisory Board since 2012)  Term expires: The Ordinary General Meeting of 2016 voting on the financial statements for the year ending December 31, 2015.	Chairman of the Board of Directors and Chief Executive Officer
Yann Godfrin 43 years old	1st appointed: The general meeting of April 2, 2013 (he had been a member of the Executive Board since 2005, Chairman of the Executive Board from 2005 to 2010, and Chief Executive Officer since 2010).  Term expires: The Ordinary General Meeting of 2016 voting on the financial statements for the year ending December 31, 2015.	Director and Delegated Managing Director
Galenos SPRL, represented by Sven Andreasson, 62 years old 25 rue Jean-Baptiste Meunier, B 1050 Ixelles, Belgium	1st appointed: The Board of Directors' meeting of April 2, 2013 (Chairman of the Supervisory Board from 2009 to 2011, Deputy Chairman of the Supervisory Board since 2011)  Term expires: The General Meeting of 2016 voting on the financial statements for the year	Director
Independent director <sup>(1)</sup> Philippe Archinard 54 years old 47 rue Professeur Deperet, 69160 Tassin-la-Demi-Lune.  Independent director <sup>(1)</sup>	ending December 31, 2015.  1st appointed: The General meeting of April 2, 2013 (member of the Supervisory Board since 2005)  Term expires: The General Meeting of 2016 voting on the financial statements for the year ending December 31, 2015.	Director
Martine Ortin George 66 years old 9 Southern Hills Drive 08558 Skillman NJ United States of America Independent director (1)	1st appointed: AGM of June 17, 2014  Term expires: The General Meeting of 2016 voting on the financial statements for the year ending December 31, 2015.	Director
Hilde Windels 49 years old	1st appointed: AGM of June 17, 2014	Director

Last name, first name, age	Term of office	Position
Rollebaan 85 9860 MOORTSELE	Term expires: The General Meeting of 2016 voting on the financial statements for the year	
Belgium	ending December 31, 2015.	
Independent director (1)		
Luc Dochez	1st appointed: Co-optation, by the Board of Directors' meeting of March 26, 2015, following the resignation of Pierre-Olivier GOINEAU	Director
	Term expires: The General Meeting voting in 2016 on the financial statements for the year ending December 31, 2015.	

(1) Independent member as understood by the Middlenext Corporate Governance Code for small and mid-caps of December 2009.

The Chief Executive Officer, Gil Beyen, and the Delegated Managing Director, Yann Godfrin, have as their professional address the Company's headquarters, 60 avenue Rockefeller – 69008 Lyon.

The professional addresses of the other directors are those shown on the table above.

There are no family relationships between the persons listed above.

None of these people, over the course of the last five years:

- has been convicted of fraud;
- has been associated with a bankruptcy, seizure, or liquidation in his/her capacity as executive officer or director;
- has been prevented by a court from acting in a capacity as a member of a board of directors, executive board, or supervisory board of an issuer or participating in the management or conduct of business and of an issuer, and
- has not been subject to a management prohibition; and
- has not been the subject of indictment or official public sanction pronounced by the statutory or regulatory authorities, including by designated professional bodies.

During the financial year ended December 31, 2014, the following modifications took place concerning the Board of Directors:

- Sven Andreasson resigned from his position as director on January 22, 2014;
- The company GALENOS SPRL was appointed director by co-optation, to replace Sven Andreasson. This appointment was ratified by the combined general shareholders' meeting of June 17, 2014;
- Martine Ortin George was appointed to a director position by the shareholders during the combined general shareholders' meeting of June 17, 2014, for a duration of three years. Her mandate will be discontinued at the end of the ordinary general shareholders' meeting to be held in 2017 to rule on the financial statements for the year ended December 31, 2016;
- Hilde Windels was appointed to a director position by the shareholders during the combined general shareholders' meeting of June 17, 2014, for a duration of three years. Her mandate will be discontinued at the end of the ordinary general shareholders' meeting to be held in 2017 to rule on the financial statements for the year ended December 31, 2016;
- The company KURMA Life Science Partners, for which Vanessa MALIER was the permanent representative, replacing Alain Munoz as of the Board of Directors' meeting of January 22, 2014, resigned from its position as member of the Board of Directors on July 17, 2014 (resignation acknowledged by the Board of Directors on August 29, 2014).

Since the financial year ended December 31, 2014, the following modifications have taken place concerning the Board of Directors:

 the resignation of Pierre-Olivier GOINEAU from his positions as Deputy Chairman, Delegated Managing Director, and Director of the Company; Luc DOCHEZ was co-opted in the Board of Directors' meeting of March 26, 2015, subject to acceptance
by the shareholders in the next general meeting, as Company director replacing Pierre-Olivier GOINEAU,
who resigned. The mandate of Luc DOCHEZ will be discontinued at the end of the ordinary general
shareholders' meeting to be held in 2017 to rule on the financial statements for the year ended December
31, 2016.

## 14.1.2 Composition of Senior Management

The Chairman and Chief Executive Officer of the Company is Gil Beyen.

The Company has two Delegated Managing Directors, Yann Godfrin and Jérôme Bailly, the Chief Pharmacist.

Together, these people form the Company's senior management.

The biographies of the officers are presented below in section 14.1.4.

## 14.1.3 Other corporate duties

The Company's current executive officers and directors have also acted as officers and/or occupied the following positions:

		Other duties performed as executive officers or other positions outside of the Company over the
	Other mandates and positions held by corporate	last five years and which
	officers during the financial year ended December 31,	have ceased as of this
Last name	2014	day
Gil Beyen	Manager of Gil Beyen BVBA Manager of AXXIS V&C BVBA Director at Novadip SA Director at Waterleau NV Chairman of ERYTECH Pharma Inc.	Director at BIO.be
Pierre-Olivier Goineau <sup>1</sup>	Chairman of France Biotech Manager of SCI du Grand Tambour (a real estate company) Secretary and Chief Financial Officer of ERYTECH Pharma, Inc.	N/A
Yann Godfrin	Member of the Supervisory Board for the NODEA MEDICAL company	N/A
Galenos SPRL, represented by Sven Andréasson	Director of Immunicum Director at Cellastra Chairman of Cantargia AB	Chairman and CEO of Beta-Cell NV Chairman of Unibioscreen SA Board Member of TiGenix NV Chairman of XImmune AB

		T	04 14 6
Last name		Other mandates and positions held by corporate officers during the financial year ended December 31, 2014	Other duties performed as executive officers or other positions outside of the Company over the last five years and which have ceased as of this day
Kurma Partners SA <sup>2</sup>	represented by Vanessa Malier until July 17, 2014	Director at Umecrine Mood Director at Xeltis Director at Step Pharma	Member of the Board of Directors of Theradiag Member of the Blink Board of Directors Observer at ABM Medical Member of the Board of Cellectis Member of the Board of Novagali Member of the Board of Vivacta Director of Vivalis Chairman of the Strategy Committee at PathoQuest Member of the Board of Directors of Prosensa Member of the Board of Directors of Adocia Member of the Board of Directors of Integragen Member of the Board of Directors of Indigix Member of the Board of Directors of Zealand Pharma Member of the Board of Directors of Auris Director at Hybrigenics Member of the Supervision Committee at PathoQuest Director and Chairman of the Supervision Committee at PathoQuest Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of AM Pharma Member of the Board of Directors of Directors Director at STAT Diagnostica Member of the Board of Meiogenics Member of the Board of Directors of Domain Therapeutics

2014 – Reference Document \_\_\_\_\_\_ ERYTECH

Last name		Other mandates and positions held by corporate officers during the financial year ended December 31, 2014	Other duties performed as executive officers or other positions outside of the Company over the last five years and which have ceased as of this day
	represented by Alain Munoz until January 22, 2014	Director at AURIS <sup>3</sup> , Director at GENTICEL <sup>3</sup> , Director at HYBRIGENICS <sup>3</sup> , Director at VALNEVA <sup>3</sup> , Director at ZEALAND <sup>3</sup> .  Director and Chief Executive Officer of Transgene <sup>3</sup> TSGH's permanent representative on the board of ARI.	N/A
Philippe Archi	nard	TSGH's permanent representative on the board of ABL Inc Chief Executive Officer of TSGH Permanent representative on the Board of Directors of Synergie Lyon Cancer for Lyonbiopôle Director at Biomérieux <sup>3</sup> Chairman of Lyonbiopôle Director of CPE Lyon, representative of FPUL President of BioAster	Permanent representative to the Finovi Board of Directors for Lyonbiopôle
Jérôme BAILLY		Manager of GELFRUIT SARL (France)	
Martine Ortin George		Vice President of Pfizer Inc. <sup>3</sup>	- Vice President of Pfizer Inc. (United States) - Senior Vice President, GPC Biotech Inc. (United States) - Director, Cytomics Inc. (France)
Hilde WINDE	LS	- Director, VIB <sup>3</sup>	- Director, MDX Health,

		Other duties menformed
		Other duties performed
		as executive officers or
		other positions outside
		of the Company over the
	Other mandates and positions held by corporate	last five years and which
	officers during the financial year ended December 31,	have ceased as of this
Last name	2014	day
	- Director, Flanders Bio	- Administrative and
	- Director and Delegated Managing Director at	Financial Director,
	BioCartis	Pronota
		- Administrative and
		Financial Director, Seps
		Pharma
		Managing
		Director/Business
Luc DOCHEZ	Managing Director Primix Bioventures BVBA	Director Prosensa
Luc DOCHEZ	Executive Director Tusk Therapeutics NV	Holding NV
		Director Ovizio SA
		Director Arcarios BV

<sup>&</sup>lt;sup>1</sup>Pierre-Olivier GOINEAU resigned from his positions at ERYTECH Pharma on January 11, 2015.

## 14.1.4 Experience with administrative and managerial bodies

The experience of each of the Company's executive officers and directors is described below.

## Gil Beyen, Chairman of the Board of Directors and Chief Executive Officer:

Gil was the Co-founder and Chief Executive Officer (CEO) of TiGenix (NYSE Euronext: TIG BB) for 12 years. Before creating TiGenix, he had directed the Life Sciences division at Arthur D. Little in Brussels. He holds a masters in bioengineering from the University of Louvain (Belgium) and an MBA from the University of Chicago (USA).

## - Yann Godfrin, Delegated Managing Director and Director:

Before co-founding the company, Yann was the R&D director at Hemoxymed Europe. He was also an industrial development consultant for BioAlliance Pharma and Hemosystem. Yann holds a Doctor in Life and Health Sciences from the University of Nantes, a Degree in Biomedical Engineering from the Université de Technologie de Compiegne, and a Master's Degree in Clinical Development of Health Products from the University of Lyon, France. He is the inventor of numerous patents and the co-author of numerous scientific publications. He is a member of several scientific societies.

## - Jérôme Bailly, Delegated Managing Director:

Before joining the company in 2007, Jérôme was the Director of QA/Production at Skyepharma and Laboratoire Aguettant. Jérôme holds a Doctor in Pharmacy and a Degree in Chemical Engineering, specializing in Biopharmaceutical Engineering and Cellular Production from École Polytechnique de Montréal.

# - Galenos, represented by Sven Andreasson, Director:

Sven is the Director of Business Affairs at Novavax (United States) and former Chairman and Chief Executive Officer of Isconova AB (Uppsalam SuèdeBeta-Cell NV (Brussels), Active Biotech AB (Lund, Sweden), and several companies in the Pharmacia group. He has much experience in international biotechnology companies and in the pharmaceutical industry.

Sven holds a Bachelor of Science and Business Administration and Finance from the Stockholm School of Economics and Business Administration.

#### Philippe Archinard, director:

Philippe was appointed General Manager of Transgene on December 7, 2004, after spending 15 years with Biomérieux in various positions including directing the American subsidiary. Philippe has been CEO of the

<sup>&</sup>lt;sup>2</sup>KURMA PARTNERS SA resigned from its positions at ERYTECH Pharma on July 17, 2014. The resignation of KURMA PARTNERS S.A. was acknowledged by the Board of Directors on August 29, 2014.

<sup>&</sup>lt;sup>3</sup>Companies listed on a regulated market

Innogenetics company since March 2000. He is a chemical engineer and holds a PhD in biochemistry from the University of Lyon completed by the Harvard Business School's Program of Management PMD.

# - Martine Ortin George, director:

A doctor of medicine, Martine George has a broad experience in the United States in clinical research, medical affairs, and regulatory matters, acquired within large and small companies specialized in oncology. Until recently, Dr. George was Vice President in charge of Global Medical Affairs for Oncology at Pfizer in New York. Previously, she held the positions of Medical Director at GPC Biotech at Princeton and Head of the Oncology Department at Johnson & Johnson in New Jersey. Martine George is a qualified gynecologist and oncologist, trained in France and in Montreal. She began her career as the Department Head at the Institut Gustave Roussy in France, and was invited to the Memorial Sloan Kettering Cancer Center of New York as a professor.

#### - Hilde Windels, director:

Hilde Windels has more than 20 years of experience in corporate financing, capital markets, and strategic initiatives. She is the Managing Director and Director at Biocartis, a molecular diagnosis and immunodiagnostic solutions company based in Belgium and in Switzerland. Hilde Windels was previously the Financial Director at Devgen (Euronext: DEVG) from 1999 to the end of 2008, and member of the Devgen Board of Directors from 2001 to the end of 2008. Between the start of 2009 and mid-2011, she worked as an independent financial director for various private companies specialized in biotechnologies, and sat on the board of directors of MDX Health (Euronext: MDXH) from June 2010 to the end of August 2011. Previously, she was a corporate banking services manager at ING for a region of Belgium. She received her degree in economics from the Université de Louvain (Belgium).

#### • Luc Dochez:

Luc Dochez was Chief Business Officer and Senior Vice-President of Business Development at the Netherlands company Prosensa (NASDAQ: RNA) until its recent acquisition by Biomarin. In this position, he played a key role in establishing a partnership with GSK valued at more than €500 M; he was likewise actively involved in the successful introduction of the company on Nasdaq and managed acquisition of the company by Biomarin for an amount of \$860 M. Before Prosensa, Luc was Vice President of Business Development at TiGenix (Euronext: TIG), Director Business Development at Methexis Genomics, and a consultant at Arthur D. Little.

# 14.2 Potential conflicts of interest and agreements

Related agreements are described in Sections 16.2 and 0 of the Reference Document.

To the company's knowledge, no current or potential conflicts of interest exist between the duties, for the Company, and the private interests and/or duties of persons comprising the administrative, management, and senior management bodies, as referenced in Section 14.1 "Executive officers and directors" above.

### 15 REMUNERATION AND BENEFITS

# 15.1 Compensation and in-kind benefits allocated to the Company's corporate officers for the last financial year

In accordance with the law of July 3, 2008, this information is established with reference to the corporate governance code for small and medium-sized companies, as published in December 2009 by MiddleNext. All the tables (from 1 to 10) of the "AMF Guidelines - Guide to preparing reference documents" are presented below.

The positions held at this date by the below-indicated persons are outlined in detail in Chapter 14 - Administrative, Management, and Supervisory Bodies of this Reference Document.

The changes in remunerations paid are notably related to:

A rebalancing of remunerations, in proportion to the Company's development and in line with the listing of its shares on a regulated market and within the context of business segments and the market (in conformity with the benchmark principle outlined under Recommendation no. 2 of the MiddleNext Code). This rebalancing was decided by the Board of Directors, pursuant to the opinion issued by the Remuneration and Appointments Committee and in conformity with Company practices;

Concerning Gil Beyen, the fact that his remuneration in 2013 is not distributed over a full year (from May 6, 2013 to December 31, 2013), contrary to 2012.

# Table no. 1:

Summary table of compensation and BSPCE (founder subscription warrants) allocated to each executive corporate officer				
	2014 Financial Year	2013 Financial Year		
Gil Beyen – Chairman & CEO				
Remuneration due in relation to the financial year (details in table 2)	€372,268	€342,700		
Valuation of options allocated during the financial year (details in table 4)	€513,960	€239,811		
Valuation of performance shares allocated during the financial year (details in table 6)				
TOTAL	€886,228	€582,511		
Pierre-Olivier GOINEAU – Deputy Chairman & Delegated Managing Director				
Remuneration due in relation to the financial year (details in table 2)	€275,422	€243,507		
Valuation of options allocated during the financial year (details in table 4)	€220,482	€107,089		
Valuation of performance shares allocated during the financial year (details in table 6)				
TOTAL	€495,904	€350,596		
Yann GODFRIN – Delegated Managing Director				
Remuneration due in relation to the financial year (details in table 2)	€275,268	€243,610		
Valuation of options allocated during the financial year (details in table 4)	€234,127	€107,089		
Valuation of performance shares allocated during the financial year (details in table 6)				
TOTAL	€509,395	€350,699		
Jérôme BAILLY – Delegated Managing Director				
Remuneration due in relation to the financial year (details in table 2)	€70,085	€62,816		
Valuation of options allocated during the financial year (details in table 4)	€39,166	€21,929		
Valuation of performance shares allocated during the financial year (details in table 6)				
TOTAL	€109,251	€84,745		

Note: the remunerations owing to Gil Beyen in the 2013 financial year are calculated pro rata temporis on a base annual salary of €342,700.

# Table no. 2:

Summary table of the compensat	ion package for each execu	tive corporate officer:			
	2014 Financial Year		2013 Financial Year		
Gil Beyen	Amounts due	Amounts paid	Amounts due	Amounts paid	
Fixed remuneration (1)	€244,000	€244,000	€251,500	€251,200	
Variable remuneration (1) (2)	€125,600	€91,500	€91,500		
Special remuneration					
Attendance fees					
Benefits in kind (3)	€2,668	€2,668			
TOTAL	€372,268	€338,168	€342,700	€251,200	
	2014 Financ	ial Year	2013 Financi	ial Year	
Pierre-Olivier Goineau	Amounts due	Amounts paid	Amounts due	Amounts paid	
Fixed remuneration (1)	€175,783	€175,783	€165,771	€165,771	
Variable remuneration (1) (2)	€90,000	€67,500	€67,500	€75,000	
Special remuneration					
Attendance fees					
Benefits in kind (3)	€9,639	€9,639	€10,236	€10,236	
TOTAL	€275,422	€252,922	€243,507	€251,007	
	2014 Financ	ial Year	2013 Financi	ial Year	
Yann Godfrin	Amounts due	Amounts paid	Amounts due	Amounts paid	
Fixed remuneration (1)	€175,550	€175,550	€164,996	€164,996	
Variable remuneration (1) (2)	€90,000	€67,500	€67,500	€75,000	
Special remuneration					
Attendance fees					
Benefits in kind (3)	€9,718	€9,718	€11,114	€11,114	
TOTAL	€275,268	€252,768	€243,610	€251,110	
	2014 Financial Year		2013 Financial Year		
Jérôme Bailly	Amounts due	Amounts paid	Amounts due	Amounts paid	
Fixed remuneration (1)	€60,755	€60,755	€55,293	€55,293	
Variable remuneration (1) (2)	€6,000	€5,172	€5,172	€5,000	
Special remuneration					

Attendance fees				
Benefits in kind (4)	€3,331	€3,331	€2,351	€2,351
TOTAL	€70,085	€69,258	€62,816	€62,644

Note: the fixed remuneration owing to Gil Beyen in the 2013 financial year is calculated pro rata temporis on a base annual salary of  $\epsilon$ 251,520.

(1) Components of gross remuneration before taxes

The variable compensation is for objective-based bonuses The goals correspond to the Company's strategic goals. This strategy consists, in the medium term, of the success of the GRASPA®/ERY-ASP project. The goals are thus directly associated with:

- The AMM application procedure; and
- The acceleration of activities in the United States; and
- The launch and development of other clinical programs.

The reaching of these goals has been strictly defined by the Board of Directors, following an opinion by the Remuneration and Appointments Committee.

- (2) The benefits in kind are composed of: vehicle rental, gas cards, as well as an unemployment insurance policy with the Garantie Sociale des Chefs et Dirigeants d'Entreprise (French GSC; unemployment insurance provider for corporate leaders)
- (3) The benefits in kind are composed of a vehicle rental

# Table no. 3:

Table of attendance fees and other compensation received by non-executive corporate officers					
Non-executive corporate officers	Amounts paid during the 2014 financial year	Amounts paid during the 2013 financial year			
Sven Andreasson					
Attendance fees	€1,000	€12,958			
Other remuneration (1) (2)		€5,250			
GALENOS SPRI					
Attendance fees	€19,476	5			
Other compensation (1)					
Philippe ARCHINARD					
Attendance fees	€20,476	€13,083			
Other remuneration					
Martine ORTIN GEORGE					
Attendance fees	€10,024				
Other compensation (1)					
Hilde WINDELS					
Attendance fees	€9,024				
Other compensation (1)					
Alain MAIORE					
Attendance fees		€7,875			
Other compensation (1)					
Gil BEYEN					

Attendance fees		
Other compensation (1)		€87,500
Marc BEER		
Attendance fees		€8,333
Other compensation (1)		
TOTAL	€60,000	€134,999

- (1) The amounts corresponding to fees and out-of-pocket expenses, paid by the Company.
- (2) Amounts paid to GALENOS SPR, a company controlled by Sven Andreasson

### Table no. 4:

Share subscription or share call options and other financial instruments giving access to the capital, allocated during the financial year to each executive corporate officer by the issuer and by any group company Number of Name of Valuation of options options Exercise price executive Type of option (call or according to the allocated duringfor each new Plan no. and date Period of exercise corporate method adopted for subscription) the financial subscribed share\* officer IFRS accounts year BSPCE<sub>2012</sub> Fair value (Black & 5,631 Lapses on Gil Beyen €7.362 Subscription 05/21/2012 Scholes) IFRS 7 05/20/2020 Pierre-Olivier  $BSPCE_{2012}$ Fair value (Black & Lapses on Subscription 2,515 €7.362 05/21/2012 Scholes) IFRS 7 05/20/2020 Goineau BSPCE<sub>2012</sub> Fair value (Black & Lapses on 2,515 Yann Godfrin Subscription €7.362 05/21/2012 Scholes) IFRS 7 05/20/2020 BSPCE<sub>2012</sub> 05/21/2012 Fair value (Black & 515 Lapses on Jérôme Bailly Subscription €7.362 Scholes) IFRS 7 in 2014 05/20/2020

### Table no. 5 is not applicable

Share subscription or call options exercised during the financial year by each executive corporate officer								
Name of executive corporate officer  Plan no. and date  Number of options exercised during the financial year  Exercise price								
n/a n/a n/a n/a								
TOTAL	TOTAL n/a n/a n/a							

<sup>\*</sup> Pursuant to the decision to divide by 10:1 at the nominal share value (decision of the general shareholders' meeting of April 2, 2013), the terms and conditions of the warrants were modified to take this modification into account. As such, the exercise price, previously  $\epsilon$ 73.62, is now set at  $\epsilon$ 7.362.

# Table no. 6 is not applicable

Performance shares allocated to each corporate officer						
Performance shares allocated by the general shareholders' meeting during the financial year to each corporate officer by the issuer and by any group company (list of names)	and date	Number of shares allocated during the financial year	Valuation of shares according to the method adopted for the consolidated financial statements	Date of acquisition	Date of availability	Performance conditions
n/a	n/a	n/a	n/a	n/a	n/a	n/a
TOTAL	n/a	n/a	n/a	n/a	n/a	n/a

# Table no. 7 is not applicable

Performance shares that became available for each corporate officer	Plan no. and date	Number of shares that became available during the financial year	Conditions for acquisition
n/a	n/a	n/a	n/a
TOTAL	n/a	n/a	n/a

# Table no. 8

HISTORICAL ALLOCATION OF SHARE SUBSCRIPTION OR CALL OPTIONS						
IN	FORMATION ON THE	SUBSCRIPTION OR C.	ALL OPTIONS			
Date of general shareholders' meeting	BSPCE <sub>2012</sub> <sup>(1)</sup> General Meeting of 05/21/2012	BSPCE <sub>2014</sub> General Meeting of 04/02/2013	BSA <sub>2012</sub> General Meeting of 05/21/2012	BSA <sub>2014</sub> General Meeting of 04/02/2013		
Date of board of directors' meeting or executive board meeting, where applicable	Executive Board meeting of 05/31/2012 Board of Director's meeting of 07/18/2013 Board of Directors' meeting of 07/17/2014	Board of Directors' meeting of 01/22/2014	Executive Board meeting of 05/31/2012 Board of Director's meeting of 07/18/2013 Board of Directors' meeting of 07/17/2014 Board of Directors' meeting of 04/29/2015	Board of Directors' meeting of 01/22/2014 <sup>(4)</sup> Board of Directors' meeting of 12/04/2014 <sup>(4)</sup>		
Total number of shares that can be subscribed or called up <sup>(2)</sup> , the number of which can be subscribed or called up by:	337,870 shares can be subscribed, representing a total of 33,787 warrants	195,000 shares can be subscribed, representing a total of 19,500 warrants	112,630 shares can be subscribed, representing a total of 11,263 warrants <sup>(5)</sup>	30,000 shares can be subscribed, representing a total of 3,000 warrants		
The corporate officers	277,370 shares 27,737 warrants	70,000 shares 7,000 warrants				
Gil BEYEN	112,630 shares 11,263 warrants	60,000 shares 6,000 warrants	n/a	n/a		
Pierre-Olivier GOINEAU	75,080 shares 7,508 warrants	10,000 shares 1,000 warrants	n/a	n/a		
Yann GODFRIN	75,080 shares 7,508 warrants	30,000 shares 3,000 warrants	n/a	n/a		

Jérôme BAILLY	14,580 shares 1,458 warrants	Undetermined <sup>(5)</sup>	n/a	n/a
GALENOS	n/a	n/a	Undetermined <sup>(5)</sup>	n/a
Philippe ARCHINARD	n/a	n/a	Undetermined <sup>(5)</sup>	n/a
Hilde WINDELS	n/a	n/a	Undetermined <sup>(5)</sup>	n/a
Martine GEORGE	n/a	n/a	Undetermined <sup>(5)</sup>	n/a
Luc DOCHEZ	n/a	n/a	Undetermined <sup>(5)</sup>	n/a
Starting point for exercise of options	05/06/2013 (day of listing of the Company's shares for trading on a regulated market) and/or immediately after subscription	Immeidately after subscription	05/06/2013 (day of listing of the Company's shares for trading on a regulated market) and/or immediately after subscription	Immediately after subscription
Expiry date	05/20/2020	01/22/2024	05/20/2020	01/22/2024
Subscription or call price	€7.362 per share €73.62 per warrant	€12.25 per share €122.50 per warrant	€7.362 per share €73.62 per warrant	€12.25 per share €122.50 per warrant
Methods of exercise (where the plan includes multiple tranches)	1 warrant = 10 shares Bearers must exercise a minimum of 50 warrants per exercise or the entirety where they hold less than this amount. Each bearer is limited to excercising warrants four times per year.		1 warrant = 10 shares Bearers must exercise a minimum of 50 warrants per exercise or the entirety where they hold less than this amount. Each bearer is limited to excercising warrants four times per year.	1 warrant = 10 shares Bearers must exercise a minimum of 50 warrants per exercise or the entirety where they hold less than this amount. Each bearer is limited to excercising warrants four times per year.
Number of shares subscribed at 04/20/2015	73,750 shares subscribed, i.e., 7,375 warrants	0	50,250 shares subscribed, i.e., 5,025 warrants	0
Cumulative number of share subscription or call options canceled or lapsed	0	3,000 <sup>(4)</sup>	0	0
Share subscription or call options remaining at year end	264,120 shares 26,412 warrants	195,000 shares 19,500 warrants	62,380 shares 6,238 warrants	30,000 shares 3,000 warrants

The General Meeting of May 21, 2012 cancelled the  $BSPCE_{Cadre2006}$ , which had been partially subscribed. The  $BSPCE_{Cadre2006}$  were replaced by the  $\begin{array}{c} BSPCE_{2012}. \\ \ ^{(2)} Whether \ or \ not \ the \ related \ options \ had \ been \ exercised \end{array}$ 

# Table no. 9

SHARE SUBSCRIPTION OR CALL OPTIONS AND FOUNDER SUBSCRIPTION WARRANTS (BSPCEs) GRANTED TO THE TOP TEN BENEFICIARY NON-CORPORATE-OFFICER EMPLOYEES, AND OPTIONS EXERCISED BY THESE PERSONS	Total number of options allocated/ of shares subscribed or called up	Average weighted price	Plan no. 1 (1)	Plan no. 2 (2)
Options granted, during the financial year, by the issuer and any company included within the option assignment perimeter, to the ten employees of the issuer and of any company included within this perimeter, for whom the number of options thus granted is the highest (global information)	2,515	n/a	2,515	0
Options held in relation to the issuer and the aforesaid companies, exercised, during the financial year, by the ten employees of the issuer and these companies, for whom the number of options thus called up or subscribed is the highest (global information)		n/a	0	0

Founder subcription warrants<sub>2012</sub>

<sup>(3)</sup> At December 31, 2014

 $<sup>^{(4)}</sup>$  3,000 BSPCE<sub>2014</sub> of the 22,500 BSPCE<sub>2014</sub> issued by the Board of Directors' meeting of January 22, 2014 were transformed into 3,000 BSA<sub>2014</sub> by decision of the Board of Directors' meeting of December 4, 2014.

<sup>(5)</sup> Undetermined means that the total number of shares that could be subscribed by persons is undetermined, but that these people have already subscribed to options.

<sup>(2)</sup> Founder subscription warrants (BSPCE)<sub>2014</sub>

# Table no. 10 is not applicable

HISTORICAL ALLOCATION OF FREE SHARES							
INFORMATION ON FREE SHARES ALLOCATED							
Date of general shareholders' meeting	Plan no. 1	Plan no. 2	Plan no. 3	Etc.			
Date of board of directors' meeting or executive board meeting, where applicable	n/a	n/a	n/a	n/a			
Total number of shares allocated free of charge, of which the number assigned to:	n/a	n/a	n/a	n/a			
The corporate officers							
Gil Beyen	n/a	n/a	n/a	n/a			
Pierre-Olivier Goineau	n/a	n/a	n/a	n/a			
Yann Godfrin	n/a	n/a	n/a	n/a			
Date of share acquisition	n/a	n/a	n/a	n/a			
End date of retention period	n/a	n/a	n/a	n/a			
Subscription or call price	n/a	n/a	n/a	n/a			
Number of shares subscribed at [] (most recent date)	n/a	n/a	n/a	n/a			
Cumulative number of shares canceled or lapsed	n/a	n/a	n/a	n/a			
Shares allocated free of charge remaining at year end	n/a	n/a	n/a	n/a			

# Table no. 11

	Conditions for remuneration and other benefits granted to the executive corporate officers only								
Executive corporate officers	corporate		Supplementary pension plan		Indemnities or benefits due or likely to be due because of discontinuation or change of position		Indemnities pertaining to a non-competition clause		
	Yes (1)	Not	Yes (2)	Not	Yes (3)	Not	Yes (4)	Not	
Gil Beyen Chairman and Chief Executive Officer		X	X		X			X	
Yann Godfrin Delegated Managing Director		X	X		X			X	
Jérôme Bailly Delegated Managing Director	X		X			X	X		

- (1) Jérôme Bailly benefited from an employment contract from November 15, 2011 until his initial appointment on December 21, 2012 as a corporate officer. He was considered, by the Supervisory Board, then by the Board of Directors, to have continued this employment contract after the aforesaid appointments, as this contract covers separate missions under his term as Chief Pharmacist, missions pursuant to which he is subject to a subordination relationship.
- (2) Subscription to the supplementary pension plan with fixed contributions, within the scope of a collective pension policy stipulated by the Company with AXA. Investment in individual accounts paid for by the 5% pension contribution by employees, gross subject to deductions of 2.50% of costs, on the "Horizon" mutual funds managed by AXA.
- (3) Indemnity in an amount equal to one year of pay (see also section 16.4.10 for performance conditions) + GSC policy for Mr. Godfrin only
- (4) Indemnity equal to 1/3 of the average monthly wage received during the last three months of presence at the company ERYTECH Pharma over 18 months.

In addition, the executive corporate officers likewise benefit from a supplementary plan for health care and social security expenses (see also Sections 16.2 and 0 of the Reference Document) and profit-sharing (see also Section 17.4 of the Reference Document).

# 15.2 Amounts allocated or identified by the Company for the payment of pensions, retirement, or other benefits

In its corporate financial statement, the Company has not allocated monies to the payment of pensions, retirement, and other benefits to non-executive corporate officers and/or executive corporate officers who do not moreover benefit (or who have not benefited) from a severance or hiring bonus.

# 15.3 Share subscription warrants, founder subscription warrants, and other securities giving access to the capital, assigned to directors and executive officers.

The BSAs (share subscription warrants) and BSCPCEs (founder subscription warrants) granted to non-executive or executive corporate officers are outlined in a precise list in Chapter 17.2 of the Reference Document.

# 15.4 Summary statement of transactions by executive officers and persons mentioned in article L.621-18-2 of the Monetary and Financial Code involving shares of the Company conducted during the past financial year

During the financial year ended December 31, 2014, the managers and persons indicated in Article L. 621-18-2 of the French Monetary and Financial Code performed the following operations on Company securities:

- On March 24, 2014 Françoise HORAND PHOTHIRATH, an executive equivalent person, exercised 200 founder subscription warrants (BSPCE2012) at a unit price of 73.62 Euros;
- on March 27, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 149 ERYTECH Pharma shares at a unit price of 13.7 Euros;
- on March 28, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold:
  - 150 ERYTECH Pharma shares at a unit price of 13.40 Euros;
  - 100 ERYTECH Pharma shares at a unit price of 13.45 Euros;
- on April 2, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 350 ERYTECH Pharma shares at a unit price of 15.67 Euros;
- on May 14, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 550 ERYTECH Pharma shares at a unit price of 15.04 Euros;
- on September 17, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 125 ERYTECH Pharma shares at a unit price of 16.88 Euros;
- on September 26, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 250 ERYTECH Pharma shares at a unit price of 23.02 Euros;
- on September 30, 2014, Jérôme BAILLY, Delegated Managing Director, exercised 500 founder subscription warrants (BSPCE2012) at a unit price of 73.62 Euros;
- on October 1<sup>st</sup>, 2014, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 300 ERYTECH Pharma shares at a unit price of 34.78 Euros;
- on October 2, 2014, Philippe ARCHINARD, Director, exercised 1,337 share subscription warrants (BSA2012) at a unit price of 73.62 Euros;
- on October 13, 2014, the company GALENOS SPRL, Director, exercised 500 share subscription warrants (BSA2012) at a unit price of 73.62 Euros;
- on October 15, 2014, Gil BEYEN, Chairman and Chief Executive Officer, exercised 3,400 founder subscription warrants (BSPCE2012) at a unit price of 73.62 Euros;
- on October 17, 2014, Jérôme BAILLY, Delegated Managing Director, sold 940 ERYTECH Pharma shares at a unit price of 25.30 Euros;
- on December 2, 2014,
  - Philippe ARCHINARD, Director, sold 1,370 ERYTECH Pharma shares at a unit price of 28 Euros;
  - Jérôme BAILLY, Delegated Managing Director, sold 550 ERYTECH Pharma shares at a unit price of 28 Euros.

Since December 31, 2014, the managers and persons indicated in Article L. 621-18-2 of the Monetary and Financial Code performed the following operations on Company securities:

- on January 13, 2015, Françoise HORAND PHOTHIRATH, an executive equivalent person, sold 400 ERYTECH Pharma shares at a unit price of 30.50 Euros;
- on January 14, 2015,
  - Yann GODFRIN, Delegated Managing Director, sold:
    - 111,687 ERYTECH Pharma shares at a unit price of 29.7951 Euros;
  - Gil BEYEN, Chief Executive Officer, sold:
    - 25,316 ERYTECH Pharma shares at a unit price of 29.7951 Euros;
- on January 15, 2015,
  - Gil BEYEN, Chief Executive Officer, sold:
    - 8,684 ERYTECH Pharma shares at a unit price of 29.0293 Euros;
  - Yann GODFRIN, Delegated Managing Director, sold:
    - 38,313 ERYTECH Pharma shares at a unit price of 29.0293 Euros;
- on February 20, 2015, Jérôme BAILLY, Delegated Managing Director, sold 300 ERYTECH Pharma shares at a unit price of 27.60 Euros;
  - on February 27, 2015, Françoise HORAND PHOTHIRATH, an executive equivalent person, exercised 160 founder subscription warrants (BSPCE2012) at a unit price of 73.62 Euros.

# 16 OPERATION OF THE ADMINISTRATIVE AND MANAGEMENT BODIES

The Company possesses a Board of Directors, a Management Committee, a Remuneration Committee, an Audit Committee and a Scientific Board.

### 16.1 Term of office for directors

Refer to section 14.1.1 "Remuneration of the Board of Directors" in this Reference Document.

# 16.2 Service agreements binding members of the Board of Directors and Senior Management with the Company

Refer to section 14.1.2 of this Reference Document.

# 16.3 Corporate governance, internal audit, and risk management

The Company complies with all provisions of the corporate governance code for small and mid-caps published by Middlenext in 2009 and validated as a coat of reference by the Autorité des Marchés Financiers (the French financial markets regulator).

For the financial year ending December 31, 2014, in addition to the information provided in the present section, the status of application of the guidelines in the Middlenext Code is as follows:

Guidelines from the MiddleNext Code	Adopted
I. Executive power	
R 1: Total employment contract and term as officer	X
R 2: Definition and transparency in remuneration for executive corporate officers	X
R 3: Severance pay	X
R 4: Supplemental pension plans	X
R 5: Stock options and awards of free shares	X
II. The power of "oversight"	
R 6: Implementation of rules of procedure for the board	X
R 7: Professional ethics for members of the board	X
R 8: Composition of the board – Presence of independent members on the board	X
R 9: Selection of board members	X
R 10: Term for which board members are elected	X
R 11: Notice to board members	X
R 12: Implementation of committees	X
R 13: Meetings of the Board and of committees	X
R 14: Remuneration for directors	X
R 15: Implementation of an evaluation of work by the Board	X

The Company believes that its organization and the procedures implemented (including, namely, the Board of Directors' Rules of Procedure, regularly revised by the directors in order to ensure its relevance and compliance with the Middlenext Code) make it possible to comply with all of the recommendations in the Code.

#### 16.3.1 ISO certification



#### 16.3.2 Chairman's report on internal audits

# A. Conditions for preparing and organizing the work of the board of directors

During its meeting on May 6,2013, the Board of Directors adopted rules of procedure which were last updated on April 25, 2014. These rules of procedure may be consulted on the Company's website. They specify the role and composition of the Board, the principles of conduct, and the obligations of the members of the Board of Directors towards the Company and the procedures for the operation of the Board of Directors and the committees, the rules for determining the remuneration of their members. Each member of the Board of Directors agrees to devote the necessary time and attention to his/her duties. He/she shall inform the Board of any situations he/she may find himself in which present a conflict of interest. Furthermore, the rules of procedure incorporate current regulations pertaining to the dissemination and use of privileged information and specify that the members must abstain from engaging in transactions involving the Company's shares when they possess privileged information. Each member of the Board of Directors is required to inform the Company and the AMF of any transactions involving the Company's shares which he/she performs whether directly or indirectly.

After having examined the provisions of the code of corporate governance for listed companies developed by MiddleNext in December 2009, particularly the elements presented in the heading "points of vigilance," the Board of Directors, in its meeting on May 6, 2013, decided to adopt rules of procedure in which it is stated that the Company shall comply with the MiddleNext Code as a corporate code of governance for the Company.

The MiddleNext Code may be viewed at the following website: <a href="http://www.middlenext.com/IMG/pdf/Code\_de\_gouvernance\_site.pdf">http://www.middlenext.com/IMG/pdf/Code\_de\_gouvernance\_site.pdf</a>.

The guidelines in the MiddleNext Code have since been applied by the Company as is specified below. It should be noted that the recommendation relative to stock options and the allocation of free shares is not applicable by the Company, as no stock options or free shares have been allocated by the Company to its corporate officers.

# A.1. Composition of the board:

During the financial year ended December 31, 2014, the following modifications took place concerning the Board of Directors:

- Sven Andreasson resigned from his position as director on January 22, 2014 (resignation acknowledged by the Board of Directors on January 22, 2014);
- The company GALENOS SPRL was appointed director by co-optation, to replace Sven Andreasson. This appointment was ratified by the combined general shareholders' meeting of June 17, 2014;
- Martine Ortin George was appointed to a director position by the shareholders during the combined general shareholders' meeting of June 17, 2014, for a duration of three years. Her mandate will be discontinued at the end of the ordinary general shareholders' meeting to be held in 2017 to rule on the financial statements for the year ended December 31, 2016;
- Hilde Windels was appointed to a director position by the shareholders during the combined general shareholders' meeting of June 17, 2014, for a duration of three years. His mandate will be discontinued at the end of the ordinary general shareholders' meeting to be held in 2017 to rule on the financial statements for the year ended December 31, 2016;
- The company KURMA Life Science Partners, for which Vanessa MALIER was the permanent representative, replacing Alain Munoz as of the Board of Directors' meeting of January 22, 2014, resigned from its position as member of the Board of Directors on July 17, 2014 (resignation acknowledged by the Board of Directors on August 29, 2014).

By virtue of legal provisions and those of the articles of incorporation, the Board of Directors is composed of no fewer than three directors and no more than eighteen. Directors are appointed, reappointed to their position, or removed by the Company's ordinary general meeting. Their term of office, in accordance with Article 17 of the articles of incorporation, is three years.

At December 31, 2014, the Board of Directors was composed of seven members, i.e.:

Last name	Date of appointment or co-optation	Expiration of the term on
Gil Beyen (Chairman and Chief Executive Officer)	05/06/2013	2016
Pierre-Olivier Goineau (Vice President and Delegated Managing Director)	05/06/2013	2016
Yann Godfrin (Delegated Managing Director)	05/06/2013	2016
GALENOS SPRL, represented by Sven ANDREASSON	01/22/2014	2016
Philippe Archinard	05/06/2013	2016
Martine ORTIN GEORGE	06/17/2014	2017
Hilde WINDELS	09/17/2014	2017

We note that the Board of Directors, in its meeting of January 11, 2015, acknowledged the resignation of Pierre-Olivier GOINEAU from his positions as Delegated Managing Director, Deputy Chairman, and Director. These directors were appointed to the Board of Directors because of their knowledge of the Company's activities, their technical and general skills and abilities, as well as their aptitude to fulfill the directors' duties required within that Board.

The Company is aware of the provisions provided in the act of January 27, 2011 pertaining to balanced representation of men and women on boards of directors. At December 31, 2014, the Company's Board of Directors was composed of five men and two women, i.e., a proportion of women greater than 20% of the members of the board of directors, as required by this law at the end of the first ordinary general shareholders' meeting following January 1<sup>st</sup>, 2014. The law of January 27, 2011 furthermore requires that the proportion of men and women be at least equal to 40% at the end of the first ordinary general shareholders' meeting following January 1<sup>st</sup>, 2017 or, where the board of directors is not composed of more than eight members, that the difference between the number of members of each gender not be greater than two.

In conformity with the MiddleNext Code, the Board of Directors includes several independent directors, the company GALENOS, Philippe ARCHINARD, Martine Ortin George, and Hilde Windels, who meet the independence criteria defined by the MiddleNext Code.

The criteria specified by the Middlenext Code make it possible to show that the members of the Board are independent, as characterized by the lack of a significant financial, contractual, or familial relationship capable of altering independent judgment, namely:

- they are neither an employee nor an executive corporate officer of the Company or a company within its group, and they have not been one of the above over the course of the last three years;
- they are not significant clients, suppliers, or bankers for the Company or its group or for which the Company or its group represent a significant share of business;
- they are not major shareholders of the Company;
- they do not have any close family connection with an officer or a major shareholder;
- they were not an auditor of the Company over the last three years.

The list of Company directors, including the positions held in other companies, is shown in paragraph 14.1.2 of the Reference document.

During the Company's combined general shareholders' meeting of June 17, 2014, the total annual amount of attendance fees allocated to directors is set at 60,000 Euros, and is applicable to the current year.

The Board of Directors' meeting of January 11, 2005 decided on the distribution of attendance fees in function of the regularity of the directors' attendance and of the time that they dedicated to their position during the financial year ended 2014, in conformity with the recommendations of the Remuneration Committee, which met on the same day.

# A.2. Frequency of meetings

Article 19 of the articles of incorporation provides that the Board shall meet as often as required for the interest of the Company.

During the financial year ended December 31, 2014,

the Board of Directors met twelve times, on January 22, 2014, April 16, 2014, April 25, 2014, May 5, 2014, May 19, 2014, June 9, 2014, July 17, 2014, August 29, 2014, September 16, 2014, September 22, 2014, September 29, 2014, and December 4, 2014.

The number of Board of Directors' meetings held during the financial year ended December 31, 2014 complies with the recommendations of the MiddleNext Code, which requires a minimum of four annual meetings.

A list of agenda items addressed in meetings of the Board of Directors during this financial year is provided below in paragraph A.6.

The attendance rate of members of the Board of Directors during the financial year ended December 31, 2014 was 87% (the rate was 86% during the financial year ended December 31, 2013).

# A.3. Summons of directors

The directors were summoned with reasonable advance notice of meetings pursuant to Article 19 of the articles of incorporation.

Pursuant to Article L.225-238 of the Code of Commerce, the Statutory Auditors were given notice to appear at the meetings of the Board, which examined and approved the interim financial statements (half-yearly financial statements) as well as the annual financial statements.

#### A.4. Information provided to directors

All documents and information necessary for the directors' mission were provided to them at the same time as the notice of meeting or delivered at the beginning of each meeting of the Board of Directors.

The Board of Directors is assisted by three permanent committees whose powers and procedures are specified in the rules of procedure: the Audit Committee, the Remuneration and Appointments Committee, and the Scientific Board.

# A.5. Location of meetings

The meetings of the Board of Directors occur at the headquarters or at any other location indicated in the notice of meeting, pursuant to Article 19 of the articles of incorporation.

# A.6. Decisions adopted

During the financial year elapsed, the main subjects listed below were discussed in particular by the Board of Directors:

- The conditions for remuneration of executive officers:
- The co-optation of a new director;
- The implementation of a new plan for 22,500 BSPCE<sub>2014</sub>;
- The appointment of a new member of the Audit Committee and of the Remuneration and Appointments Committee:
- Approval of the annual budget;
- A capital increase through the issue of new shares;
- Capital increases associated with the exercise of BSA<sub>2012</sub> and BSPCE<sub>2012</sub>;
- The list of beneficiaries of the BSA<sub>2012</sub> and the BSPCE<sub>2012</sub>;
- The modification in the characteristics of the  $BSA_{2012}$  and the  $BSPCE_{2012}$ ;

- The transformation of 3,000 BSPCE<sub>2014</sub> into BSA<sub>2014</sub>;
- The half-yearly accounts and the half-yearly financial report;
- Professional gender equality;
- The implementation of a "Level 1 ADR" program in the United States.

# A.7. Meeting minutes

Minutes of the meetings of the Board of Directors are drawn up following each meeting and immediately sent to all directors. They are approved at the beginning of the following board meeting.

#### A.8. Evaluation by the Board of Directors

The Chairman, once per year, shall ask the directors for an opinion about the operation and preparation of the work by the Board. During the Board of Directors' meeting of March 26, 2015, the Chairman invited members of the Remuneration and Appointments Committee to issue a reasoned opinion on these matters. On the basis of this opinion, the directors shall express themselves during the next Board of Directors meeting.

# A.9. Specialized committees

ERYTECH Pharma pursues an information policy relative to corporate governance and the transparency of compensation of all its primary corporate officers.

Accordingly, in 2007, a Scientific Board was formed and in 2008, an Audit Committee and a Remuneration and Appointments Committee were formed to assist the Supervisory Board which then became the Board of Directors in its considerations and its decisions. These committees are described in the rules of procedure, which was last updated by the Board of Directors on April 25, 2014.

The Board of Directors establishes the composition and powers of the committees which conduct their activities under its responsibility. These powers may involve delegating powers to a Committee which are expressly allocated to it by law or by the articles of incorporation or by any other shareholder agreement enforceable as against the Company.

These Committees are purely internal to the Company. They do not have any inherent power and particularly no decision-making power. Their role is strictly advisory.

Each Committee reports on its missions to the Board of Directors.

The Board of Directors then has sole discretion to assess any follow-up it intends to make with respect to the findings presented by the Committees. Each director remains free to vote as he or she sees fit, without being bound by studies, investigations, or reports from the Committees, nor any of their recommendations.

Each Committee shall include no fewer than two members and no more than ten members. Members are appointed personally by the Board of Directors based on their experience and may not be represented. The Committees may be composed solely of directors or even include outside persons. The composition of these Committees may be modified at any time by a decision of the Board of Directors.

The term of office for the Committee members coincides with that of their term as directors when they are board members. The term of a Committee member may be renewed at the same time as that of the director. For Committee members who are not part of the Board of Directors, the term of office is set at one (1) year, automatically renewable.

Committee meetings are held at the Company's headquarters or at any other location decided by the Committee Rapporteur. However, Committee meetings may be held, if necessary, by teleconference or videoconference.

For the correct operation of the Committees and their administrative process, the Rapporteur of each Committee:

- Draws up the agenda for each meeting according to the needs expressed by the Board of Directors;
- Formally serves notice to the members; and
- Directs discussion.

Within each Committee, the Rapporteur appoints one person who shall be tasked with writing minutes following each meeting. The minutes shall be sent to the Chairman of the Board of Directors. The minutes shall be kept by the Company. The reports on the work and recommendations from each Committee shall be presented by the Rapporteur to the Board of directors.

In its field of competence, each Committee issues recommendations, proposals, and opinions.

### **Confidentiality:**

Because information communicated to the Committees or to which the Committee members have access for their missions is confidential in nature, Committee members are required to adhere to the strictest confidentiality in matters pertaining to the Board of Directors with regards to any third party and identical to that applicable to directors. This provision also applies to any outside persons who might be invited.

# A.9.1. Audit Committee

To date, the Audit Committee is composed of three members appointed for the duration of their director mandate.

The Audit Committee must meet at least once per year.

The Audit Committee's mission is to monitor the existence and efficacy of the Company's financial audit and risk control procedures on an ongoing basis. This committee is tasked with:

- examining the corporate and consolidated annual and interim financial statements;
- validating the relevance of the accounting methods and choices;
- verifying the relevance of financial information published by the Company;
- assuring the implementation of internal control procedures;
- verifying the correct operation of internal controls with the assistance of internal quality audits;
- examining the schedule of work for internal and external audits;
- examining any subject capable of having a meaningful financial and accounting impact;
- examining the state of significant disputes;
- examining off-balance-sheet commitments and risks;
- examining the relevance of risk monitoring procedures;
- examining any regulated agreements;
- directing the selection of statutory auditors, their remuneration, and ensuring their independence;
- verifying the correct performance of the statutory auditors' mission;
- establishing the rules for the use of statutory auditors for work other than auditing accounts and verifying the correct execution thereof.

The Audit Committee may conduct visits or interviews of any directors of operational or functional entities useful to fulfill its mission. It can also hear from the external auditors, including without the presence of corporate officers. It may make use of outside experts with prior approval from the Board of Directors.

Currently, the members of the audit committee are:

- Hilde WINDELS, rapporteur and independent member;
- The company GALENOS, represented by Sven ANDREASSON, independent member (see also Section A.1 above);
- Philippe ARCHINARD, independent member.

The experience of the members of the Audit Committee is presented in Section 14.1.3 of the Reference document.

It is hereby specified that these three members hold specific financial and accounting competencies, as a result of their experience of nearly 25 years in the pharmaceutical industry and general management positions that they have held and still hold.

The previous committee members met twice during the financial year ended December 31, 2014.

Among the points discussed during these meetings:

- The annual financial statements and the annual report for the year ended December 31, 2013;
- The interim financial statements and the interim financial report.

# A.9.2. Remuneration and Appointments Committee

The Remuneration and Appointments Committee is composed of three members, two of whom are independent members, pursuant to the provisions of the rules of procedure:

- Hilde WINDELS, rapporteur and independent member,
- Philippe ARCHINARD, independent member,
- The company GALENOS, represented by Sven ANDREASSON and an independent member.

The experience of the members of the Remuneration and Appointments Committee is presented in section 14.1.3 of the Reference document.

This committee hears directors about the evaluation of the Company's performance in light of the defined goals. Additionally, and particularly, this committee performs the following duties:

- It formulates recommendations and proposals concerning (i) the various components to compensation, pension and health insurance plans for officers and directors, and defines in particular, (ii) the procedures for establishing the variable portion of their compensation; (iii) and formulates recommendations and proposals concerning a general policy for awarding share subscription warrants and founder subscription warrants;
- It examines the amount of attendance fees and the system for distributing them between the directors taking into account their dedication and the tasks performed within the Board of Directors;
- It advises and assists as necessary the Board of Directors in the selection of senior executives and the establishment of their remuneration;
- Assessing any increases in capital reserved to employees;
- Assisting the Board of Directors when selecting new members;
- Ensuring the implementation of structures and procedures to allow the application of good governance practices within the Company;
- Preventing conflicts of interest within the Board of Directors;
- Implementing the Board of Director's evaluation procedure.

The committee met once during the financial year ended December 31, 2014.

Among the points discussed during these meetings:

- The conditions for remuneration of executive officers;
- The issuance of a new capital incentive plan.

### A.9.3. Scientific Board

The members of the Scientific Board were selected because of their scientific expertise in the fields of activity engaged in and developed by the Company.

The Board is thus primarily composed of persons from outside the Company, it meets at least once per year to evaluate, from a scientific point of view, (i) the conduct and evolution in research programs conducted by the Company (ii) the Company's development strategy, particularly given therapeutic needs and market needs and (iii) any risks which might be posed by the research and development programs of the Company's competitors.

The six members of this Board were appointed for a term of one (1) year, automatically renewable (except for the Deputy General Manager in charge of scientific duties and who is the rapporteur and automatically a member).

The members of the Scientific Board as well as their relations with the Company are detailed in the table below:

Last name	Connection with the Company	Member of the Scientific Board since
Dr. Yann Godfrin	Delegated Managing Director	2007
Prof. Eric Raymond	Consultant	2009
Dr. Philip L. Lorenzi	Consultant	2010
Dr. Bridget Bax	Consultant	2012
Prof. Arthur E. Frankel	Consultant	2012
Dr. Kurt Gunter	Consultant	2012

The experience of Dr. Yann GODFRIN is presented in Section 14.1.3 of the Reference Document.

#### Prof. Eric Raymond, Doctor of Medicine,

Head of the Cancer Treatment Department (SIHC) at the University Hospital of Beaujon-Bichat (Paris), Prof. Raymond is an expert in oncology. He has published more than 100 articles and is a member of several international associations of experts in oncology.

Prof. Raymond holds an advanced Master's degree (DEA) in Biomedical Engineering with a specialization in bio-imaging from the University of Créteil.

# Dr. Philip L. Lorenzi, Doctor of Medicine

Currently, he is the Laboratory and Research Supervisor in the Department of Bioinformatics and Computational Biology at MD Anderson Cancer Center, Houston, Texas, United States. He is an expert in pharmacogenomics, systems pharmacology, and translational research, specializing in the identification of biomarkers associated with the use of L-asparaginase in chemotherapy.

# Dr. Bridget Bax, PhD (Doctor of Sciences)

Bridget Bax is an associate professor at London Metropolitan University and conducts her research in the Department of Clinical Development Sciences at the Saint George Hospital.

She is an expert in metabolic diseases and enzyme replacement therapy.

# Prof. Arthur E. FRANKEL, Doctor of Medicine

Arthur E. Frankel heads the Hematology/Oncology Department of the Scott & White Cancer Institute in Texas and is a professor at the Texas Health Science Center, College of Medicine. He is interested in the involvement of amino acids in cancer and particularly their reduction as a cancer therapy.

#### Dr. Kurt Gunter, Doctor of Medicine

Kurt Gunter is chairman of the International Society of Cellular Therapy until 2014 and, since March 2013, has been Chief Medical Officer of Cell Medica (U.K.). Until the end of March 2013, he headed the Department of Regenerative Medicine at the Hospira Inc. in Chicago (USA). He is an expert in the development of medicine and particularly with respect to regulatory aspects. He was Acting Deputy Director at the FDA (Food and Drug administration) of the CBER (Center for Biologics Evaluation and Research).

# B. Internal control and risk management procedures within the Company

# B.1. Conceptual framework for internal controls and risk management

#### Data warehouse

The Company relies on the AMF's framework of reference (guideline 2010-16) pertaining to risk management and internal control mechanisms, AMF guideline no. 2010-15 of December 7, 2010 pertaining to the AMF's additional report on corporate governance, remuneration of executive officers, and internal controls for small and mid-cap companies referring to the MiddleNext Code, and AMF guideline 2013-17 entitled Chairmen's Reports on Internal Control and Risk Management Procedures – Consolidated presentation of guidelines contained in the annual reports from the AMF.

#### **B.2.** Risk management

#### Goals:

- Promote achieving the Company's objectives (see also Section B.4 below);
- Analyze and process risks identified by the Company to date and presented in Chapter 3.2 of this report, namely by:
  - Maintain a high level of product quality and safety;
  - Protect the Company's interests;
  - Secure the Company's processes.

# Components of the system:

The responsibilities for risk management are held by the Chief Executive Officer, Gil BEYEN.

The risk management system particularly provides:

- risk analysis (identification, analysis, and treatment of risk according to PO-QUAL-007 the last version of which is dated 05/23/2011);
  - processes and especially the Production process, as well as;
  - physical security and information systems;
  - the Company's assets and reputation.
- A risk management procedure (PG-QUAL-017 the last version of which dates from 03/29/2012) encompassing, namely:
  - the role:
    - of the process managers;
    - of the Quality Assurance department and Chief Pharmacist.
    - guidance of the system, notably via the Management process (PG-MAQ-A3 OF 09/02/2013) and the Continuous improvement process (PG-MAQ-A4 of 07/30/2013) and management reviews (PG-QUAL-012 the last version of which dates from 06/25/2013);
    - appropriate communication for its implementation by both external and internal actors.

### **B.3.** Internal controls

# Goals of internal control:

Internal control is one of the Company's mechanisms which is intended to ensure:

- compliance with laws and regulations;
- application of the instructions and orientations established by Senior Management;
- the correct operation of the Company's internal processes, particularly those intended to assist in the protection of its assets;
- reliability of financial information;
- and, generally speaking, contributes to the mastery of its activities, the efficacy of its operations, and the efficient use of its resources.

By contributing to the prevention and governance of risks of not achieving the objectives established by the Company (see also Section B.4 below), the internal control mechanism plays a key role in the conduct and steering of its various activities.

However, internal controls cannot provide an absolute guarantee that the Company's objectives shall be reached.

#### Components:

In collaboration particularly with the audit committee (see also Section B.4.4 below), the responsibility for internal controls lies with the Chief Executive Officer, Gil BEYEN.

The internal audit mechanism provides:

- an organization including a clear definition of responsibilities, possessing adequate skills, abilities, and resources (*see also Section B.4.4 below*)), and relying on procedures, information systems, tools, and appropriate practices (*see also Section B.4.1 below*);
- The internal dissemination of relevant and reliable information (namely via an electronic document management system), the knowledge of which allows each person to exercise his/her responsibilities;
- a system intended to survey and analyze the primary identifiable risks with regard to the Company's goals and ensure the existence of procedures to manage these risks;
- control activities proportionate to the stakes inherent to each process, designed to reduce risks likely to affect the achievement of the Company's goals;
- ongoing monitoring of the internal control mechanism as well as regular examination of its operation.

# B.3.1. Scope of risk management and internal control

# B.3.2. Procedures pertaining to financial information

The Company has, in particular, implemented the following organization to limit risks in terms of managing finance and bookkeeping matters:

- The Company's Senior Management, and more particularly, personnel within the Corporate Division
  are attentive with regard to improving internal controls and integrating recommendations from external
  auditors and the Audit Committee;
- The Company has implemented several procedures to manage the Procurement process. In these
  procedures, the resources to prevent risks inherent to the size of the Company and which are associated
  with internal separation between production and supervision of financial statements have already been
  provided;
- A certified public accountant participates to verify the statements presented in accordance with IFRS standards for the 2013 and 2014 financial years.

# B.3.3. Quality policy (PG-MAQ-A1):

ERYTECH Pharma develops and provides patients, clients, and partners with products that combine safety, quality, and technology.

ERYTECH Pharma, specialty pharma, commercializes drugs and therapeutic solutions intended for the treatment of serious pathologies, orphan indications for fragile patients in the fields of hematology, oncology, and immunology.

These technologies and products represent a new generation of drugs using red blood cells as a vector for therapeutic agents. They seek to:

- Provide a therapeutic solution where alternatives are lacking;
- Improve the therapeutic index of current treatments;
- Improve patient comfort.

ERYTECH's management has always sought to offer the best possible service and the best advice in order to fully respond to the needs and requirements of hospital-based healthcare professionals. This orientation allows it to guarantee its development and its continued existence.

The application of this quality policy involves all of the company's department. It is reflected by the establishment and the tracking of shared goals.

The quality objectives of ERYTECH Pharma for 2015 are:

- 1. Submitting the AMM file within the anticipated timelines;
- 2. Rationalizing and simplifying the processes, redefining the "develop a product" process;
- 3. Integrating the United States into our quality management system:
- 4. Renewing the ISO 9001 certification;
- 5. Improving the management of our internal and external communication.

# B.3.4. Quality System and the Management's commitment:

In order to correctly implement this policy, the Company relies on its existing quality system, certified ISO 9001 and described in the Quality Manual.

With the goal of having this policy applied, executive officers personally commit and delegate to the Quality Assurance department (in collaboration with the relevant departments) the implementation and monitoring of the quality system. Directly under management, it must report on the operation of the system. It relies on process managers for efficient management of the quality system.

Management also undertakes to deploy all current resources to personally ensure the implementation and efficacy of the quality system during management reviews and meetings of the Management Committee.

The company's evolution from a research and development structure towards a structure that integrates sales requires modification in the current system to account for new client demands by striving to achieve operational excellence, with collective involvement in this undertaking.

# B.3.5. Actors in risk management and internal control

# Senior Management:

Senior Management is tasked with defining, providing impetus, and overseeing the most appropriate mechanism for the Company's conditions and activity.

In this framework:

- It ensures that the necessary corrective actions are undertaken;
- It informs the Board of Directors about the important points.

Senior Management is responsible for reporting on the essential characteristics of the risk management and internal control mechanism to the Audit Committee.

The members of Senior Management are:

- Gil BEYEN, Chief Executive Officer;
- Yann GODFRIN, Delegated Managing Director;
- Jérôme BAILLY, Delegated Managing Director.

The duties of the Deputy General Managers are specified below in section C.

# Management Committee

The members of the Executive Committee are responsible for keeping Senior Management regularly informed of any malfunctions, deficits, and difficulties.

The Executive Committee is composed of Senior Management and Françoise HORAND-PHOTHIRAH, Director of R&D Operations.

# The Audit Committee:

In accordance with the internal rules established by the Board of Directors, last updated 04/25/2014, the Audit Committee is responsible for reporting to the Board of Directors on all major risks and/or weaknesses in the internal controls such as may have a significant impact on accounting and financial information.

#### The Board of Directors:

As needed, the Board may make use of its general powers to engage in any audits and inspections it deems useful or take any other initiative it believes appropriate in the matter.

#### The internal quality auditors:

Pursuant to procedure PG-QUAL-004, the last version of which dates from 02/21/2011, the Company trains and then appoints internal auditors in order to verify whether the procedures and/or processes have been followed and are effective.

Each year, Management defines a program for internal audits, with priority given to: activities having a direct connection to the pharmaceutical facility and patient safety.

Internal auditors are specifically responsible for reporting to the Quality Assurance department any deviation from the procedures and/or processes.

#### The Quality Assurance department:

The Quality Assurance department is responsible for reporting to Senior Management, specifically, any significant deviation from the quality policy and/or procedures and/or processes.

# External auditors or certifying bodies or regulatory authorities:

Accordingly:

- The Agence Nationale de la Sécurité du Médicament [National Agency for the Safety of Drug and Healthcare Products] (ANSM) the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) and;
- the IOS auditor (http://www.iso.org/iso/home.htmlInternational Organization for Standardization);
- the statutory auditors;

participate in risk management through their audits and/or controls.

# **B.4.** Areas for improvement/Outlooks for change

In 2015, the Company will continue its efforts to improve the monitoring of risk analysis action plans and to better coordinate internal controls with risk management.

#### C. Powers of the Chief Executive Officer

Please note that there has been no limitation made to the powers of Gil Beyen, Chief Executive Officer.

On May 6, 2013, the Board of Directors stated that:

- Yann Godfrin is especially tasked with the activities of scientific strategy, preclinical research and development, clinical and regulatory affairs;
- Jérôme Bailly, in turn, was granted his powers as pursuant to Article R. 5124-36 of the French Public Health Code.

Further, until the date of his resignation, Pierre-Olivier Goineau was especially in charge of the following activities: strategy, organization and management of operations, internal control, finance, administration, legal, human resources, sales and partnerships.

Refer also to Section 14.1.2 of the Reference Document, "Composition of Senior Management".

# D. Attendance at the General Meeting of Shareholders and information required under Article L.225-100-3 of the Code of Commerce

There are no specific procedures pertaining to the shareholder participation in the general meeting of shareholders outside of those provided in Article 27 of the Articles of Incorporation.

The information referenced in Article L.225-100-3 of the Code of Commerce (concerning elements that may have an impact where is a public take-over bid for the Company) is shown in the Section 16.6 of the Reference Document.

**ERYTECH** 

# 16.4 Elements capable of having an impact in the event of a public offering

# 16.4.1 Capital structure of the company

See Chapter 18 of the Reference document

16.4.2 Restrictions resulting from the articles of incorporation respecting the voting rights and transfers of shares or clauses of which the Company has been informed in application of Article L.233-11 of the Code of Commerce

None

16.4.3 Direct or indirect stakes held in the Company's share capital of which it is aware by virtue of Articles L.233-7 and L.233-12 of the Code of Commerce

See Chapter 18 of this Reference document.

16.4.4 Parties holding any securities involving special rights of control and description thereof

None

16.4.5 Control mechanisms provided in any system for employee shareholding, when the controller rights are not exercised by the latter

None.

16.4.6 Agreements between shareholders of which the Company is aware and which may result in restrictions to transfers of shares and the exercise of voting rights

None.

16.4.7 Rules applicable to the appointment and replacement of members of the board of directors as well as modification of the articles of incorporation

The applicable rules in this matter are found in the articles of incorporation and comply with the law.

16.4.8 Powers of the board of directors, particularly the issuance or redemption of shares

The Company's general shareholders' meeting of June 17, 2014 authorized the Board of Directors, on the suspensive condition that the Company's shares be listed on the Euronext Paris market, to implement a buyback program on the Company shares, in conformity with the provisions of Article L. 225-209 and following of the Code of Commerce and the market practices approved by the Autorité des marchés financiers (*see Section 21.1.2 of this Reference Document*).

- 16.4.9 Agreements stipulated by the Company that have been modified or that will end if there is a change in control of the Company.
- The characteristics of the share subscription warrants/founder subscription warrants contain procedures for early exercise subject to certain conditions if there is a change in control of the Company (*See also Section 21.5 of this Reference Document*).
- See also Chapter 22 of this Reference Document, "Significant contracts".

# 16.4.10 Agreements providing for indemnities to members of the board of directors or employees if they resign or are dismissed without real or serious cause or if their employment is terminated due to a public offering

Pursuant to the "TEPA" law and the Middlenext Code of corporate governance, during its meeting of May 24, 2013, the Board of Directors established the terms for severance pay awarded to the company's executive corporate officers (specifically Gil Beyen, Pierre-Olivier Goineau, and Yann Godfrin).

This commitment provided that should the party in question leave the Company, that is to say in the event of:

- expiry of his term of office (except where renewal is rejected by the interested party) or
- removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation),

the party in question may claim an indemnity equal to 12 times the mean monthly remuneration (bonuses included) effectively received over the course of the 12 months preceding the removal decision or the expiration of the term of office (or concerning only Gil Beyen, the annual fixed remuneration defined by the Board of Directors, should the removal be decided within 12 months following his appointment).

The decision by the Board of Directors on May 24, 2013, made with respect to the procedure for regulated commitments and agreements provided under the "TEPA" act, was published in its entirety on the Company's website. The commitment was approved by the general shareholders' meeting of June 17, 2014 as a specific resolution pertaining to each of the executive corporate officers.

The Board of Directors decided that payment of severance pay is subordinate to the compliance, duly recorded by the Board of Directors at the time of or after the departure from the position, with the conditions associated with the performances of the party in question assessed with regard to those of the Company, defined on this day as being:

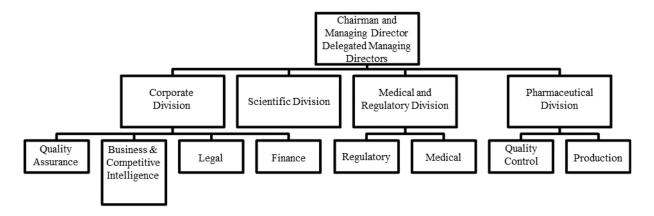
- Compliance with the Company's expenditure budget and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.

### 17 EMPLOYEES

### 17.1 Personnel

See also Annex 2 of the Reference Document "Environmental, Social, and Corporate Responsibility Policy".

# 17.1.1 Functional organization chart



# 17.1.2 Experience and positions of the principal managers

The experience and positions of the principal managers are described in Section 14.1.4 above.

# 17.1.3 Personnel distribution

The Company's workforce included 44 people at March 31, 2015.

# Change in personnel

The average workforce has varied in the following proportions:

Year	mean personnel	change
2004	1	
2005	2	+ 100%
2006	8	+ 300%
2007	14	+ 75%
2008	24	+ 71%
2009	37	+ 54%
2010	41	+ 11%
2011	41	+0%
2012	38	- 7%
2013	36	- 5%
2014	38	+ 5%

 $Source: Tax\ bundles,\ table\ 2058-C\ \ ``miscellaneous\ information''$ 

### Distribution by area of activity

At December 31, 2014, the Company's personnel (including executive officers) was distributed based on the following areas:

Departments	Personnel
<b>Business &amp; Competitive Intelligence</b>	2
Clinical Affairs	3
Finance	2
Legal	3
Administration	2
Public Relations/Investors	1
Production	12
Quality Assurance	3
Preclinical	15
Regulatory	1
Grand total	44

# Distribution by status

Status	Number
Management	23
Non-management	21
Grand total	44

### 17.1.4 Human Resources Management

The management of employees is of great importance for the Company. Indeed, the Company must retain qualified employees who possess strong skills and abilities as ERYTECH's business is, in fact, partially based on the quality and efficacy of its key employees.

The Company believes that it has good relations with its personnel.

The Company's employment contracts are controlled by the national collective-bargaining agreement in the pharmaceutical industry.

The Company has two employee representatives (one elected and one alternate) who meet with management every month.

The large majority of the Company's employees are employed on the basis of permanent contracts; however, the Company does make use of employees on fixed-term contracts, notably to satisfy the demands of periodic increases in business.

Insofar as the remuneration policy is concerned, the employment contracts may provide for, depending on the case, additional remuneration consisting of bonuses determined on the basis of goal attainment.

# 17.1.5 Organization of work time

The organization of work time at ERYTECH complies with all legal and regulatory provisions. The legal length of the workweek is 35 hours for full-time employees.

Senior executives are not covered by the laws respecting hours of work.

# 17.2 Investment stakes held by corporate officers

Based on the makeup of the share capital and the existing diluting elements as of the date of this document, stakes held by the company's corporate officers and executive officers can be summarized as follows:

					Subscription warrants						
	Number of shares	% capital **	% voting right	Type of warrants	Creation date	Number awarded and not exercise d	Number subscrib ed and not exercise d***	Exercise price in € per new share subscribed** **	Last date for exercise	Maximu m number of shares associate d	Stocks options
				Founder subscription warrants <sub>2012</sub>	05/21/12	7,863	7,863	7.362	05/20/20	78,630	N/A
Gil Beyen*	-	-	-	Founder subscription warrants (BSPCE) <sub>201</sub>	01/22/14	6,000	0	12.25	01/22/24	60,000	N/A
				Founder subscription warrants <sub>2012</sub>	05/21/12	7,508	7,508	7.362	05/20/20	75,080	N/A
Yann Godfrin *	142,990	2.08%	3.53%	Founder subscription warrants (BSPCE) <sub>201</sub>	01/22/14	3,000	0	12.25	01/22/24	30,000	N/A
Philippe Archinard *	4,000	0.06%	0.05%								
GALENOS *	4,500	0.07%	0.06%	Share subscription	05/21/12		0	7.362	05/20/20	62,380	N/A
Martine Ortin George*	-	-	-	(BSA) <sub>2012</sub>	03/21/12	6,238	U	7.302	03/20/20	02,360	IN/A
Hilde Windels*	-	-	-								
Jérôme Bailly*	3,000	0.04%	0.04%	Founder subscription warrants <sub>2012</sub>	05/21/12	N/A	958	7.362	05/20/20	9,580	N/A

<sup>\*</sup> See details for positions currently held in Chapter 14- Administrative and management bodies

<sup>\*\*</sup> Registered shares

<sup>\*\*\*</sup> See also section 21.2.4 of the Reference Document

<sup>\*\*\*\*</sup> As delegated by the General Meeting

<sup>\*\*\*\*</sup> one warrant gives rights to 10 new shares

# 17.3 Investment stakes held by company non-corporate officers

Based on the composition of the capital and dilutive elements existing at the date of financial year end, December 31, 2014, the investment stakes held by non-corporate-officer employees can be summarized as follows:

				Subscription warrants							
	Number of shares and voting rights*	% capital *	% voting right*	Type of warrants	Creation date	Number allocated and not exercised ***	Number subscribed and not exercised	Exercise price in € per new share subscribed	Last date for exercise	Maximum number of shares associated	Stocks
Employees who are not			0.09%	BSPCE <sub>2012</sub>	05/21/2012	1,793	1,793	7.362	05/20/202 0	17,930	N/A
officers or directors	8 800	0.13%	0.0970	BSPCE <sub>2014</sub>	01/22/2014	N/A	0	12.25	01/22/202 4	N/A	N/A

<sup>\*</sup> Registered shares

# 17.4 Incentive agreement

The Company has implemented a profit-sharing agreement for the years 2014 to 2016, at the end of which a percentage (2.5% in 2014) of the gross annual remuneration at December 31 of each year may be distributed:

- Among the beneficiaries, in proportion to their gross remuneration and their length of employment (up to certain limits);
- Upon the achievement of performance goals. The Company is presently at a key stage in its development, with the research and clinical trials cycle entering into its final phase before a potential placement on the market. The next years will be, accordingly, decisive in achieving the objectives necessary for the culmination of many years of research, involving sustained and targeted efforts by all of its teams. The objectives may include, for example, depending on the year considered, achieving clinical objectives and/or maintaining quality certifications and/or the status of "Pharmaceutical facility".

#### 18 MAJOR SHAREHOLDERS

# 18.1 Distribution of share capital and voting rights

In conformity with the provisions of Article L.233-13 of the Code of Commerce, we provide you, below, with the identity of shareholders who hold a stake exceeding the threshold of 5% of the capital and/or 5% of the voting rights. To the Company's knowledge, no other shareholders directly or indirectly, alone or jointly, hold more than 5% of the capital or voting rights.

<sup>\*\*\*</sup> See also section 21.2.4 of the Reference document

<sup>\*\*\*</sup> As delegated by the General Meeting

The Company's shareholder structure at December 31, 2014 is presented as follows, based on information available:

Last name, first na	me / Company name	% Share capital	% Voting rights	Number of shares
FCPR AURIGA	A VENTURES III	14.79%	21.46%	1,018,212
RECORDATI (	DRPHAN DRUGS	6.26%	5.20%	431,034
YANN	GODFRIN	4.26%	7.07%	292,990
PIERRE-OLIV	/IER GOINEAU	3.83%	6.36%	263,490
HOLDING ENTREPR	ISE AND PATRIMOINE <sup>1</sup>	0.75%	1.24%	51,530
	s who hold capital less than or to 0.5%	1.66%	1.85%	114,513
BEARER SECURITIES	Held by the Company within the scope of the buyback program <sup>2</sup>		0.00%	4,500
	OTHER BEARER SHARES	68.38%	56.77%	4,706,492
TO	TAL	100.00%	100.00%	6,882,761

<sup>&</sup>lt;sup>1</sup> Funds managed by IDINVEST PARTNERS

The Company's shareholder structure at April 20, 2015 is presented as follows, based on information available:

Last name, first na	me / Company name	% Share capital	% Voting rights	Number of shares
FCPR AURIGA	VENTURES III	14,78%	21,97%	1,018,212
RECORDATI C	RPHAN DRUGS	6,26%	5,32%	431,034
GOINEAU	Pierre-Olivier	3.09%	5,26%	212,900
GODFF	RIN Yann	2,08%	3,53%	142,990
HOLDING ENTREP	RISE ET PATRIMOINE	0.75%	1.27%	51,530
	ossess no more than 0.5% share pital	1,16 %	1.45 %	79,733
	Held by the Company within the scope of the buyback program <sup>2</sup>	0.04%	0.00%	2,500
BEARER SECURITIES	Other bearer shareholders <sup>3</sup>	71.90%	61,17%	4,952,692
TO	TAL	100.00%	100.00%	6,888,441

<sup>&</sup>lt;sup>1</sup>Funds managed by IDINVEST PARTNERS

During the financial year ended December 31, 2014, the Company received information on the following thresholds crossed:

- on February 13, 2014, following a sale of shares:
  - the threshold of 5% of the capital and voting rights, crossed downward by Ardian France (FCPR Axa Venture Funds IV). At that date, Ardian France no longer held any Company shares;
  - the threshold of 20% of the capital and voting rights, crossed downward by IDInvest Partners. At that date, IDInvest Partners held 989,543 shares representing 17.80% of the capital and voting rights;
- on February 28, 2014, following a decrease in the total number of voting rights in the Company,
  - the threshold of 25% of the voting rights, crossed upward by Auriga Partners (FCPR Auriga Ventures III). At that date, Auriga Partners held 1,147,522 shares representing 20.64% of the capital and 27.12% of the voting rights;
  - the threshold of 15% of the capital and voting rights, crossed downward by IDInvest Partners. At that date, IDInvest Partners held 989,543 shares representing 17.80% of the capital and 14.80% of the voting rights;
- on October 2, 2014, following a sale of shares on the market, the threshold of 15% of the capital was crossed downward by IDInvest Partners. At that date, IDInvest Partners held 813,400 shares representing 14.61% of the capital and 12.30% of the voting rights;

<sup>&</sup>lt;sup>2</sup> see Section 3.8.9 of the present Annual Financial Report

<sup>&</sup>lt;sup>2</sup> see Section 3.8.9 of the present Annual Financial Report

- following the Company's capital increase (Prospectus bearing AMF visa no. 14-566 of October 23, 2014):

- on October 23, 2014:
  - the threshold of 10% of the capital and voting rights, crossed downward by IDInvest Partners. At that date, IDInvest Partners held 704,599 shares representing 10.24% of the capital and 9.09% of the voting rights;
  - the threshold of 5% of the voting rights and capital, crossed upward by Baker Bros Advisors. At that date, Baker Bros held 674,027 shares representing 9.79% of the capital and 8.10% of the voting rights;
  - the threshold of 5% of the capital, crossed downward by Yann Godfrin. At that date, Yann Godfrin held 292,990 shares representing 4.26% of the capital and 7.05% of the voting rights.
- on October 28, 2014:
  - the threshold of 25% of the voting rights, crossed downward, and 20% of the capital, crossed downward by Auriga Partners (FCPR Auriga Ventures III). At that date, Auriga Partners held 1,147,522 shares representing 16.67% of the capital and 22.95% of the voting rights;
- on October 27, 2014, following a sale of shares, the threshold of 10% of the capital was crossed downward by IDInvest Partners. At that date, IDInvest Partners held 687,687 shares representing 9.99% of the capital and 8.89% of the voting rights.

Since December 31, 2014, the Company has received declarations of the following thresholds crossed:

- The threshold of 5% of the voting rights, crossed downward by Yann Godfrin on February 14, 2015, following a sale of ERYTECH Pharma shares on the market. At that date, Yann Godfrin held 124.990 shares representing 2.08% of the capital and 3.45% of the voting rights;
- The threshold of 5% of the voting rights, crossed downward by Pierre-Olivier GOINEAU on May 6, 2015, following an increase in the total number of voting rights in the Company. At that date, Pierre-Olivier GOINEAU held 212,000 shares representing 3.08% of the capital and 4.28% of the voting rights;
- The threshold of 5% of the voting rights, crossed downward by Idinvest Partners on May 19, 2015, following an increase in the total number of voting rights in the Company. At that date, Idinvest Partners held 429,112 shares representing 5.48% of the shares and 4.91% of the voting rights;
- The threshold of 5% of the voting rights, crossed downward by Idinvest Partners on May 28, 2015, following a sale of shares affecting the total number of voting rights in the Company. At that date, Idinvest Partners held 334,473 shares representing 4.86% of the shares and 4.43% of the voting rights.

# 18.2 Major shareholders not represented on the Board of Directors

At the date of the present Reference Document, three significant registered shareholders, i.e., Auriga Venture III, Recordati Orphan Drugs, and Pierre-Olivier GOINEAU, were not represented on the Board of Directors. In effect, since January 11, 2015, Pierre-Olivier GOINEAU is no longer a member of the Board of Directors.

# 18.3 Shareholder voting rights

In the ordinary and extraordinary general meetings of the Company, each share gives the right to one vote, except where there is a right for a double vote.

A double voting right is nevertheless assigned, in accordance with legal conditions, to all shares fully paid up for which evidence is provided, at the latest on the second day prior to the date of the shareholders' meeting, of nominal registration for at least two years in the name of the same shareholder, or in the name of a person holding such rights following a succession, a sharing of the community of property between spouses, or an inter vivos gift granted by a shareholder to his/her spouse or to a relative in the direct line of succession, or following a transfer resulting from a merger or a division of a shareholder company.

In the event of a capital increase through the incorporation of reserves, income, or issue premiums, the double voting right is granted, upon their issue, to nominal shares assigned free of charge to replace the previous shares already receiving such benefit.

The double voting right shall be duly withdrawn from any share having been converted to a bearer share or been subject to a transfer of ownership, except where this transfer results from a succession, a sharing of the community of property between spouses, or an inter vivos gift granted by a shareholder to his/her spouse or to a relative in the direct line of succession, or following a transfer resulting from a merger or a division of a shareholder company.

# 18.4 Control of the Company

To the Company's knowledge:

 no shareholder holds, whether directly or indirectly, a fraction of the share capital that would grant him/her/it the majority of voting rights in the Company's general meetings;

- no agreement has been formed among the shareholders so as to confer to one shareholder the majority of voting rights in the Company;
- no shareholder is able to dictate, on the basis of the voting rights that he/she/it holds, the decisions in the Company's general meetings of shareholders; and
- no shareholder has the power to name or remove the majority of members in the Company's management or oversight bodies.

Furthermore, to the Company's knowledge, no shareholder or group of shareholders directly or indirectly holds more than 40% of the voting rights in the Company, capable of creating a presumption of control of the Company with regard to one of the shareholders or a group of shareholders.

# 18.5 Shareholders' agreement

The shareholders' agreement dated December 22, 2006 entered into between the Shareholders of the Company, as amended on June 11, 2010, binding as of the registration date for the Reference document, became null and void starting on the day of the first listing of shares of the Company on Euronext Paris.

The shareholders have not indicated an intention to enter into a new shareholders' agreement.

#### 18.6 Concerted action

To the Company's knowledge, there is no concerted action among the shareholders.

# 18.7 Agreements capable of resulting in a change in control

To the Company's knowledge, there are no agreements in place whose implementation might, at a later date, result in a change in control.

### 19 OPERATIONS WITH RELATED PARTIES

All currently existing regulated agreements are mentioned in the special reports by the statutory auditor presented below.

Since preparation of the special report by the statutory auditor relative to the 2014 financial year:

- on January 11, 2015, the Board of Directors approved an increase in the fixed gross annual remuneration for Jérôme Bailly, Delegated Managing Director of the Company, pursuant to his employment contract.
- On March 26, 2015, the Board of Directors endorsed the following agreements with:
  - Gil BEYEN, Chief Executive Officer:
    - Profit sharing
    - PEE contribution
    - PERCO contribution
    - Share management assistance (Société Générale Securities Division)
    - Tax assistance (Delsol)
  - Yann GODFRIN, Delegated Managing Director of the Company:
    - Profit sharing
    - PEE contribution
    - PERCO contribution
    - Share management assistance (Société Générale Securities Division)
  - Jérôme BAILLY, Delegated Managing Director of the Company:
    - Profit sharing
    - PEE contribution
    - PERCO contribution
  - Pierre-Olivier GOINEAU, Delegated Managing Director of the Company until January 11, 2015:
    - Profit sharing
    - Share management assistance (Société Générale Securities Division)

The annexed IFRS consolidated financial statements provide details of related parties under Section 7.11, Chapter 20.1 of this document.

# 19.1 Intra-group transactions

During the financial year ended December 31, 2014, the Company paid \$100,000 to its subsidiary, ERYTECH Pharma Inc.

Since closure of the financial year ended December 31, 2014, the Company has stipulated a cash management agreement with its subsidiary, ERYTECH Pharma Inc.

# 19.2 Related party transactions

# 19.2.1 Special report by the statutory auditor on regulated agreements – Financial year ended December 31, 2014

# **Erytech Pharma SA**

Headquarters: 60 Avenue Rockefeller – Bâtiment Adénine – 69008 Lyon

Share capital: €688,276.10

### Special report by the statutory auditor on regulated agreements and commitments

Financial year ended December 31, 2014

Dear Shareholders,

In our capacity as statutory auditor for your company, we hereby present to you our report on regulated agreements and commitments.

Our task is to inform you, on the basis of the information that has been provided to us, of the characteristics and essential mechanisms of those agreements and commitments of which we have been informed or which we uncovered during our assignment, while not discussing their usefulness and their merits, nor searching for the existence of other agreements and commitments. It is your responsibility, in accordance with the terms of Article R.225-58 of the Code of Commerce, to assess the interest presented by the stipulation of these agreements and commitments, with a view to their approval.

Furthermore, our task is, as applicable, to provide you with the information specified in article R.225-31 of the Code of Commerce respecting the execution of agreements and commitments already approved by the general meeting over the course of the past financial year.

We have conducted the due diligence that we believed necessary in light of the professional doctrine of the Compagnie Nationale des Commissaires aux Comptes pertaining to this mission. This due diligence consisted in verifying that the data provided to us was consistent with the underlying documents from which they came.

# AGREEMENTS AND COMMITMENTS REQUIRING APPROVAL BY THE GENERAL MEETING

#### Agreements and commitments not previously authorized

In application of Articles L. 225-42 et L. 823-12 of the Code of Commerce, we hereby inform you that the following agreements and commitments have not been previously authorized by your Board of Directors.

It is our responsibility to inform you of the circumstances due to which the authorization procedure was not followed.

#### **With Pierre-Olivier Goineau**

<u>Carré VIP securities management consulting contract for Société Générale Securities Services</u> Person concerned: Pierre-Olivier Goineau, Delegated Managing Director of the Company.

- Nature and purpose: securities management consulting contract for the company subscribed for the 2014 financial year by Société Générale to the benefit of Pierre-Olivier Goineau, authorized by the Board of Directors on March 26, 2015.
- Terms: the cost of the VIP contract for the 2014 financial year is €200.

Pierre-Olivier Goineau resigned from his positions as Director and Delegated Managing Director on January 11, 2015.

#### With Yann Godfrin

Carré VIP securities management consulting contract for Société Générale Securities Services

Person concerned: Yann Godfrin, Delegated Managing Director of the Company.

- Nature and purpose: securities management consulting contract for the company subscribed for the 2014 financial year by Société Générale to the benefit of Yann Godfrin, authorized by the Board of Directors on March 26, 2015.
- Terms: the cost of the VIP contract for the 2014 financial year is €200.

### With Gil Beyen

Carré VIP securities management consulting contract for Société Générale Securities Services

Person concerned: Gil Beyen, Chairman of the Board of Directors and Managing Director of the Company.

- Nature and purpose: securities management consulting contract for the company subscribed for the 2014 financial year by Société Générale to the benefit of Gil Beyen, authorized by the Board of Directors on March 26, 2015.
- Terms: the cost of the VIP contract for the 2014 financial year is €200.

Tax consultancy services provided by Delsol

Person concerned: Gil Beyen, Chairman of the Board of Directors and Managing Director of the Company.

- Nature and purpose: tax consultancy services provided by Delsol during the 2014 financial year for Gil Beyen's tax situation, authorized by the Board of Directors on March 26, 2015.
- Terms: the charge undertaken for the 2014 financial year is €2,322.

Your Company considers that these agreements fall under Article L.225-39 of the Code of Commerce and, therefore, that the pre-authorization procedure specified in Article L.225-38 of this Code does not apply to them.

#### AGREEMENTS AND COMMITMENTS ALREADY APPROVED BY THE GENERAL MEETING

# Agreements and commitments approved during previous financial years that continued into the previous financial year

In application of Article R.225-31 of the Code of Commerce, we have been informed that the execution of the following agreements and commitments, already approved by the general meeting during previous financial years, were continued in the previous financial year.

### With Pierre-Olivier Goineau

1. Severance pay:

Person concerned: Pierre-Olivier Goineau, Delegated Managing Director of the Company.

- Nature and purpose: Severance pay, authorized by the Board of Directors on May 24, 2013, in the event of:
  - expiry of a term of office (except where renewal has been refused by the interested party),
  - removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation).

Pierre-Olivier Goineau may claim an indemnity equal to twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office.

Payment of this indemnity shall be subject to the finding that the following performance conditions have been met:

- Compliance with the Company's expenditure budget, and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.
- Terms: No charge was entered into the accounts in this respect by your Company for the 2014 financial year.

# 2. <u>Profit sharing:</u>

Person concerned: Pierre-Olivier Goineau, Delegated Managing Director of the Company.

- Nature and purpose: incentive
- Methods: on November 29, 2013, the Company stipulated a profit-sharing agreement for the period from January 1<sup>st</sup>, 2014 to December 31, 2016. On December 22, 2006, your Supervisory Board authorized the inclusion of Pierre-Olivier Goineau in a future profit-sharing agreement. The profit-sharing expense sustained in relation to the 2014 financial year had a gross value of 1,800 Euros.

Pierre-Olivier Goineau resigned from his positions as Director and Delegated Managing Director on January 11, 2015.

# With Yann Godfrin

1. Severance pay:

Person concerned: Yann Godfrin, Delegated Managing Director of the Company.

- Nature and purpose: Severance pay, authorized by the Board of Directors on May 24, 2013, in the event of:
  - expiry of a term of office (except where renewal has been refused by the interested party),
  - removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation).

Yann Godfrin may claim an indemnity equal to twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office.

Payment of this indemnity shall be subject to the finding that the following performance conditions have been met:

- Compliance with the Company's expenditure budget, and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.
- Terms: No charge was entered into the accounts in this respect by your Company for the 2014 financial year.

#### 2. Profit sharing:

Person concerned: Yann Godfrin, Delegated Managing Director of the Company.

- Nature and purpose: incentive
- Methods: on November 29, 2013, the Company stipulated a profit-sharing agreement for the period from January 1<sup>st</sup>, 2014 to December 31, 2016. On December 22, 2006, your Supervisory Board authorized the inclusion of Yann Godfrin in a future profit-sharing agreement. The profit-sharing expense sustained in relation to the 2014 financial year had a gross value of 1,800 Euros.

#### With Gil Beyen

#### 1. Severance pay:

Person concerned: Gil Beyen, Chairman of the Board of Directors and Managing Director of the Company.

- Nature and purpose: Severance pay, authorized by the Board of Directors on May 24, 2013, in the event of:
  - expiry of a term of office (except where renewal has been refused by the interested party),
  - removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation).

Gil Beyen may claim an indemnity equal to:

- twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office, or
- the fixed annual remuneration established by the Board of Directors, in the event of revocation decided within twelve months following the appointment of Gil Beyen.

Payment of this indemnity shall be subject to the finding that the following performance conditions have been met:

- Compliance with the Company's expenditure budget, and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.
- Terms: No charge was recorded in the accounts in this respect by your Company for the 2014 financial year.

#### 2. <u>Incentive:</u>

Person concerned: Gil Beyen, Chairman of the Board of Directors and Managing Director of the Company.

- Nature and purpose: incentive
- Methods: on November 29, 2013, the Company stipulated a profit-sharing agreement for the period from January 1<sup>st</sup>, 2014 to December 31, 2016. On May 24, 2013, your Board of Directors authorized the inclusion of Gil Beyen in a future profit-sharing agreement. The profit-sharing expense sustained in relation to the 2014 financial year had a gross value of 1,800 Euros.

#### With Jérôme Bailly

- Person concerned: Jérôme Bailly, Delegated Managing Director of the Company.
- Nature and purpose: Modification in the fixed gross annual remuneration as part of Jérôme Bailly's employment contract, starting on January 1, 2014. This agreement was authorized by your Board of Directors on January 22, 2014.
- Terms: The fixed annual remuneration for Jérôme Bailly is set at €60,000, payable over 12 months. The gross remuneration allocated during the 2014 financial year, variable portion included, totaled €75,132.70.

# With all of the Senior Management

- Persons concerned: Gil Beyen, Pierre Olivier Goineau, Yann Godfrin, Jérôme Bailly.
- Nature and purpose: Your Supervisory Board, on January 24, 2013, and your Board of Directors, on May 24 2013, authorized the Company to assume the cost of certain services and expenses benefiting the Senior Management, as shown in the table attached, expressed in euros.
- Terms

Charges sustained in the 2014 financial year	Gil Beyen	Jérôme Bailly	Pierre-Olivier Goineau	Yann Godfrin
Contractual professional health insurance APGIS (PRC)	3,932.16	1,394.15	3,519.23	3,517.89
Additional health insurance (VIVENS)	1,096.44	504.65	1,096.44	1,096.44
Unemployment insurance (GSC)			8,562.79	8,566.02
Additional pension plan (AXA)	7,509.60	3,456.63	7,509.60	7,509.60
Supply of a company car and fuel paid for				
-Rents paid during the financial year	17, 185.15	6,191.40	10,778.46	10,877.87
-Amount of fuel paid for	1,874.18	1,282.46	1,811.20	2,066.60
TOTAL	31,597.53	12,829.29	33,277.72	33, 634.42

Pierre-Olivier Goineau resigned from his positions as Director and Delegated Managing Director on January 11, 2015.

# AGREEMENTS AND COMMITMENTS AUTHORIZED SINCE THE YEAR-END

We have been informed of the following commitments which were authorized following the close of the last financial year and which were previously authorized by your Board of Directors:

#### With all of the Senior Management

- Persons concerned: Gil Beyen, Yann Godfrin, Jérôme Bailly.
- Nature and purpose: March 26, 2015 Board of Directors authorization of a PEE contribution and a PERCO contribution
- Terms: no charge was recorded for these agreements for the 2014 financial year

#### With Jérôme Bailly

- Person concerned: Jérôme Bailly, Delegated Managing Director of the Company.
- Nature and purpose: Modification of the fixed gross annual remuneration as part of Jérôme Bailly's employment contract, starting on January 1, 2015. This agreement was authorized by your Board of Directors on January 11, 2015.
- Terms: The fixed annual remuneration for Jérôme Bailly is henceforth set at €90,000, payable over twelve months.

The statutory auditors Lyon, March 30, 2015

For KPMG Audit Rhône Alpes Auvergne

For RSM CCI Conseils

Sara RIGHENZI DE VILLERS Statutory Auditor Gaël DHALLUIN Associate

# 19.2.2 Special report by the statutory auditor on regulated agreements – Financial year ending December 31, 2013

#### **Erytech Pharma SA**

Headquarters: 60 avenue Rockefeller – Bâtiment Adénine

69008 Lyon Share capital: €555,895

#### Special report by the statutory auditor on regulated agreements and commitments

General Meeting for approval of the financial statements for the year ended December 31, 2013

Dear Shareholders,

In our capacity as statutory auditor for your company, we hereby present to you our report on regulated agreements and commitments.

Our task is to inform you, on the basis of the information that has been provided to us, of the characteristics and essential mechanisms of those agreements of which we have been informed or which we have uncovered during our mission, while not discussing their usefulness and their merits, nor searching for the existence of other agreements and commitments. It is your responsibility, according to the terms of articles R.225-31 and R.225-58 of the Code of Commerce to assess the interest presented by the formation of these agreements and commitments in order to approve them.

Furthermore, it is our job, as applicable, to provide you with the information specified in articles R.225-31 and R.225-58 of the Code of Commerce pertaining to the execution of agreements and commitments already approved by the general meeting over the course of the past financial year.

We have conducted the due diligence that we believed necessary in light of the professional doctrine of the Compagnie Nationale des Commissaires aux Comptes pertaining to this mission. This due diligence consisted in verifying that the data provided to us was consistent with the underlying documents from which they came.

### AGREEMENTS AND COMMITMENTS REQUIRING APPROVAL BY THE GENERAL MEETING

#### Agreements and commitments authorized during the past financial year

In application of article L.225-88 and L.225-40 of the Code of Commerce, we have been informed of the following agreements and commitments which received prior authorization from your Supervisory Board and your Board of Directors subsequent to the change in governance approved by the General Meeting on April 2, 2013.

#### With the company Auriga Partners

- Entity concerned: Auriga Partners, shareholder holding a portion of voting rights greater than 10%.
- Nature and purpose: Compensation for the increase in capital by offsetting bond interest. This compensation was authorized by the Supervisory Board on April 4, 2013.
- Terms: Under this compensation, your company recorded in the accounts a charge in the amount of €120,000 for the 2013 financial year.

#### With the company Idinvest Partners

- Entity concerned: Idinvest Partners, a shareholder holding a portion of the voting rights greater than 10%.
- Nature and purpose: Compensation for the increase in capital by offsetting bond interest. This compensation was authorized by the Supervisory Board on April 4, 2013.

• Terms: Under this compensation, your company recorded in the accounts a charge in the amount of €120,000 for 2013 financial year.

#### With Pierre-Olivier Goineau

- Person concerned: Pierre-Olivier Goineau, Delegated Managing Director of the Company.
- Nature and purpose: Severance pay, authorized by the Board of Directors on May 24 2013, in the case of:
  - expiry of a term of office (except where renewal has been refused by the interested party)
  - removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation)

Pierre-Olivier Goineau may claim an indemnity equal to twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office.

Payment of this indemnity shall be subject to the finding that the following performance conditions have been met:

- Compliance with the Company's expenditure budget and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.
- Terms: No charge was recorded in the accounts in this respect by your company for the 2013 financial year.

#### With Yann Godfrin

- Person concerned: Yann Godfrin, Delegated Managing Director of the Company.
- Nature and purpose: Severance pay, authorized by the Board of Directors on May 24 2013, in the case of:
  - expiry of a term of office (except where renewal has been refused by the interested party)
  - removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation)

Yann Godfrin may claim an indemnity equal to twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office.

Payment of this indemnity shall be subject to the finding that the following performance conditions have been met:

- Compliance with the Company's expenditure budget and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.
- Terms: No charge was recorded in the accounts in this respect by your company for the 2013 financial year.

# With Gil Beyen

- Person concerned: Gil Beyen, Chairman of the Board of Directors and Managing Director of the Company.
- Nature and purpose: Severance pay, authorized by the Board of Directors on May 24, 2013, in the event of:
  - expiry of a term of office (except where renewal has been refused by the interested party)
  - removal (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the companies section of the Court of Cassation).

Gil Beyen may claim an indemnity equal to:

- twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office, or
- the fixed annual remuneration established by the Board of Directors, in the event of revocation decided within twelve months following the appointment of Gil Beyen.

Payment of this indemnity is subject to the finding that the following performance conditions have been met:

- Compliance with the Company's expenditure budget and
- At least one of the two following conditions:
  - at least one collaboration or licensing agreement underway;
  - at least one product in active clinical development phase by the Company.
- Terms: No charge was recorded in the accounts in this respect by your company for the 2013 financial year.

# With all of the Senior Management

- Persons concerned: Gil Beyen, Pierre Olivier Goineau, Yann Godfrin, Jérôme Bailly
- Nature and purpose: Your Supervisory Board, on January 24, 2013, and your Board of Directors, on May 24 2013, authorized the company to assume the cost of certain services and expenses benefiting the Senior Management, as shown in the table attached, expressed in euros
- Terms

Charge sustained in 2013	Gil Beyen	Jérôme Bailly	Pierre-Olivier Goineau	Yann Godfrin
Traditional professional health insurance APGIS (PRC)	2,290	1,291	3,484	3,484
Additional health insurance (GAN)	971	626	1,481	1,481
Additional pension plan (AXA)	4,855	3,122	7,406	7,406
Provision of a company vehicle and coverage of fuel expenses				
- Rents paid during the financial year	5,373			
- Amount of fuel paid for.	407	1,163		

#### AGREEMENTS AND COMMITMENTS AUTHORIZED SINCE THE YEAR-END

We have been informed of the following commitments which were authorized following the close of the last financial year and which were previously authorized by your Board of Directors:

#### With Jérôme Bailly

- Person concerned: Jérôme Bailly, Delegated Managing Director of the Company.
- Nature and purpose: Modification in the fixed gross annual remuneration as part of Jérôme Bailly's employment contract, starting on January 1, 2014. This agreement was authorized by your Board of Directors on January 22, 2014.
- Terms: The fixed annual remuneration for Jérôme Bailly is set at €60,000, payable over 12 months.

#### AGREEMENTS AND COMMITMENTS ALREADY APPROVED BY THE GENERAL MEETING

#### Agreements and commitments approved during previous financial years

In application of Articles R.225-30 and R.225-57 of the Code of Commerce, we have been informed that the execution of the following agreements and commitments, already approved by the general meeting during previous financial years, were continued during the past financial year.

# With the company Gil Beyon BVBA

- Person concerned: Gil Beyen, Chairman of the Board of Directors and Chief Executive Officer.
- Nature and purpose: this contract was authorized by the Supervisory Board on January 21, 2012 and ended on April 30, 2013.

Your company entered into a permanent consultancy agreement with the Gil Beyen BVBA company starting in January 2012. This contract was intended to assist management in the search for financial partners and to contribute its expertise and assistance in the implementation of the company's strategy. In return for the delivery of these services, your company agreed to pay €1,200/day of work by Gil Beyen, with the average number of days being estimated at 12 per month, although in no case is would it be below or above a range of between 8 and 16 days.

Additional fees were also provided in the contract, particularly in the event that capital was raised, bonds were issued, shareholder loans, payment of advances or firm "milestones" contingent on commercial development (starting from a cumulative payment threshold of €15 million).

If the consultancy agreement was terminated by the Company for any reason other than wrongdoing by the consultant, ERYTECH SA would be required to pay to Gil Beyen BVBA an indemnity equal to three months of normal activity preceding the termination and at least €43,200 if the termination occurred within three months following the signature of the consultancy agreement.

Travel costs were borne by the consultant, except for exceptional travel costs incurred as part of his mission.

#### • Terms:

By virtue of this contract, for the 2012 financial year, your company recorded in the accounts fees totaling an amount of €112,763, corresponding to:

- €95,463 for daily invoices,
- €17,300 for expenses.

#### With Jérôme Bailly

- Person concerned: Jérôme Bailly, Delegated Managing Director of the Company.
- Nature and purpose: Your company allocated fixed annual gross remuneration to Jérôme Bailly, Delegatd Managing Director of the Company, by virtue of his employment contract.
- Terms: By virtue of this contract, for the 2013 financial year, your Company recorded in its accounts a charge of €54,600.

#### **With the Delegated Managing Directors**

- Persons concerned: Pierre Olivier Goineau, Yann Godfrin, and Jérôme Bailly
- Nature and purpose: on December 22, 2006 and December 21, 2011, your Supervisory Board authorized the company to assume the costs of certain services and expenses benefiting the Delegating Managing Directors as shown in the attached table, expressed in euros
- Terms:

Charge sustained in 2013	Pierre-Olivier Goineau	Yann Godfrin	Jérôme Bailly
Unemployment insurance policy with the Association pour la Garantie Sociale des Chefs et Dirigeants d'Entreprise (French GSC - unemployment insurance provider for corporate leaders)	5,619	5,619	
Provision of a company vehicle and coverage of fuel			
expenses			
- Rents paid during the financial year	8,770	9,235	5,878
- Amount of fuel paid for	1,773	1,889	

Lyon, April 28, 2014

KPMG Audit Rhône Alpes Auvergne

Gaël Dhalluin *Deputy auditor* 

# 20 FINANCIAL INFORMATION CONCERNING THE COMPANY'S EQUITY, FINANCIAL POSITION, AND RESULTS

# 20.1 Financial statements prepared in accordance with IRFS standards for the year ended December 31, 2014

# CONSOLIDATED STATEMENT OF NET INCOME AND STATEMENT OF OTHER COMPREHENSIVE INCOME ITEMS

n euros) notes		12.31.2014 (12 months)	12.31.2013 (12 months)	
Sales revenue				
Other income from activities	6.1	2,025,687	1,802,262	
Income from regular operations		2,025,687	1,802,262	
Research and development costs		(2,243,971)	(2,502,790)	
Clinical studies	6.2 to 6.4	(3,875,421)	(2,461,836)	
Intellectual property costs		(493,481)	(363,363)	
Overhead and general costs		(4,361,181)	(3,587,200)	
Regular operating results		(8,948,367)	(7,112,926)	
Other operating income and expenses			27,776	
Operating results		(8,948,367)	(7,085,150)	
Net cost of debt	6.5	(50,006)	(1,119,787)	
Other financial income and expenses	6.5	118,179	20,199	
Financial results		68,173	(1,099,589)	
Before-tax results		(8,880,194)	(8,184,739)	
Income tax	6.6	20,158	40,018	
NET INCOME		(8,860,036)	(8,144,721)	
Elements that may be recycled at a later time as earnings None Elements that may not be recycled at a later time as earnings				
Reappraisal of liabilities for defined-benefits schemes		58,547	5,755	
Tax effect		(20,158)	(1,981)	
Other comprehensive income		38,389	3,774	
COMPREHENSIVE INCOME		(8,821,647)	(8,140,947)	
Basic earnings per share		(1.51)	(1.74)	
Diluted earnings per share		(1.51)	(1.74)	

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (in euros)	notes	12.31.2014	12.31.2013
NON-CURRENT ASSETS		1,080,239	910,132
Intangible assets	7.1	30,951	14,277
Tangible fixed assets	7.2	967,474	812,947
Non-current financial assets	7.3	81,814	82,908
Other non-current assets			
Deferred tax assets			
CURRENT ASSETS		39,526,400	17,038,828
Inventories	7.4	198,356	138,238
Clients and associated accounts		104,870	87,192
Other current assets	7.5	2,234,738	1,700,874
Cash and cash equivalents	7.6	36,988,436	15,112,523
TOTAL ASSETS		40,606,639	17,948,960
LIABILITIES AND SHAREHOLDERS EQUITY (in euros)		12.31.2014	12.31.2013
SHAREHOLDERS' EQUITY		35,824,303	13,586,634
Capital	<b>7.7</b>	688,276	550,602
Premiums	7.7	72,426,817	42,741,059
Reserves	7.7	(28,430,754)	(21,560,305)
Net income		(8,860,036)	(8,144,721)
NON-CURRENT LIABILITIES		524,629	0.45 < 0.0
Provisions - Non-current portion	7.8	88,594	847,689
Financial liabilities - Non-current portion	<b>=</b> 0		·
Financial habilities - Non-current portion	<b>7.9</b>	436,035	117,144
Deferred tax liabilities	7.9	436,035	117,144
•	7.9	436,035	117,144
Deferred tax liabilities	7.9	436,035 4,257,706	117,144
Deferred tax liabilities Other non-current liabilities  CURRENT LIABILITIES  Provisions - Current portion	7.9		117,144 730,545
Deferred tax liabilities Other non-current liabilities  CURRENT LIABILITIES  Provisions - Current portion Financial liabilities - Current portion	7.9	<b>4,257,706</b> 333,502	117,144 730,545 <b>3,514,636</b> 281,341
Deferred tax liabilities Other non-current liabilities  CURRENT LIABILITIES  Provisions - Current portion	7.9	<b>4,257,706</b> 333,502 2,084,546	117,144 730,545 <b>3,514,636</b> 281,341
Deferred tax liabilities Other non-current liabilities  CURRENT LIABILITIES  Provisions - Current portion Financial liabilities - Current portion		<b>4,257,706</b> 333,502	117,144 730,545 <b>3,514,636</b>

# CONSOLIDATED STATEMENT OF VARIATIONS IN SHAREHOLDERS' EQUITY

TABLE OF CHANGES IN SHAREHOLDERS' EQUITY (in euros)	Capital	Issue premium	Reserves	Results	Shareholders' equity
12/31/2012	315,355	17,767,715	(19,938,025)	(2,172,035)	(4,026,990)
Issuance of common stock	240,540				240,540
Issue premium increase	,	25,567,623			25,567,623
Treasury shares	(5,294)	(594,279)	(34,639)		(634,212)
Allocation of Earnings N-1	, ,	, ,	(2,172,035)	2,172,035	
Earnings for the period				(8,144,721)	(8,144,721)
Actuarial gains and losses			3,773		3,773
IFRS 2 Charges			580 621		580,621
12/31/2013	550,602	42,741,059	(21,560,305)	(8,144,721)	13,586,634
12/31/2013	550,602	42,741,059	(21,560,305)	(8,144,721)	13,586,634
Issuance of common stock	132,381				132,381
Issue premium increase		29,040,376			29,040,376
Treasury shares	5,294	645,382			650,675
Allocation of Earnings N-1			(8,144,721)	8,144,721	
Earnings for the period				(8,860,036)	(8,860,036)
Actuarial gains and losses			38,389		38,389
IFRS 2 Charges			1,235,883		1,235,883
12/31/2014	688,276	72,426,817	(28,430,754)	(8,860,036)	35,824,303

# CONSOLIDATED CASH FLOW STATEMENT

euros)	notes	12.31.2014	12.31.2013
Net income		(8,860,036)	(8,144,72)
Expenses (income) not affecting cash - Depreciation (write backs) and provisions of non-current assets		276,522	286 96
- Depreciation (write backs) and provisions of current assets		4 227 002	(106,665
<ul> <li>Expenses (income) as share-based payments</li> <li>Investment grants written back to income</li> </ul>		1,235,883	580,62
- Gains and losses on disposals			
Operating subsidies		(1,794,919)	(1,660,80
Cost of net financial debt		50,006	1,119,7
Income tax expense (current and deferred)		(20,158)	(40,01
Internal financing capacity before financial results and tax		(9,112,701)	(7,964,84
Taxes paid		-	
Changes in working capital needs related to business activities		1,874,169	1,491,6
Net cash flow generated by business activities		(7,238,532)	(6,473,23
Cash flow related to investment operations			
Purchase of fixed assets		(547,171)	( 430,6.
- Intangible assets		(25,798)	(9,00
- Tangible fixed assets		(521,270)	(418,39
- Investments		(103)	(3,23
<u>Disposal of fixed assets</u> - Intangible assets		<u>126,826</u>	<u>14, 0</u>
- Tangible fixed assets		125,629	142,0
- Investments		1,197	142,0
Grants cashed		-	
Effects of changes in perimeter		-	
Net cash flow generated by investment operations		(420,345)	(288,59
Cash flows from financing activities			
Increase in cash capital		30,731,174	16,551,1
Costs of cash capital increase		(1,558,417)	(2,013,98
Loan issue		-	193,2
Costs of loan issue		-	
Repayment of loans		(281,341)	(130,00
Treasury shares		650,675	(599,5)
Interest paid		(7,301)	(1,62
Net cash flow generated by financing operations		29,534,791	13,999,2
Changes in cash position		21,875,913	7,237,4
Cash position at year start		15,112,523	7,875,1
		36,988,436	15,112,5
Cash position at year end		30,988,430	13,112,3

# ERYTECH PHARMA GROUP NOTES ANNEXED TO THE FINANCIAL STATEMENTS

The present annex forms an integral part of the consolidated financial statements for the year ended December 31, 2014.

The financial statements were issued by the Board of Directors on March 26, 2015.

#### 1. DESCRIPTION OF THE GROUP'S ACTIVITY

The Group's main activity is research and development in the areas of treatment of acute leukemias and other orphan diseases.

Since its creation, the Group has concentrated its efforts:

- On the development of a patented technology based on the encapsulation of molecules in the red blood cells, offering an innovative approach to the treatment of acute leukemias and other solid tumors. Development of the main product, ERY-ASP, initiated upon creation of the Group, has led to the issue of 10 patent families held by the Company. The Group has likewise established a patented industrial process capable of producing clinical batches of ERY-ASP, and capable of responding to demand upon the product's placement on the market.
- The implementation of clinical study programs intended initially to validate Graspa® in terms of safety of usage and toxicology through a Phase I clinical study on ALL in adult and pediatric patients with a relapse of ALL. Based on the results obtained, the Group performed a Phase II clinical study that likewise demonstrated the safety of the product's use and its efficacy in patients older than 55 years of age with ALL. The Group has completed a Phase II/III clinical study, at the end of which Erytech intends to file an application, in 2015, for approval for the placement of Graspa® on the European market for the treatment of ALL. The Group has likewise initiated a Phase IIb study on acute myeloid leukemia (AML), as well as a Phase II study on pancreatic cancer.

The Group's business model is to develop its products up to the point of obtaining authorization for their placement on the market in Europe and then in the United States. Commercial partnerships established by Erytech will allow for the distribution of ERY-ASP to be ensured first in Europe and then in the United States and in the rest of the world. Erytech has the capacity to ensure the supply of Graspa® for the first years of its sale in Europe, through its production unit in Lyon.

## 2. FACTS CHARACTERIZING THE FINANCIAL YEAR

#### 2.1 Funds raised on the stock market

The parent company, ERYTECH PHARMA SA, raised approximately €30 M in October 2014 on Euronext, pertaining to a total of 1,224,489 new shares issued within the scope of a capital increase, with suppression of the preferential subscription right, reserved for investors regularly investing in securities specific to the fields of health care, representing approximately 17.8% of the number of shares in circulation (post-issue).

The issue price was set at 24.50 Euros per share, in compliance with resolution no. 10 of the combined general shareholders' meeting of June 17, 2014. This price reflects a 3.5% reduction as compared to the weighted average of the parent company's share price in the last five trading sessions prior to establishing the price, i.e., 25.39 Euros. In total, 80% of the issue was performed internationally, with 68% in the United States.

#### 2.2 Clinical trials

On 09/30/2014, the Group announced the positive Phase III results on its Phase II/III clinical study with GRASPA® in the treatment of ALL. Analysis of the data from the GRASPIVOTALL clinical trial

(GRASPALL2009-06), after one year of monitoring, demonstrates that the study convincingly achieved its primary objectives, and its secondary objectives confirm a favorable profile for the clinical efficacy of GRASPA®. The study also shows favorable results in patients with histories of allergies to L-asparaginase.

During the financial year, the Group also recruited the first patient for its Phase II study on pancreatic cancer in Europe, as well as its first patient for its Phase I/II study in the United States.

The Group announced the positive opinion by its second committee of independent experts (DSMB) for its Phase IIb study on AML. The independent experts analyzed the tolerance data for the first 60 patients treated, and as with the first DSMB committee review on 30 patients, continuation of the study was unanimously confirmed, without requesting any modifications to the study or formulating any particular observations.

The Group likewise obtained Orphan Drug Designation from the FDA for its product ERY-ASP in the treatment of AML in the United States.

# 2.3 American subsidiary

The parent company ERYTECH PHARMA SA created the subsidiary "ERYTECH PHARMA Inc." in the USA in April 2014. The Company then proceeded to appoint the firm RSM-CCI Conseils as co-Statutory Auditors in the AGM of June 17, 2014. At June 30, 2014, the Group's financial statements were supplemented, for the first time, by consolidation of the 100% held American subsidiary. This activity had no impact on the financial year.

#### 3. EVENTS SUBSEQUENT TO YEAR-END

Pierre-Olivier Goineau, co-founder of the company Erytech Pharma SA and Delegated Managing Director, submitted his resignation to the Group from his positions within ERYTECH PHARMA SA during the parent company's board of directors' meeting of January 11, 2015; Mr. Goineau remains treasurer and secretary of the American subsidiary ERYTECH PHARMA Inc.

#### 4. BUSINESS CONTINUITY

The Group's loss-making situation is explained by the innovative nature of the products developed, therefore involving a multi-year research and development phase. The general accounting conventions were applied in compliance with the principle of prudence, in accordance with the underlying assumptions of:

- business continuity,
- permanence of accounting methods from one year to the next,
- independence of financial years,

and in conformity with the general rules for the preparation and presentation of consolidated financial statements in accordance with the IFRS.

#### 5. ACCOUNTING PRINCIPLES AND METHODS

In application of European regulation 1606/2002 of July 19, 2002, the financial statements for the ERYTECH PHARMA Group are prepared in conformity with the International Financial Reporting Standards (IFRS) published by the International Accounting Standards Board (IASB), as adopted by the European Union at the date of issue of the financial statements by the board of directors, as applicable at December 31, 2014.

This framework is available on the European Commission's website, at the following address: (http://ec.europa.eu/internal\_market/accounting/ias/index\_fr.htm).

The accounting methods outlined below have been applied in a continuous manner to all the periods presented in the Group financial statements, after taking into account or with the exception of the new standards and interpretations described below.

The financial statements are presented in Euros, which is the functional currency of the parent company. All amounts mentioned in this annex to the financial statements are denominated in Euros, save where indicated otherwise.

# 5.1. New standards, amendments to standards, and interpretations applicable as of the financial year begun January 1, 2014

The accounting principles adopted for their preparation are those applied by the Group at December 31, 2013, with the exception of the following new standards and interpretations applied for the first time as of January 1st, 2014:

- IFRS 10 Consolidated Financial Statements
- IFRS 11 Joint Arrangements
- IFRS 12 Disclosure of Interests in Other Entities
- Amendment to IAS 32 Offsetting of financial assets and liabilities
- Amendments to IFRS 10, IFRS 11, and IFRS 12
- Amendments to IFRS 10, IFRS 12, and IAS 27: Investment Entities
- Amendments to IAS 36 Impairment of Assets: Disclosure Recoverable Amount of Non-Financial Assets
- Amendments to IAS 39 Financial Instruments: Recognition and Measurement Novation of Derivatives and Continuation of Hedge Accounting

These new texts published by the IASB had no significant impact on the Group financial statements.

# 5.2. Standards and interpretations published but not yet in force

- IFRS 9 Financial Instruments Amendments to IFRS 9: postponement of the date of entry into force and information to be disclosed on the transition
- IFRIC 21 Levies Charged by Public Authorities
- Amendments to IAS 19 Defined Benefit Plans: Employee Contributions
- Amendments to IFRS 11 Partnerships: Accounting for Acquisitions of Interests in Joint Operations
- IFRS 15 Revenue from Contracts with Customers
- Amendment IAS 36 and IAS 38 Clarification of Acceptable Methods of [Depreciation and] Amortisation
- IFRS Improvements (2010-2012 cycle and 2011-2013 cycle)

The Group has not applied in advance any standards and interpretations for which application was not obligatory at January 1st, 2014.

#### 5.3. Presentation

The statement of comprehensive income presents the classification of expenses and income per item, with the exception of other operating income and expenses.

The comparative information is presented using an identical classification.

The cash flow table was prepared according to the indirect method.

#### 5.4. Year-end

The Group closed its annual accounts on December 31, 2014.

### 5.5. Consolidation perimeter

The company ERYTECH Pharma SA (headquarters: 60 avenue Rockefeller, Bâtiment Adénine, 69008 LYON, FRANCE) holds 100% of its subsidiary, ERYTECH Pharma Inc. (headquarters: 185 Alawife Brook Parkway Ste 410, CAMBRIDGE, MA 02138, UNITED STATES).

The Group's financial statements include consolidation of the American subsidiary.

# 5.6. Use of estimates and judgment

Preparation of the financial statements in accordance with the rules prescribed by the IFRS requires the use of estimates and the formulation of hypotheses having an impact on the financial statement. These estimates can be revised where the circumstances on which they are based change. The actual results may therefore differ from the estimates initially formulated. The use of estimates and judgment primarily concern the measurement of share-based payments (Note 5.17 and Note 6.3), as well as the estimate of expenses owing relative to clinical trials (Note 9).

## 5.7. Intangible assets

<u>Intangible assets generated internally – Research and development costs</u>

In accordance with IAS 38, "Intangible Assets," research expenditures are accounted for in the period during which they are incurred.

An intangible asset internally generated relating to a development project is booked as an asset if, and only if, the following criteria are met:

- Technical feasibility required to complete the development project;
- Intention to complete the project, use or sell it;
- Demonstration of the probability of future economic benefits related to the asset;
- Availability of appropriate resources (technical, financial and other) to complete the project;
- Ability to reliably assess the expenditures attributable to the development project underway.

The initial measurement of the development asset is the sum of expenses sustained starting on the date on which the development project meets the above criteria.

Considering the strong uncertainty associated with the development projects performed by the Group, these conditions will only be met when the regulatory procedures necessary for placement of the products on the market have been finalized. Most of the expenditures being incurred before that stage, the development costs, are accounted for in the period in which they are incurred.

# Other intangible assets

The other intangible assets are recognized at their cost, decreased by the aggregate amortizations and any losses in value. The amortization is calculated on a straight-line basis in function of the duration of the asset's use. The duration of use and the amortization method are reviewed at each year-end. All significant modifications to the anticipated use of the asset are recognized prospectively.

The other intangible assets are primarily composed of computer software and are amortized on a straight-line basis over 1 to 5 years.

An impairment is recorded where the asset's book value is greater than its recoverable value (see Note 7.1).

#### 5.8. Tangible fixed assets

Fixed assets are recorded in the balance sheet at their purchase cost, composed of their purchase price and all directly associated costs sustained to place the asset in use and in a state of operation according to the usage intended by the company's management.

These assets are amortized according to the straight-line method, in function of their duration of use.

The primary durations of use adopted are as follows:

Industrial equipment: 1 to 5 years;Systems and layout: 3 to 10 years;

- Office equipment: 3 years;

- Furniture: 3 to 5 years.

The duration of use of fixed assets, any residual values, and the amortization method are reviewed at each year-end result and, in the event of a significant change, in a forward-looking revision of the amortization plans.

In compliance with the IFRS, the different components of a single fixed asset having a different duration of use or procuring economic benefits for the company according to a different rhythm are recognized separately.

#### 5.9. Impairment tests

According to the standard IAS 36, "Impairment of Assets," a loss in value must be recognized where the net book value is lower than the recoverable value. The recoverable value of an asset is the highest value between the fair value less disposal costs and the value in use.

The fair value less disposal costs is the amount that can be obtained from the sale of an asset in a transaction under conditions of normal competition between well-informed, consenting parties, less the disposal costs.

The value in use is the present value of estimated future cash flow anticipated from the ongoing use of an asset. The value in use is determined based on cash flows estimated based on budgets and plans, then discounted by adopting the long-term market rates after taxes that reflect the market estimates of the time value of money and the risks specific to the assets.

#### Amortizable fixed and intangible assets

Where new events or situations indicate that the book value of certain fixed or intangible assets may not be recoverable, this value is compared to its recoverable value, approached based on the value in use or its market value less disposal costs. Where the recoverable value is less than the net book value of these assets, the latter is changed to its recoverable value and a loss in the asset value is recognized under "provisions for impairment." The new value of the asset thus has a forward-looking amortization based on the new duration of the asset's residual life.

#### 5.10. Other non-current financial assets

Non-current financial assets are initially recognized at their fair value, increased where applicable by the costs directly ascribable to their purchase, then further measured at the amortized cost. They cannot form the object of a loss in value where an objective indication of impairment exists. The loss in value is recognized in the profit or loss and is reversible where the recoverable value experiences a positive change in the future.

#### 5.11. Inventories

In compliance with the IAS 2 standard for "Inventories," inventories are recognized at their cost or at their net realizable value, where this is lower. In the latter case, the loss in value is recorded under current operating income. Inventories are measured according to the FIFO method.

### **5.12.** Lease agreements

A lease agreement is considered as being a finance lease where it transfers to the borrower substantially all the risks and benefits inherent in ownership of the asset. The other contracts are considered as being simple lease agreements.

The assets held within the scope of a finance lease are recognized in the balance sheet assets and liabilities under their fair value at the start of the contract or, where this is lower, at the discounted value of the minimum payments on the lease. These assets are then amortized in function of the anticipated duration of the asset's use.

#### 5.13. Cash and cash equivalents

The item "cash and cash equivalents" in the balance sheet includes highly liquid securities for which the initial maturity is equal to or less than three months, considered equivalent to liquid assets. The fair value of these securities is very near their book value, given their short-term maturity.

#### 5.14. Provisions and potential liabilities

A provision is recognized where the Group has a current or implicit legal obligation resulting from a prior event, where the obligation can be reliably estimated, and where it is probable that an outflow of resources representing economic benefits will be necessary to discharge the obligation. The portion of a provision estimated as payable in less than one year is recorded under current liabilities, and the balance under non-current liabilities. The provisions are discounted where the impact is significant.

Provisions notably include:

- obligations pertaining to retirement indemnities and long-service awards,
- provisions for disputes.

Disclosure is made in the detailed notes on any potential assets and liabilities where the impact is significant, except where the probability of occurrence is low.

#### Provisions for retirement indemnities - defined benefit plans

In compliance with IAS 19, "Employee Benefits," within the scope of defined benefit plans, the post-employment benefits and other long-term benefits are measured every year using the projected unit credit method. According to this method, each service period gives rise to an additional unit of rights to benefits, and each of these units is measured separately to obtain the final obligation. This final obligation is then discounted.

These calculations primarily include:

- a theorized benefit payment date;
- a financial discount rate;
- an inflation rate;
- theorized wage increases, rate of employee turnover, and mortality.

The primary actuarial assumptions adopted at December 31, 2014 are described in note 7.8.

The positive or negative actuarial differences include the effects, on the commitment, of a change in calculation assumptions as well as adjustments to the obligation linked to experience. In conformity with the standard IAS 19 "Post-employment benefits [employee benefits]", the Group recognizes these actuarial differences under other items of the comprehensive income for post-employment benefits.

The provision showing in the balance sheet under a specific line corresponds to the total commitment at yearend. The cost of prior services associated with a change in the plan are recognized in the statement of comprehensive income.

The expense for the period, composed of the cost of services rendered and the financial expense of accretion, constitutes an operating expense.

#### **5.15.** Income from regular operations

The other income from activities involves products pertaining to grants. The grants are initially recognized at their fair value under deferred income, where a reasonable assurance exists that they will be received and the Group will conform with the conditions attached to these grants.

They are then recognized as income, pro rata of costs sustained, in compliance with IAS 20. Due to this, the grants to be received can be recorded in the accounts where the assignment contract is signed but the grants have not yet been received.

In compliance with IAS 20, the "Research Tax Credit" is also presented on the line "Other income from regular operations" in the statement of comprehensive income.

#### Partnership with Orphan Europe

Within the scope of its partnership agreement with Orphan Europe on the development of AML, the Group reinvoices, with no margin, certain clinical costs incurred and invoiced to the Group by external providers.

In application of the standard IAS 18, the Group estimates that, within the scope of this partnership, it acts as agent insofar as concerns external costs re-invoiced, in that:

- The Group does not have primary responsibility for provision of the goods or service, the majority of services being provided by third parties, the most significant of which, the CRO (company responsible for a portion of the service provision associated with biomedical research for which ERYTECH Pharma SA is the sponsor) directly invoices Orphan Europe. The Group is only directly invoiced for the associated services;
- The Group sustains no inventory risk;
- The Group has no capacity to determine prices, all of the external costs being invoiced to the nearest euro, with no margin, and it absorbs no price changes applied by the suppliers;
- The Group sustains a credit risk not considered to be significant.

Consequently, the re-invoicing of these external costs to Orphan Europe is presented as a decrease in corresponding expenses sustained by the Group. For 2014, the amount of external costs re-invoiced within the scope of this partnership totaled 562,000 Euros.

Within the scope of this same agreement, the Group also re-invoiced certain internal clinical costs, such as personnel costs associated with the management of clinical trials, or personnel involved in the production of batches necessary for the AML clinical trial. These re-invoiced internal costs are recognized by the Group as other income from ordinary activities. They total 231,000 Euros for the 2014 financial year.

### **5.16.** Regular operating results

The regular operating results are formed by income from regular operations less regular operating costs. The regular operating costs primarily include the research and development costs, the clinical studies, the intellectual property costs, the structural and general costs, the net allocations of reversals to amortizations and operating provisions, as well as the costs of share-based payments.

The regular operating results are an indicator used by the Group, enabling it to present "a level of operational performance that can serve as a forward-looking approach to recurring performance" (in conformity with Recommendation CNC2009-R03, relative to the format for corporate financial statements under the international accounting framework). In effect, the regular operating results are a management balance that

facilitates an understanding of the Group's performance by excluding the other operating income and expenses defined below.

## 5.17. Share-based payments

In compliance with IFRS 2, the benefits granted to certain employees in the form of share-based payments are measured at the fair value of the instruments granted.

This remuneration can take the form of either equity or cash instruments.

Share call and subscription options are granted to directors and to certain employees of the Group.

In compliance with IFRS 2, "Share-Based Payment," the fair value of the options is determined on the grant-date.

To determine their value, the Group uses the Black & Scholes mathematical model. This allows them to take into account the characteristics of the plan (exercise price, period of exercise), the market data at the time of assignment (risk-free rate, volatility, expected dividends), and recipient behavior assumptions. Changes in value subsequent to the grant-date have no effect on this initial measurement.

The value of options is notably a function of their expected lifetime. This value is recorded under personnel expenses using the straight-line method between the grant date and the maturity date (rights acquisition period), with a direct contra-entry in the shareholders' equity.

#### 5.18. Measurement and recognition of financial liabilities

#### Financial liabilities at the amortized cost

Loans and other financial liabilities are initially measured at their fair value, and then at the amortized cost, calculated using the effective interest method ("EIM").

The transaction costs directly ascribable to the acquisition or issue of a financial liability decrease this financial liability. These costs are then actuarially amortized on the lifetime of the liability, based on the EIM.

The EIM is the rate that equalizes the flow anticipated from future cash outflows at the current net book value of the financial liability, with a view to deducting its amortized cost.

## Liabilities at fair value through profit and loss

The liabilities at fair value through profit and loss are measured at their fair value.

#### 5.19. Other operating income and expenses

The other operating income and expenses correspond to individual, unusual, and infrequent items that the Group presents separately in its statement of comprehensive income to facilitate comprehension of its regular operational performance. These items, where significant, form the object of a precise description, including their amount and nature, in the note "Other operating income and expenses."

#### 5.20. Segment reporting

In conformity with IFRS 8 "Operating Segments", reporting by operating segment is derived from the internal organization of the Group's activities; it reflects management's viewpoint and is established based on internal reporting used by the chief operating decision maker (the Chairman - CEO) to implement the allocation of resources and to assess performance.

The Group's current reporting has enabled it to define a single operating segment.

#### 5.21. Financial results

The net cost of debt includes:

- interest expenses on the financial debt (cost of gross financial debt includes the financial costs and the issue costs on the financial debts) composed of loans and other financial debts (notably overdrafts and debts on financial leases);
- decreased by income from the cash and cash equivalents.

The other financial income and expenses are composed of:

- other costs paid to the banks on financial transactions;
- the effect of term investments on the results.

#### **5.22.** Taxes

#### Current taxes

Considering the level of tax losses that can be carried forward, no tax expense is owing, save for the exceptions established under standard IAS 12.

#### Deferred taxes

Deferred taxes are calculated for all the time-based differences between the book value of an asset or a liability and its tax value.

Changes in the tax rates are recorded in the results of the financial year during which the rate change is decided.

Deferred tax assets resulting from time-based differences or taxes losses carried forward are limited to the deferred tax liabilities with the same maturity, except where their allocation on future taxable income is probable.

Deferred taxes are calculated in function of the most recent tax rates adopted at the date of each financial yearend.

Deferred tax assets and liabilities are not discounted and are classified in the balance sheet under non-current assets and liabilities.

The parent company is subject to the territorial economic contribution (Contribution Economique Territoriale - CET), which combines the corporate real estate contribution (cotisation foncière des entreprises - CFE) and the corporate value added contribution (cotisation sur la valeur ajoutée des entreprises - CVAE):

- the corporate real estate contribution, the amount of which is in function of property rental values and which can, where applicable, have a ceiling at a percentage of the value added, presents significant similarities to the business tax and is recognized under operating expenses;
- the corporate value added contribution meets, based on the Group's analysis, the definition of an income tax as established under IAS 12.2 ("taxes owing based on taxable income"). To enter within the scope of IAS 12, a tax must be calculated based on a net amount of income and expenses, and this net amount can be different from the net book results. The Group has judged that the corporate value added contribution satisfies the characteristics outlined in this conclusion, insofar as the value added constitutes the intermediate level of income that systematically serves as the basis, according to French tax law, for determining the amount owing in relation to the corporate value added contribution.

In conformity with the provisions of IAS 12, qualification of the corporate value added contribution as an income tax leads to the recognition of deferred taxes relative to time-based differences existing at year end, with a contra-entry of a net expense in that year's statement of comprehensive income. Where applicable, this deferred tax expense is presented on the line "taxes." For the moment, the parent company does not pay the CVAE.

#### 5.23. Consolidated cash flow statement

The cash flow table is prepared using the indirect method and separately presents the cash flows associated with operating, investment, and financing activities.

Operating activities correspond to the company's primary income-generating activities and all the other activities that do not meet the investment or financing criteria. The Group has decided to classify grants received under this category. The cash flows associated with operating activities are calculated by adjusting the net results of variations in working capital requirements, of items with effects of a non-cash nature (amortization, impairment), of disposal gains, of calculated expenses.

Cash flows associated with investment activities correspond to cash flows associated with the purchase of assets, net of supplier debts on the assets, and with the disposal of assets and other investments.

Financing activities are operations that result in changes in the size and composition of the contributed equity and borrowings of the entity. Capital increases and the obtaining or repayment of loans are classified under this category. The Group has chosen to classify the repayable advances under this category.

The increases in assets and liabilities with non-cash effects are eliminated. As such, the assets financed through a finance lease are not included in the period's investments. The decrease in financial debt associated with leases is therefore included under the period's loan repayments.

#### 5.24. Earnings per share

The Group presents the basic earnings per share and the diluted earnings per share.

The basic earnings per share are calculated by dividing the Group's net results by the weighted average number of shares in circulation during the financial year.

The diluted earnings per share are calculated by dividing the results by the weighted average number of common shares in circulation, increased by all dilutive potential common shares. The dilutive potential common shares include, in particular, the share subscription warrants.

#### **5.25.** Off-balance sheet commitments

The Group has defined and implemented monitoring for its off-balance sheet commitments so as to know their nature and object. This monitoring pertains to information relative to the following commitments given:

- personal guarantees (guarantees, endorsements, and bonds),
- security interests (mortgages, pledges, and sureties),
- simple leases, purchase and investment obligations,
- other commitments.

# 6. NOTES RELATIVE TO THE NET CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

#### 6.1 other income from activities

The other income from activities is composed of the following elements:

(in euros)	12.31.2014	12.31.2013
Research Tax Credit	1,523 688	1,366,656
Grants	271,231	294,150
Other earnings	230,769	141,456
Other income from activities	2,025,687	1,802,262

The other income was primarily generated by the research tax credit, the grants associated with the pre-clinical research programs in partnership with BPI France.

The "Other income" totaled €230,769 in 2014, representing the sum of the internal costs sustained by the Group within the scope of the AML study, and re-invoiced to the company Orphan Europe to this end. The other external costs associated with this clinical trial were re-invoiced to Orphan Europe with no margin, and do not appear under income from activities, but rather deducted from the associated expenses.

# 6.2 Details of expenses by item

12/31/2014 in €	Research and development costs	Clinical studies	Intellectual property costs	Overhead and general	Grand total
Consumables	251,917	171,975	-	28,257	452,149
Rental and maintenance	216,780	277,778	-	290,508	785,066
Services, subcontracting, and fees	356,144	2,186,597	416,030	1,045,220	4,003,990
Employee charges	1,351,320	1,016,651	74,835	2,367,872	4,810,679
Other	35,375	32,682	2,616	601,259	671,931
Net depreciation expense provisions	32,435	189,738	-	28,065	250,238
Grand total	2,243,971	3,875,421	493,481	4,361,181	10,974,054

12/31/2013 in €	Research and development costs	Clinical studies	Intellectual property costs	Overhead and general costs	Grand total
Consumables	288,280	186,997	-	31,929	507,206
Rental and maintenance	146,297	173,456	-	416,265	736,018
Services, subcontracting, and fees	629,890	1,060,498	265,371	449,780	2,405,539
Employee charges	1,331,773	814,789	97,992	1,839,667	4,084,221
Other	25,362	84,803	-	810,878	921,043
Net depreciation expense provisions	81,187	141,293	-	38,681	261,161
Grand total	2,502,789	2,461,836	363,363	3,587,200	8,915,188

#### **6.3** Personnel costs

The personnel costs are broken down as follows:

12/31/2014 in €	Research and development costs	Clinical studies	Intellectual property costs	Overhead and general	Grand total
Wages and salaries	732,970	631,854	43,120	1,051,374	2,459,317
JV Share-based compensation plan	283,559	88,598	11,408	852,318	1,235,883
Social security charges	334,791	296,199	20,308	464,180	1,115,479
Total employee costs	1,351,320	1,016,651	74,835	2,367,872	4,810,679

12/31/2013 in €	Research and development costs	Clinical studies	Intellectual property COSts	Overhead and general	Grand total
Wages and salaries	819,239	221,068	38,708	1,287,914	2,366,928
JV Share-based compensation plan	135,830	397,314	40,025	7,452	580,621
Social security charges	376,705	196,407	19,259	544,302	1,136,673
Total employee costs	1,331,774	814,789	97,992	1,839,667	4,084,222

# **Share-based payment (IFRS 2)**

Share options have been allocated to the directors, to certain employees, as well as to members of the Board of Directors in the form of share subscription warrants ("BSA") or founder subscription warrants ("BSPCE").

#### 6.3.1 <u>"2012 Plan"</u>

Types of securities	Founder subscription warrants BSPCE2012	Share subscription warrants BSA2012	
Number of warrants authorized for issue	33,788	30,034	
Number of warrants that the shares authorized to issue, for all types of shares	45,	050	
Total number of warrants issued	33,788 11,262		
Total number of warrants Allocated 2012/2013/2014	33,788	5 025	
Number of warrants exercised	6,807	5,025	
Date of General Meeting	May 2	1, 2012	
Exercise price per new share subscribed	€7.:	362	
Final date for exercising warrants	May 20	0, 2020	
Parity	1 warrant fo	or 10 shares	
	Warrant holders can only exercise their subscribed warrants:  (i) )only upon the occurrence of a firm, definitive operation involving the initial list of Company shares for trading on a regulated or unregulated stock market, in France the European Union, or a foreign securities exchange;  (ii) on one single occasion, or  (iii) on multiple occasions, within a limit of twice a year and at least 100 warrants.  Warrant holders shall only be able to exercise the entirety of their warrants, already subscribed or Allocated but not yet subscribed, in the event that one of the following operations occurs:  (i) acceptance, by shareholders representing at least sixty-six point six seven pere (66.67%) of the shares constituting the Company's capital, of a firm, definitive buybhoffer pertaining to control of the Company (as pursuant to Article L. 233-3 of the Coff Commerce).		
	(ii) the formation of a merger agreement providing for absorption of the Company.		
	The securities to which the warrants give rights are common shares.  Each warrant shall give the right to ten (10) shares in the Company's share capital.		
	The new shares resulting from the exercise of founder subscription warrants (BSPCEs) shall form the object of periodic requests for admission for trading on the regulated market NYSE Euronext.		
Maximum number of new shares that can be issued			

Within the context of the  $BSA_{2012}$  and  $BSPCE_{2012}$  plans, the Board of Directors' meeting of July 17, 2014 defined the additional list of beneficiaries, as well as the number of warrants to which each employee may subscribe within the scope of the  $BSA_{2012}$  and  $BSPCE_{2012}$ , in relation to the period of June  $1^{st}$ , 2013 to May 31, 2014. As such, 1,000 additional  $BSA_{2012}$  and 13,176 additional  $BSPE_{2012}$  were allocated to Erytech employees.

In conformity with IFRS 2, Erytech performed a valuation of these instruments, and used the Black & Scholes measurement model to this end.

The primary assumptions used to determine the fair value of these instruments are:

- Risk-free rate: 0.18% (in function of the zero coupon government bond rates curve);
- Anticipated dividends: zero;
- Volatility: 20.37% based on the historical volatility observed on the NextBiotech index;
- Anticipated maturity: 2.9 years.

The fair value of warrants allocated in 2014 in relation to the 2012 plan was valued at €1,078,084.80 and was fully reported under income for the 2014 financial year.

At the end of 2014, the subscription warrants for the 2012 plan were broken down as follows:

BSA / BSPCE reference	Extraordinary shareholder' meeting reference	Parity	Period of exercise	Number of warrants issued	Number of warrants allocated	Financial year	Number of warrants remaining to be exercised	Number of warrants remaining to be allocated
BSPCE 2012	21/05/2012	1 warrant = 10 shares	20/05/2020	33,788	33,788	6,807	26,981	-
BSA 2012	21/05/2012	1 warrant = 10 shares	20/05/2020	11,262	5,025	5,025	-	6,237
			Total	45,050	38,813	11,832	26,981	6,237

#### 6.3.2 "2014 Plan"

On January 22, 2014, the Board of Directors used the delegation granted by the combined general shareholders' meeting of April 2, 2013, in its twenty-fifth resolution, to decide on a plan for the free allocation of 22,500 founder share subscription warrants (hereinafter entitled BSPCE<sub>2014</sub>) to the benefit of Erytech directors (12,000 warrants) and to a category of "employees with management status" not yet identified by name (10,500 warrants).

The plan's characteristics are as follows:

Types of securities	Founder share subscription warrants (BSPCE)2014	
Number of warrants issued	22,500	
Number of warrants awarded	12,000	
Number of warrants exercised	0	
Board of Directors' meeting date	Jan. 22, 2014	
Exercise price per new share subscribed	€ 12.250	
Final date for exercising warrants	Jan. 22, 2024	
Parity	1 warrant for 10 shares	
General conditions of exercise	In the event of the beneficiary's death, it is stipulated that, pursuant to the provisions of article 163 bis G of the general tax code, the decedent's heirs may exercise the warrants within six months starting from the death.  The founder subscription warrants (BSPCE)2014 can be exercised:  on one single occasion, or  except in the event of an M&A operation, at most four (4) times per year, and for the exercise of a minimum of fifty (50) founder subscription warrants (BSPCE)2014.  In the event of a so-called M&A operation, holders of BSPCE20124 shall have five (5) business days starting from notice by the Company of the occurrence of such an event to exercise all of their BSPCE20124. However, the exercise of the BSPCE2014 may be canceled in the event of the ultimate non-performance of the takeover or the merger operation, for any reason whatsoever.	
Maximum number of new shares that can be issued	120,000	

In the event of a beneficiary's departure from the Group for any reason whatsoever, this beneficiary shall retain the BSPCE $_{2014}$  to which he subscribed prior to his departure. However, in the event of a beneficiary's departure from the Group, for any reason whatsoever, prior to subscription of the BSPCE $_{2014}$  to which the beneficiary has a right, the BSPCE $_{2014}$  shall be considered invalid vis-a-vis this beneficiary. Within this hypothesis, the

BSPCE<sub>2014</sub> not subscribed may be re-allocated to other beneficiaries within the same category and/or replacing the person who left the company.

In any case, the BSPCE<sub>2014</sub> not exercised at January 22, 2024 shall become duly and fully expired.

Concerning the directors and in accordance with IFRS 2, it was considered that the entirety of the 12,000 warrants were assigned on January 22, 2014. The fact that the directors can only subscribe to one third of these warrants each year constitutes a condition of service. In other words, these warrants form the object of a gradual 3-year acquisition period.

In the absence of a nominal allocation to "employees with management status", the Group estimated that definition of the allocation date in accordance with IFRS 2 could not be January 22, 2014 for the latter warrants, and that the allocation of each tranche of warrants would take place subsequently, during the 2nd quarter of each year over the period of 2015 to 2017, upon designation of the beneficiaries (with immediate acquisition of the rights associated with each tranche of warrants). Consequently, as no designation had yet been made at December 31, 2014, the Group did not record any expense for the period in relation to these BSPCE<sub>2014</sub>.

In conformity with IFRS 2, Erytech performed a valuation of the BSPCE $_{2014}$  allocated to directors, and used the Black & Scholes measurement model to perform this valuation.

The primary assumptions used to determine the fair value of the BSPCE<sub>2014</sub> allocated to directors are:

- Risk-free rate: between 1.12% and 1.70% in function of the tranches (in function of the zero coupon government bond rates curve);
- Anticipated dividends: zero;
- Volatility: 18.98% based on the historical volatility observed on the NextBiotech index;
- Anticipated maturity: between 5.6 and 6.7 years in function of the tranches allocated.

The fair value of the plan was valued at  $\in$ 372,059. This expense will be distributed gradually over the duration of the 3-year plan in conformity with IFRS 2 ("graded vesting method"). An expense of  $\in$ 157,798 was recorded to this end under personnel expenses, "Structural and general costs", at December 31, 2014.

Moreover, the board of directors' meeting of December 4, 2014 transformed 3,000 BSPCE $_{2014}$  into 3,000 BSA $_{2014}$  for a Medical Director at the subsidiary ERYECH PHARMA INC., in accordance with Annex IV-BSA $_{2014}$  Regulations, as recorded in the minutes. This allocation is conditional upon the recruitment of a person to this position. As this suspensive clause has not yet been lifted, these BSA $_{2014}$  had no accounting effect on the 2014 financial year.

#### 6.4 Net allocation to amortizations and provisions

in euros	12.31.2014	12.31.2013
Research and development costs	32,435	81,187
Clinical studies	189,738	141,293
Intellectual property costs	-	-
Structural and general costs	28,065	38,681
Net allocation to amortizations and provisions	250,238	261,161

#### **6.5** Financial results

in euros)	12.31.2014	12.31.2013
Interest on leasing	(6,801)	(4,656)
Interest on bonds	-	(1,059,272)
Financial charges	(43,205)	(55,860)
Net cost of debt	(50,006)	(1,119,788)
Earnings (losses) from disposal of VMP	140,935	19,689
Other Financial Income	619	3,210
Other Financial Charges	(23,375)	(2,700)
Other income & financial charges	118,179	20,199
Total Income (Loss)	68,173	(1,099,589)

The financial expenses were impacted in 2013 by the fair-value conversion of the A, B, and Recordati bonds, an amount of €240,000 paid to bondholders within the scope of the conversion and for expenses related to the restatement performed on the repayable advances. These bonds were converted in 2013.

#### 6.6 Income tax

in euros	12.31.2014	12.31.2013
Deferred tax assets	-	-
Deferred tax liabilities	-	-
Net deferred taxes	-	-

# **Proof of tax**

in euros	12.31.2014	12.31.2013
Before-tax results	(8,880,194)	(8,285,346)
Nominal tax proceeds	3,057,451	2,852,645
Non-activated deficit from financial year	(3,144,880)	(2,626,328)
CICE ( jobs & competitiveness tax credit) non-	14,748	9,877
Tax credits	524,606	470,540
Cancellation of the non-conversion premium.		(476,742)
Impact of the IFRS 2 restatement	(425,515)	(201,374)
Other differences	(6,252)	11,400
Effective tax (loss)/income	20,158	40,018

As a prudential measure, the losses that can be carried forward were activated only in the amount of the deferred tax liabilities; the amounts activated are not significant.

# 7. NOTES RELATIVES TO THE CONSOLIDATED STATEMENT OF FINANCIAL POSITION $% \left( 1\right) =\left( 1\right) \left( 1\right) \left($

# 7.1 Intangible assets

in euros	12.31.2013	Acquisitions/Provisio n for depreciation	Disposals	12.31.2014
Other intangible assets				
Gross	109,177	25,798	-	134,975
Amortization and depreciation	(94,900)	(9,124)	-	(104,024)
Net book value	14,277	16,674		30,951

in euros	12.31.2012	Acquisitions/Provisi on for depreciation	Disposals	12.31.2013
Other intangible assets				_
Gross	100,168	9,009	-	109,177
Amortization and depreciation	(70,575)	(24,325)	-	(94,900)
Net book value	29,593	(15,316)		14,277

# 7.2 Tangible fixed assets

in anno	12.31.2013	Acquisitions/Provision	Disposals/Transfe	12.31.2014
in euros	12.51.2015	for depreciation	rs	12.31.2014
Assets financed through lease with option				
<u>to buy</u>				
Laboratory equipment				
Gross	973,877			973,877
Amortization and depreciation	(654,154)	(98,593)		(752,747)
Net book value	319,723			221,130
Assets under construction	20,000		(20,000)	
Assets not financed through lease with				
option to buy				
Plant, equipment, and tooling				
Gross	337,673	279,784		617,457
Amortization and depreciation	(308,027)	(38,371)		(346,398)
Net book value	29,646			271,059
General equipment, fixtures and fittings				
Gross	953,455	5,390		958,845
Amortization and depreciation	(540,239)	(95,616)		(635,855)
Net book value	413,216			322,990
Office equipment and computers				
Gross	57,668	17,988		75,656
Amortization and depreciation	(27,306)	(8,535)		(35,841)
Net book value	30,362			39,815
Assets under construction		218,109	(105,629)	112,480
GRAND TOTAL				
Gross	2,342,673	521,270	(125,629)	2,738,314
Amortization and depreciation	(1,529,726)	(241,114)	-	(1,770,840)
Net book value	812,947	280,156	(125,629)	967,474

in euros	12.31.2012	Acquisitions/Provision for depreciation	Disposals/Transfers	12.31.2013
Assets financed through lease with option to		•		
<u>buv</u>				
Laboratory equipment				
Gross	733,464	240,413		973,877
Amortization and depreciation	(547,573)	(106,581)		(654,154)
Net book value	185,891	-		319,723
Assets under construction	40,000	122,340	(142,340)	20 000
Assets not financed through lease with option to buy				
Plant, equipment, and tooling				
Gross	318,096	19,577		337,673
Amortization and depreciation	(281,622)	(26,405)		(308,027)
Net book value	36,474	<u> </u>		29,646
General equipment, fixtures and fittings				
Gross	949,721	3,734		953,455
Amortization and depreciation	(444,513)	(95,726)		(540,239)
Net book value	505,208			413,216
Office equipment and computers				
Gross	25,041	32,627		57,668
Amortization and depreciation	(21,184)	(6,122)		(27,306)
Net book value	3,857	'		30,362
Assets under construction				
GRAND TOTAL				
Gross	2,066,322	418,691	(142,340)	2,342,673
Amortization and depreciation	(1,294,892)	(234,834)	-	(1,529,726)
Net book value	771,430	183,857	(142,340)	812,947

# 7.3 Non-current financial assets

in euros	12.31.2013	12.31.2014	
Security deposits and bonds	82,908	81,814	
Total other non-current financial assets	82,908	81,814	

# 7.4 Inventories

in euros	12.31.2014	12.31.2013
Production inventory	122,936	55,848
Laboratory inventory	75,420	82,391
<b>Total Inventory</b>	198,356	138,238

### 7.5 Other current assets

in euros	12.31.2014	12.31.2013
Research Tax Credit	1,523,68	1,366,656
Tax receivables (VAT, etc.) and other	494,2	71 233,151
Prepayments	216,7	79 101,067
Other subsidies to be received	-	-
Other current assets	2,234,73	38 1,700,874

### 7.6 Cash and cash equivalents

in euros	12.31.2014	12.31.2013
Cash and cash equivalents	36,988,436	15,112,523
Bank overdrafts	-	-
Net cash on hand and at bank	36,988,436	15,112,523

The cash position is composed of the following items:

- At 12/31/2014:
  - €3.0 M in money market funds,
  - €1.9 M in current accounts,
  - €32.0 M in term deposits distributed between 3 banking institutions, with maturities of 1 month to 3 years, but available without penalty subject to a 32-day notice.
- As of 12/31/2013: €12.1 million in cash, €1 million in a term deposit (1 month maturity), and €2 million in an account with a 6-month guaranteed rate of return.

#### Liquidity agreement

On April 30, 2013, the Group signed a liquidity agreement with the company Bryan Garnier for an amount of 600,000 euros. The agreement was since reduced, in April 2014, to  $\epsilon$ 200,000. At December 31, 2014, the Group held under mandate, within the scope of the liquidity agreement,  $\epsilon$ 251,102 in cash included in the net cash position ( $\epsilon$ 0 at December 31, 2013).

#### 7.7 Shareholders' equity

At December 31, 2013, the capital of the parent company was broken down into 5,558,952 shares, fully paid up, with a nominal value of 0.1 euro.

Following a new raising of funds on the Euronext market in October 2014, as well as the exercise of subscription warrants, the capital was increased to 6,882,761 shares with a nominal value of 0.1 euro.

Number of shares

Number of shares as of December 31, 2013	5,558,952
Exercise of share warrants	99,320
Issue of new shares on Euronext	1,224,489
Number of shares as of December 31, 2014	6,882,761

The costs for listing on the regulated market were allocated to the issue premium.

At December 31, 2014, the Group held, under mandate within the scope of the liquidity agreement signed with Bryan Garnier, 4,500 company shares at a weighted price of  $\in$ 28.00, i.e.,  $\in$ 126,006 (52,935 shares at a weighted price of  $\in$ 11.34, i.e.,  $\in$ 599,573 at December 31, 2013).

# Basic earnings per share and diluted earnings per share

in euros	12.31.2014	12.31.2013	
Net income	(8,860,036)	(8,144,721)	
Weighted number of shares for the period	5,874,794	4,686,150	
Basic earnings per share	(1.51)	(1.74)	
Diluted earnings per share	(1.51)	(1.74)	

At December 31, 2014, the 452,180 potential shares that could be issued within the scope of exercising subscription warrants issued were not taken into consideration in calculation of the diluted earnings, as their effects would be anti-dilutive.

#### 7.8 Provisions

The provisions can be broken down in the following manner:

in euros	12.31.2014	12.31.2013
IDR provisions	88,594	117,144
Provisions for disputes.	-	-
Provisions	88,594	117,144

The regime applicable at Erytech Pharma SA is defined by the collective agreement for the pharmaceutical industry.

The Group recognizes actuarial differences under other items of comprehensive income. The pension commitments are not covered by plan assets. The portion of the provision for which the maturity is less than one year is not significant.

The calculation assumptions for measuring the provision concerning employees are as follows:

	12.31.2014	12.31.2013
Discount rate	1.49%	3.17%
Wage increase	2%	3%
Social welfare contribution rate	Non-executive 44%	Non-executive 47%
	Executive 54%	Executive 55%
Age of retirement:	65-67 years	65-67 years
Mortality table	INSEE 2014	INSEE 2013

The breakdown of provisions is as follows:

in euros	FINANCIAL YEAR START	Other*	Provisions	Unused reversals	Used reversals	FINANCIAL YEAR END
Period from 01.01 to 12.31.2014						
IDR provision	117,144	(28,550)				88,594
Provision for disputes.	-					-
Net closing balance	117,144	(28,550)		-	-	88,594
Period from 01.01 to 12.31.2013						
IDR provision	97,098	20,046				117,144
Provision for disputes.	106,665			106,665		-
Net closing balance	203,763	20,046		106,665		117,144

<sup>\*</sup> The "Other movements" correspond to actuarial differences recognized.

# **7.9 Debt**

# Debt by type

in Euros	12.31.2014	12.31.2013
Debt associated with leases	220,376	303,217
Bank overdrafts	-	-
Conditional advances	549,161	693,669
Convertible bonds	-	-
Loans	-	15,000
Debt	769,537	1,011,886

# **Debt by maturity**

in Euros		2014			
	Amour	Amounts due			
	Less than one yea	Less than one year More than one			
Loans			-		
Conditional advances	257,500	291,661	549,161		
Debt associated with leases					
Convertible bonds	76,002	144,374	220,376		
Bank overdrafts			-		
Total loans	333,502	436,035	769,537		

in Euros		2013			
	Amour	Amounts due			
	Less than one yea	Less than one year More than one			
Loans	15,000		15,000		
Conditional advances	144,502	549,167	693,669		
Debt associated with leases					
Convertible bonds	82,841	220,376	303,217		
Bank overdrafts	-	-	-		
Total loans	242,343	769,543	1,011,886		

The conditional advances from public authorities form the object of agreements with BPI FRANCE. The Group benefits from three agreements on repayable advances with BPI FRANCE Innovation. These advances are not interest-bearing and are 100% repayable (nominal value) in the event of technical and/or commercial success.

Within the IFRS framework, the fact that a repayable advance does not require an annual interest payment amounts to the consideration that the Group has benefited from a zero-interest loan, i.e., more favorable than market conditions. The difference between the amount of the advance at its historical cost and that of the advance discounted at the risk-free rate (10 year OAT) increased by an estimated credit spread is considered as a grant received from the State. These grants are distributed over the estimated duration of the projects financed by these advances.

The portion of the conditional advances at more than one year is recorded under financial debts - non-current portion, while the portion at less than one year is recorded under financial debts - current portion. Since its creation, the Group has received 3 advances from BPI FRANCE, repayable under certain conditions, the main terms of which are presented below:

#### BPI FRANCE/PANCREAS

The first assistance, granted by BPI FRANCE, for a total amount of €735,000, concerns the program for the "development of a new treatment against pancreatic cancer through the administration of allogenic red blood cells incorporating L-asparaginase".

This assistance was distributed in 3 phases:

- €294,000 upon signature of the agreement (paid in 2008)
- €294,000 upon calls for funds (paid in 2010)
- balance upon completion of work with end of program identified by BPI FRANCE (paid in 2011)

The repayment of this conditional advance will be made according to a fixed payment schedule that will end at the latest on 06/30/2016.

The Group has undertaken to repay the entirety of the loaned amount according to the following payment schedule:

- €100,000 at the latest on June 30, 2013
- €150,000 at the latest on June 30, 2014
- €225,000 at the latest on June 30, 2015
- €260,000 at the latest on June 30, 2016.

#### BPI FRANCE FEDER

The second assistance, granted by BPI FRANCE FEDER, which provided for a total amount of €135,000, concerns a program for the "preclinical validation of the encapsulation of interfering RNA for therapeutic use in red blood cells, notably to limit inflammation of the cirrhotic liver and/or prevent the development of hepatocellular carcinomas".

This assistance provided for distribution in 4 phases:

- €40,500 upon signature of the agreement (paid in 2009)
- €40,500 upon calls for funds (paid in 2010)
- €27,000 upon calls for funds
- balance upon completion of work with end of program identified by BPI FRANCE.

The Group will have received €81,000 from BPI FRANCE/FEDER under this program. As the work corresponding to the FEDER assistance is currently terminated, the Group will not receive the last two payments of €27,000.

The repayment of this conditional advance will be made according to a fixed payment schedule that will end at the latest on June 30, 2016.

The Group has undertaken to repay the entirety of the loaned amount according to the following payment schedule:

- €7,500 at the latest on September 30, 2013
- €7,500 at the latest on December 31, 2013
- €7,500 at the latest on March 31, 2014
- €7,500 at the latest on June 30, 2014
- €9,250 at the latest on September 30, 2014
- €9,250 at the latest on December 31, 2014
- €9,250 at the latest on March 31, 2015
- €9,250 at the latest on June 30, 2015
- €14,000 at the latest on September 30, 2015.

#### • BPI FRANCE/TEDAC:

The third assistance, granted by BPI FRANCE within the scope of the TEDAC project, is for a total amount of €4,895,052. This assistance is distributed upon completion of the following key milestones:

- €62,607 upon signature of the agreement (paid in 2012)
- the remainder upon calls for funds in function of the key milestones.

The Group undertakes to repay BPI FRANCE initially:

- a) a sum of €5,281,000 upon achieving a cumulative amount of before-tax sales revenue equal to or greater than 10 million Euros, according to the following payment schedule:
  - €500,000 at the latest on June 30 of the first year in which this cumulative sales revenue is achieved,
  - $\ensuremath{\in} 750,000$  at the latest on June 30 of the second year,
  - $\in 1,500,000$  at the latest on June 30 of the third year,
  - €2,531,000 at the latest on June 30 of the fourth year,
- b) and, where applicable, an annuity equal to 50% of the income generated through the sale of intellectual property rights resulting from the project, within the limit of a total repayment of €5.3 million.

In a second phase, where the cumulative sales revenue reaches €60,000,000, the Group undertakes to pay BPI FRANCE a sum of 2.5% of the sales revenue generated by development of the products resulting from the project, within the limit of a total repayment of €15M over 15 years.

#### 7.10 Other liabilities

in euros	12.31.2014	12.31.2013
Other current liabilities		
Taxation and social security	970,629	815
Deferred income	368,436	648
Other payables	500,593	347
Other current liabilities	1,839,658	1,811,859

# 7.11 Related parties

Gil Beyen, Pierre Olivier Goineau, and Yann Godfrin are the Group directors; Jérôme Bailly is its chief pharmacist. The other related parties are members of the board of directors.

For 2014 in Euros	Total gross compensation	Fixed portion	Variable or exceptional portion	In-kind benefits (excluding GSC)	Net attendance fees	Fees, net of outlays	Optional unemployment scheme GSC
Gil Beyen	€338,168	€244,000	€91,500	€2,668			
Pierre-Olivier Goineau	€252,922	€175,783	€67,500	€4,020			€5,619
Yann Godfrin	€252,768	€175,550	€67,500	€4,099			€5,619
Jérôme Bailly	€69,258	€60,755	€5,172	€3,331			
Galenos sprl *	€1,000				€1,000		
Sven Andreasson	€19,476				€19,476		
Philippe ARCHINARD	€20,476				€20,476		
Hilde WINDELS	€9,024				€9,024		
Martine GEORGE	€10,024				€10,024		

For 2014 in Euros	Total warrants allocated end 2013	warrants allocated in 2014	warrants exercised in 2014	Balance end 2014	Fair Market Value of warrants allocated in 2014
		by value			
Gil Beyen	5,632	7,631	3,400	9,863	€513,960
Pierre-Olivier Goineau	4,993	3,515	-	8,508	€220,482
Yann Godfrin	4,993	3,515	-	8,508	€234,127
Jérôme Bailly	943	515	500	958	€39,166
Galenos sprl *	-			-	
Sven Andreasson	1,288	500	1,788	-	€38,025
Philippe ARCHINARD	837	500	1,337	-	€38,025
Hilde WINDELS	-			-	
Martine GEORGE	-			-	

<sup>\*</sup> Company controlled by Sven Andreasson

For 2013, in Euros	Total gross compensation	Fixed portion	Variable or exceptional portion	In-kind benefits (excluding	Net attendance fees	Fees, net of outlays	Optional unemployment scheme GSC
Gil Beyen	€164,736	€164,736					
Gil Beyen BVBA	€87,500					€87,500	
Pierre-Olivier Goineau	€251,007	€165,771	€75,000	€4,351			€5,885
Yann Godfrin	€251,110	€164,996	€75,000	€5,229			€5,885
Jérôme Bailly	€62,644	€55,293	€5,000	€2,351			
Galenos sprl *	€5,250					€5,250	
Sven Andreasson	€12,958				€12,958		
Philippe ARCHINARD	€13,083				€13,083		
Marc BEER	€8,333				€8,333		
Alain MAIORE							
Auriga Partners	€120,000					€120,000	
IDInvest Partners	€120,000					€120,000	

For 2013, in Euros	Total warrants allocated end 2012	warrants allocated in 2014	warrants exercised in 2013	Balance end 2013	Fair Market Value of warrants allocated in
		by value			
Gil Beyen		5 632		5,632	€239.811
Gil Beyen BVBA					
Pierre-Olivier Goineau	2,478	2,515		4,993	€107,089
Yann Godfrin	2,478	2,515		4,993	€107,089
Jérôme Bailly	428	515		943	€21,929
Galenos sprl *					
Sven Andreasson	1,033	255		1,288	€10,858
Philippe ARCHINARD	684	153		837	€6,515
Marc BEER	1,033	51	1 084		€2,172
Alain MAIORE	816		816		·

<sup>\*</sup> Company controlled by Sven Andreasson

The Group has no further related parties.

Fair market

Loans and

Debt at

Fair market

# 7.12 Financial instruments recorded in the balance sheet and effect on results

Balance sheet

12/31/2014 in Euros		Balance sheet value	value by earnings	Loans and receivables	amortized cost	Fair market value
Non-current financial assets	(1)	81,814		81,814		81,814
Other current assets	(1)	2,234,738		2,234,738		2,234,738
Cash and cash equivalents	(2)	36,988,436	36,988,436			36,988,436
Total financial assets		39,304,988	36,988,436	2,316,552	-	39,304,988
Financial liabilities - Non-current portion	(1)	436,035			436,035	436,035
Financial liabilities - Current portion	(1)	333,502			333,502	333,502
Trade payables & related accounts	(1)	2,084,546			2,084,546	2,084,546
Total		2,854,083	-	-	2,854,083	2,854,083
12/31/2013 in Euros		Balance sheet value	Fair market value by earnings	Loans and receivables	Debt at amortized cost	Fair market value
Non-current financial assets	(1)	82,908		82,908		82,908
Other current assets	(1)	1,700,874		1,700,874		1,700,874
Cash and cash equivalents	(2)	15,112,523	15,112,523			15,112,523
Total financial assets		16,896,305	15,112,523	1,783,782	-	16,896,305
Financial liabilities - Non-current portion	(1)	730,545			730,545	730,545
Financial liabilities - Current portion	(1)	281,341			281,341	281,341
Trade payables & related accounts	(1)	1,421,436			1,421,436	1,421,436
Total		2,433,323			2,433,323	2,433,323

<sup>(1)</sup> The book value of these assets and liabilities is a reasonable approximation of their fair value.

12/31/2014 in Euros

<sup>(2)</sup> Fair value at level 2

#### 8. MANAGEMENT OF MARKET RISK

# Exchange rate risk

The Group uses the Euro as its reference currency within the scope of its disclosures and financial communications. However, a significant portion, in the amount of 10% of its operating expenses, is denominated in US dollars (agency office in Philadelphia, collaborations relating to the production of clinical batches with the American Red Cross, business development consultants, consultants for the development of clinical trials in the United States, and various collaborations around tests and clinical projects in the United States).

To date, the Group has not opted to use active hedging techniques, and has not made recourse to derivative instruments to this end. Unfavorable exchange rate fluctuations between the euro and the dollar that are difficult to predict could affect the financial position of the Company.

This dependency will increase, as the Group will perform clinical trials in the USA and, in the longer term, sell on this market. The Group will opt to use exchange rate hedging techniques.

Expenses in US Dollars totaled \$949,232 during the 2014 financial year. The counter-values recorded in the accounts totaled  $\[ \in \]$  714,807 in relation to the receipt of invoices and price fluctuations. This represents an average annual rate of \$1.328 per  $\[ \in \]$  (\$1.324/ $\[ \in \]$  on average in 2013).

However, the EUR/USD rate fell considerably at the period end, reaching \$1.2141 per €1 at December 31, 2014.

The Group purchased 1 million dollars at the rate of \$1.2197 per €1 during December 2014.

The exchange rate differences are not significant for the periods presented.

# Liquidity risk

The Group has been structurally loss-generating since its creation. The net cash flows associated with the Group's operating activities were respectively -7.2 million Euros at December 31, 2014 and -6.5 million Euros at December 31, 2013.

Historically, the Group has financed its growth by strengthening its shareholders' equity in the form of capital increases and the issue of convertible bonds. The capital increase associated with its introduction on the stock market in May 2013, as well as the operation renewed in 2014, enables the Group to ensure its business continuity over several years.

The remaining contractual maturities of financial liabilities are broken down as follows (including interest payments):

in euros		20	14	
	Book value	Contra	actual cash flows	
	Dook value	Total	Less than 1	1 to 5 years
Loans				
Conditional advances	549,161	(580,107)	(257,500)	(322,607)
Debt associated with leases				
Convertible bonds	220,376	(230,183)	(80,702)	(149,481)
Bank overdrafts				
Trade payables and related				
accounts				
	2,084,546	(2,084,546)	(2,084,546)	
Total	2,854,083	(2,894,836)	(2,422,748)	(472,088)

in euros		20	13	
	Dook walno	Contra	actual cash flows	
	Book value	Total	Less than 1	1 to 5 years
Loans	15,000	(15,499)	(15,499)	-
Conditional advances	693,669	(763,607)	(183,500)	(580,107)
Debt associated with leases				
Convertible bonds	303,217	(319,826)	(89,643)	(230,183)
Bank overdrafts	-	-	-	-
Trade payables and related accounts	-	-	-	-
accounts	1,421,436	(1,421,436)	(1,421,436)	
Total	2,433,322	(2,520,368)	(1,710,078)	(810,290)

#### 9. OFF-BALANCE SHEET COMMITMENTS

## Clinical trials

The costs associated with clinical trials are recognized as expenses as and when they are sustained. Each patient included results in an obligation for Erytech to sustain certain costs whether or not the study continues, and to do so in addition to the expenses already incurred. When a patient is recruited, the Group establishes a provision to cover all the costs sustained to continue the clinical trial.

The remainder of the costs sustained leading up to the end of the clinical trial (patients not yet recruited) are monitored off-balance sheet.

12/31/2014 in	Keuros	ERYTECH contra	actual commitment	
Clinical trial name	Accrued payables, tax incl.	Definite accrued payables	Uncertain (Off- balance sheet, net of taxes)	Comment
2007/04	-	-	1	Trial ended
2008/02	-	-	-	Trial ended
2009/06	200	-	-	Trial ended
2012/09	41	-	1 014	Recruitment begun
2012/10	4	-	1	Recruitment begun
2013/03	256	-	4 526	Recruitment begun
	Accr	rued payables	off-balance sheet	
		501	5 539	

12/31/2013 in	n Keuros	ERYTECH contr	ractual commitment	
Clinical trial name	Accrued payables, tax incl.	Definite accrued payables	Uncertain (Off- balance sheet, net of taxes)	Comment
2007/04	-	-	-	Trial ended
2008/02	-	-	-	Trial ended
2009/06	347	-	-	Recruitment ended
2012/09	-	-	-	Recruitment not begun
2012/10	-	-	-	Recruitment not begun
2013/03	-	-	-	Recruitment not begun
	Acci	rued payables	off-balance sheet	

The off-balance sheet commitments relating to simple leases total €687,000 and essentially correspond to the lease of buildings.

The maturities on these expenses are as follows:

- Less than 1 year: €397,000

- Between 1 year and 5 years: €290,000

- More than 5 years: €0

# 10. AUDITORS' FEES

For the 2014 financial year, the auditor fees paid on the financial year totaled:

- within the scope of its legal term of office: €95,000, excluding out-of-pocket expenses,
- within the scope of the capital increase by the parent company: €12,000

# 20.2 Corporate financial statements prepared (French standards) for the years ended December 31, 2013 and 2014

## **Statement of Assets**

**ERYTECH PHARMA** 

**INTANGIBLE ASSETS** Start-up costs Development costs

**INVESTMENTS** 

**HEADINGS** 

atement of Assets		Period	from 01/01/14	to 12/31/14
YTECH PHARMA				
HEADINGS	GROSS	Amortization	Net (N) 12/31/2014	Net (N-1) 12/31/2013
SUBSCRIBED CAPITAL NOT CALLED UP				
NTANGIBLE ASSETS				
Start-up costs				
Development costs				
Licenses, Patents, and similar rights	134,975	104,025	30,951	14,277
Business goodwill				
Other intangible assets				
Advances and payments on intangible assets				
TOTAL intangible assets	134,975	104,025	30,951	14,277
TANGIBLE FIXED ASSETS	-		-	
Land				
Buildings				
Technical systems, industrial equipment and infrastructure	617,457	346,398	271,059	29,646
Other tangible assets	1,034,501	671,695	362,806	443,579
Assets under construction	112,480		112,480	20,000
Advances and deposits				
TOTAL tangible assets	1,764,439	1,018,093	746,345	493,225
NVESTMENTS	, , , , , ,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		,
Investments in companies counted using the equity method				
Other participating interests	1		1	
Receivables relating to participating interests				
Other investments				
Loans				
Other financial assets	458,923		458,923	581,873
TOTAL Investments	458,524		458,924	581,873
NONCURRENT ASSETS	2,358,337	1,122,117	1,236,220	1,089,375
NVENTORY AND WORKS IN PROGRESS				
Raw materials and supplies	198,356		198,356	138,238
Inventory of in-process goods				
Inventory of in-process services				
Inventories of intermediate and finished products				
Inventory of goods for resale				
TOTAL Inventory	198,356		198,356	136,238
RECEIVABLES				
Advances and payments on account				429
Trado rocoivablos	104 970		104 970	97 102

INVENTORY AND WORKS IN PROGRESS			
Raw materials and supplies	198,356	198,356	138,238
Inventory of in-process goods	150,550	130,330	130,230
Inventory of in-process services			
Inventories of intermediate and finished products			
Inventory of goods for resale			
TOTAL Inventory	198,356	198,356	136,238
RECEIVABLES	150,550	130,330	130,230
Advances and payments on account			429
Trade receivables	104,870	104,870	87,192
Other receivables	2,128,952	2,128,962	1,716,965
Called up share capital, not paid			
TOTAL receivables:	2,233,832	2,233,832	1,804,586
MISCELLANEOUS CASH AT BANK AND IN HAND			
Marketable securities	3,000,583	3,000,583	
Cash at bank and in hand	33,654,518	33,654,518	15,112,523
Prepayments	216,779	216,779	
TOTAL Miscellaneous cash at bank in hand:	36,871,880	36,871,880	15,213,590
CURRENT ASSETS	39,304,069	39,304,069	17,156,414

Debt issuance costs to be spread out  Bond redemption premiums			
Bond redemption premiums			Debt issuance costs to be spread out
			Bond redemption premiums
Asset translation adjustments			Asset translation adjustments

41,662,406

1,122,117

Page | 183 of 265

TOTAL ASSETS

Period from 01/01/14

to 12/31/14

# **Statement of Liabilities**

## **ERYTECH PHARMA**

HEADINGS	Net (N) 12/31/2014	Net (N-1) 12/31/2013
NET FINANCIAL POSITION		
Individual or share capital of which paid 688,276	688,276	
Issuance, merger, contribution premiums, etc.	71,375,715	42,335,338
Revaluation adjustments of which includes the equity method evaluation Legal reserve		
Reserves required by articles of association or contract		
Regulated reserves		
Other reserves		
Carry forward	(28,774,932)	(22,295,938)
Financial year's results	(7,283,237)	(6,478,994)
TOTAL Net financial position:	36,005,821	14,116,301
INVESTMENT GRANTS REGULATED PROVISIONS		
SHAREHOLDERS' EQUITY	36,005,821	14,116,301
•		, ,,,,,,
Proceeds from the issuance of equity securities		
Conditional advances	580,107	763,607
OTHER SHAREHOLDERS' EQUITY	580,107	763,607
Provisions for liabilities Provisions for charges		
Provisions for charges		
PROVISIONS FOR RISKS AND LIABILITIES		
FINANCIAL DEBTS		
Convertible bonds		
Other bonds		
Bank loans and overdrafts		15,000
Miscellaneous other loans and advances		
TOTAL debt:		15,000
ADVANCES AND DEPOSITS RECEIVED ON CONTRACTS		
OTHER LIABILITIES		
Trade payables and related accounts	2,096,901	1,524,652
Taxation and social security	988,430	829,988
Liabilities on fixed assets and related Other payables	500,593	347,388
TOTAL miscellaneous debt:	3,585,925	2,702,028
DEFERRED INCOME	368,436	648,854
DEBTS	3,954,360	3,365,881
Translation differences - liabilities		
	<u> </u>	
TOTAL ASSETS	40,540,288	18,245,790

Period from

01/01/14 to 12/31/14

10,297,787

8,767,638

# **Income Statement (Part One)**

ERYTECH PHARMA		T OHOU HOIH	01/01/11	12/01/11
HEADINGS	France	Export	Net (N) 12/31/2014	Net (N-1) 12/31/2013
Sale of goods purchased for resale				
Production of goods sold				
Services sold	791,853		791,853	483,964
Net sales revenue	791,853		791,853	483,964
Production transferred to inventory				1
Production capitalized				
Operating subsidies			271,231	294,150
Reversals of provisions and amortization, trai	nsfers of charges		39,754	133,225
Other eamings			10,294	464
	OPER <i>A</i>	ATING INCOME	1,113,132	911,804
EVERNAL GUARGES			T	
EXTERNAL CHARGES				
Purchases of goods for resale (including cust	toms duties)			
Change in inventory of goods for resale				
Purchases of raw materials and other consur			613,929	•
Change in inventory [raw materials and cons	umables]		(60,118)	(22,255)
Other purchases and external charges			5,866,460	4,308,504
	TOTAL ex	ternal charges:	6,420,271	4,865,164
TAXES DUTIES AND SIMILAR PAYMENTS			66,537	38,114
EMPLOYEE CHARGES				
Wages and salaries			2,359,456	
Social security charges			1,211,628	1,192,720

Social Security Charges		1,211,020	1,132,720
	TOTAL employee charges:	3,571,084	3,668,456
PROVISIONS FOR OPERATIONS			
Charges to impairment of non-current assets		151,645	152,578
Charges to provisions of non-current assets			
Charges to provisions on current assets			
Provisions for liabilities and charges			
	TOTAL operating provisions:	151,645	152,578
OTHER OPERATING CHARGES		88,250	43,325

OPERATING RESULTS	(9,184,655)	(7,855,834)
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**OPERATING CHARGES** 

# **Income Statement (Part Two)**

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

HEADINGS	Net (N) 12/31/2014	Net (N-1) 12/31/2013
OPERATING RESULTS	(9,184,655)	(7,855,834)
Allocated profit or transferred loss Loss borne or profit transferred		
FINANCIAL INCOME		
Financial income from participating interests Income from other securities and fixed asset receivables Other interest and similar income	317,545 100,607	534,771
Reversals of provisions, transfers of charges Foreign exchange gains Net proceeds from the disposal of marketable securities	605 513	3,195
	419,270	537,966
FINANCIAL EXPENSES Financial allocations for amortization and provisions Interest payable and similar expenses Foreign exchange losses Net expenses on the disposal of term investments	429 24,867	100,607 436,881 2,700
	25,367	542,188
NET FINANCIAL INCOME(LOSS)	393,903	(4,222)
EARNINGS BEFORE INCOME TAX	(8,790,751)	(7,860,056)
NON-RECURRING INCOME  Non-recurring income on revenue transactions  Exceptional income on capital operations	(8,790,751) 201	( <b>7,860,056</b> ) 27,829
NON-RECURRING INCOME  Non-recurring income on revenue transactions  Exceptional income on capital operations  Reversals on provisions and transfers of expenses		
NON-RECURRING INCOME  Non-recurring income on revenue transactions Exceptional income on capital operations Reversals on provisions and transfers of expenses  NON-RECURRING CHARGES Non-recurring charges on revenue transactions Non-recurring charges on capital transactions	201	27,829
NON-RECURRING INCOME  Non-recurring income on revenue transactions Exceptional income on capital operations Reversals on provisions and transfers of expenses  NON-RECURRING CHARGES Non-recurring charges on revenue transactions	201 201 15,605	27,829 <b>27,929</b>
NON-RECURRING INCOME  Non-recurring income on revenue transactions Exceptional income on capital operations Reversals on provisions and transfers of expenses  NON-RECURRING CHARGES Non-recurring charges on revenue transactions Non-recurring charges on capital transactions	201 201 15,605 770	27,829 27,929 13,423
NON-RECURRING INCOME  Non-recurring income on revenue transactions Exceptional income on capital operations Reversals on provisions and transfers of expenses  NON-RECURRING CHARGES Non-recurring charges on revenue transactions Non-recurring charges on capital transactions Non-recurring allocations for amortization and provisions	201 201 15,605 770 16,375	27,829 27,929 13,423
NON-RECURRING INCOME Non-recurring income on revenue transactions Exceptional income on capital operations Reversals on provisions and transfers of expenses  NON-RECURRING CHARGES Non-recurring charges on revenue transactions Non-recurring charges on capital transactions Non-recurring allocations for amortization and provisions  NONRECURRING PROFIT (LOSS)	201 201 15,605 770 16,375	27,829 27,929 13,423
NON-RECURRING INCOME Non-recurring income on revenue transactions Exceptional income on capital operations Reversals on provisions and transfers of expenses  NON-RECURRING CHARGES Non-recurring charges on revenue transactions Non-recurring charges on capital transactions Non-recurring allocations for amortization and provisions  NONRECURRING PROFIT (LOSS)  Employee profit sharing	201 201 15,605 770 16,375 (16,174)	27,829 27,929 13,423 13,423 14,406

Appendix to the balance sheet prior to annual distribution, characterized by:

total from statement of financial position in €:
sales revenue in €:
net book results in €:
€40,540,288.21
€791,852.77
(€7,283,237.28)

The financial year had a duration of 12 months, covering the period from 01/01/2014 to 12/31/2014.

The notes and tables presented below form an integral part of the annual financial statement.

#### 1. FACTS CHARACTERIZING THE FINANCIAL YEAR

In October 2014, the company successfully raised €30 M, pertaining to a total of 1,224,489 new shares issued within the scope of a capital increase, with suppression of the preferential subscription right, reserved for investors regularly investing in securities specific to the fields of health care, representing approximately 17.8% of the number of shares in circulation (post-issue).

The issue price was set at 24.50 Euros per share, in compliance with resolution no. 10 of the combined general shareholders' meeting of June 17, 2014. This price reflects a 3.5% reduction as compared to the weighted average of the Company's share price in the last five trading sessions prior to establishing the price, i.e., 25.39 Euros. In total, 80% of the issue was performed internationally, with 68% in the United States.

Prior to this, the company had announced the positive Phase III results on its clinical study with GRASPA® in the treatment of AML. Analysis of the data from the GRASPIVOTALL clinical trial (GRASPALL2009-06), after one year of monitoring, demonstrates that the study convincingly achieved its primary objectives, and its secondary objectives confirm a favorable profile for the clinical efficacy of GRASPA®. The study also shows favorable results in patients with histories of allergies to L-asparaginase.

During the financial year, the company also recruited the first patient for its Phase II study on pancreatic cancer in Europe, as well as its first patient for its Phase I/II study in the United States.

The company announced the positive opinion by its second committee of independent experts (DSMB) for its Phase IIb study on AML. The independent experts analyzed the tolerance data for the first 60 patients treated, and as with the first DSMB committee review on 30 patients, continuation of the study was unanimously confirmed, without requesting any modifications to the study or formulating any particular observations.

The company likewise obtained Orphan Drug Designation from the FDA for its product ERY-ASP in the treatment of AML in the United States.

The company created its subsidiary "ERYTECH PHARMA Inc." in the USA in April 2014. The Company then proceeded to appoint the firm RSM-CCI Conseils as co-Statutory Auditors in the AGM of June 17, 2014. At June 30, 2014, the Group's financial statements were supplemented, for the first time, by consolidation of the 100% held American subsidiary.

## 2. SIGNIFICANT EVENTS SUBSEQUENT TO YEAR-END

Pierre-Olivier Goineau, co-founder of the company ERYTECH Pharma SA, Delegated Managing Director, member of the Board of Directors, and Deputy Chairman, submitted his resignation from all his positions within the company ERYTECH PHARMA SA at the end of the parent company's Board of Directors' meeting of January 11, 2015. Mr. Goineau remains treasurer and secretary of the American subsidiary ERYTECH PHARMA Inc.

## 3. BUSINESS CONTINUITY

The Company's loss-making situation is explained by the innovative nature of the products developed, therefore involving a multi-year research and development phase. The general accounting conventions were applied in compliance with the principle of prudence, in accordance with the underlying assumptions of:

- business continuity,
- permanence of accounting methods from one year to the next,
- independence of financial years,

and in accordance with the general rules for the preparation and presentation of annual financial statements.

### 4. ACCOUNTING PRINCIPLES AND METHODS

## 4.1 GENERAL PRINCIPLES AND CONVENTIONS

The annual financial statement was prepared and presented in accordance with the accounting rules in effect in France, in compliance with the principle of prudence and the independence of financial years, and within the assumption of business continuity.

The basic method adopted for measuring the items recorded in the accounts is the historical cost method.

The accounting conventions were applied in conformity with the provisions of the Code of Commerce, the accounting decree of November 29, 1983, as well as CRC Regulations no. 2000-06, no. 2004-06, and no. 2002-10, and of ANC Regulation no. 2014-03 of June 5, 2014 relative to the general chart of accounts.

## 4.2 CONTINUITY OF METHODS

No changes in accounting regulations or accounting methods took place during the financial year ended December 31, 2014.

## 4.3 OTHER ACCOUNTING PRINCIPLES

The primary other methods used are as follows:

#### **Intangible assets**

The intangible assets are measured at their capitalized cost or at their production cost.

R&D costs are recognized based on the following method in the research phase:

- No intangible assets resulting from research can be recognized,
- Research expenses (or expenses for the research phase of an internal project) must be recognized as expenses as and when they are incurred,
- Intangible assets are recognized if, and only if, the company can demonstrate:
  - technical feasibility,
  - the intention and capacity to complete the asset or to sell it,
  - the manner in which the intangible asset will generate probable future economic benefits,
  - the availability of resources to complete the development, use, or sell the intangible asset,
  - the capacity to reliably measure the expenses ascribable to the intangible asset or during its development.

The balance of the research and development costs item is zero on the balance sheet. In effect, not all of the criteria for recognition under intangible fixed assets have been met, and the corresponding expenses have therefore been kept under operating expenses.

# Tangible fixed assets

The tangible fixed assets are measured at their purchase cost (purchase price and accessory costs, excluding costs for the purchase of assets) or at their production cost.

The amortizations for impairment are calculated according to the straight-line or decreasing charge method in function of anticipated lifetime:

Licenses, software, patents
 Technical systems
 1 to 10 years
 3 to 10 years

Industrial equipment and infrastructure
 Office equipment and furniture
 1 to 5 years
 3 to 5 years

# Participating interests, other securities, term investments

The gross value is composed of the purchase cost excluding accessory expenses. Where the current value is lower than the gross value, a provision for impairment is established in the amount of the difference.

#### **Inventories**

Inventories are measured according to the FIFO method.

The gross value of merchandise and supplies includes the purchase price and the accessory expenses.

Manufactured products are valued at their production cost, including consumption and direct and indirect production expenses, the amortization of assets involved in production. The cost of the sub-activity is excluded from the value of inventories.

A provision for the impairment of inventories, equal to the difference between the gross value determined based on the above-indicated methods and the spot price or the realizable value less the proportional sales costs, is made where this gross value is greater than the other value given.

#### **Receivables**

Receivables are valued at their nominal value. A provision for impairment is made where the current value is lower than the book value.

#### **Convertible bonds**

The accounting method for convertible bonds is that entitled "two separate transactions," i.e., the bond, non-conversion premium included, is recorded under the liabilities in the balance sheet, and the non-conversion premium is recorded under the assets.

The non-conversion premium is then amortized proportionately to the accrued interest.

# Recognition of grant income

The grant income is recognized, where it is granted, upon its collection.

According to the matching principle, the corresponding pace of spending is taken into account and, where applicable, a portion of the grant is recorded under "deferred revenue" where the grant agreement explicitly stipulates the expenses that must be incurred. Vice-versa, an accrual is recorded where the expenses incurred allow for recognition of a portion of the grant receivable.

The Company therefore records a deferred income corresponding to the portion of the grant received corresponding to expenses not incurred.

### **Conditional advances**

The advances received from the State generally contain a portion in grants for which repayment is not required, and a portion repayable in the event of technical or commercial success, classified as conditional advances.

Conditional advances are presented in the balance sheet under the item "Other shareholders' equity" where a doubt exists regarding the technical or commercial success.

A public grant to be received either in compensation for the expenses or losses already incurred, or in the form of immediate financial support to the Company with no related future costs, is recognized under income for the financial year during which the expenses relating to the program in question are incurred.

#### **Clinical trials**

The costs associated with clinical trials are recognized as expenses as and when they are sustained.

Each patient included results in an obligation for ERYTECH to sustain certain costs whether or not the study continues, and to do so in addition to the expenses already incurred. When a patient is recruited, the company establishes a provision to cover all the costs sustained to continue the clinical trial over a one-year horizon.

The remainder of the costs sustained leading up to the end of the clinical trial (patients not yet recruited) are monitored off-balance sheet.

#### **Provisions**

A provision for risks and liabilities is recorded where an equity item has a negative economic value for the entity, which translates into an obligation in relation to a third party for which it is probable or certain that it will result in an outflow of resources to the benefit of this third party, without an at least equivalent compensation anticipated by this third party.

# Transactions with related parties that have not been performed under normal market conditions

No transactions of this nature were performed during the financial year.

#### Pension and retirement commitments

The company has signed no special agreements relating to retirement commitments.

These commitments are therefore limited to the contractual retirement indemnity. No provision for liabilities was recognized in relation to this financial year.

The method adopted is the projected unit credit method (or the accrual of rights method).

The technical assumptions used are the following:

- Age of retirement: 65-67 years
- Average turnover (non-management), high turnover (management)
- Evolution of wages: management and non-management at 2%
- INSEE 2014 mortality table
- Discount rate: IBOXX Corporates AA rate of 1.49% at December 2014
- Employer contribution rate adopted: 50% (non-management) and 54% (management and directors).

# Tax credit for competition and jobs ("credit d'impot pour la competitivite et l'emploi" - CICE)

The tax credit for competition and jobs (CICE) is a tax benefit for companies with employees and is equivalent to a decrease in their social security contributions.

The CICE must be allocated to the corporate tax due for the year in which the remuneration taken into account for calculation of the CICE was paid.

According to the ANC [French accounting standards authority] guidelines, the Company recognizes the CICE as a credit in the sub-account dedicated to account 64 "Personnel expenses."

# 5. ADDITIONAL INFORMATION RELATIVE TO THE STATEMENT OF FINANCIAL POSITION

## **Intangible assets**

The amount of research costs recognized as expenses for the financial year and not activated total €4,886,273.

#### **Financial assets**

The Company has stipulated a liquidity agreement with the company Bryan Garnier with a view to encouraging the liquidity of transactions and the regularity of share prices, as well as avoiding discrepancies in share price that are not warranted by market trends.

To this end, the Company carried a credit on the liquidity account initially in the amount of €600,000, which was reduced in March 2014 by €400,000 to €200,000.

The company Bryan Garnier reported on its portfolio of Erytech Pharma securities at 12/31/2014, which totaled 4,500 securities valued at an average price of  $\in 28.00$ , i.e.,  $\in 126,000$  (recorded under financial assets).

The available cash balance at 12/31/2014 totaled €251,1023.

The other financial assets are composed of deposits & sureties in the amount of €81,814.

The company holds, in equity securities, 100% of the capital of the subsidiary ERYTECH PHARMA Inc., i.e., 1 USD valued at €0.73.

The company's investment stakes can be summarized as follows:

	Capital	Reserves and retained earnings before allocation of earnings	Portion of capital held (in %)	Book value held		Loans and advance s granted by the company and not yet repaid	Amount of bonds and deposits made by the company	Pretax revenue from the last financial year	Earnings (profit or loss of the last financial year ended)	Dividends received by the company during the financial year	Remarks
A- DETAILED INFORMATION CONCERNING SUBSIDIARIES AND PARTICIPATING INTERESTS											
Subsidiary (+50% of the capital owned by the company)     ERYTECH PHARMA Inc.	0.73	0,00	100.00	0.73	0.73	80,847.28	0.00	0.00	-108.72	0,00	
2. Participating interest (10 to 50% of the capital held by the company)											
B - GENERAL INFORMATION ABOUT THE OTHER SUBSIDIARIES AND PARTICIPATING INTERESTS											
1. Subsidiaries not shown in A 1. French											
2. Foreign											
2. Participating interests not shown in A 1. French											

# **Fixed assets**

ERYTECH PHARMA

Period from 01/01/14

to 12/31/14

HEADINGS	Gross value start of year	Increases through revaluations	Purchases, contributions, creation of transfers
INTANGIBLE ASSETS			
Startup and development costs			
Other intangible assets	109,177		25,798
TOTAL intangible assets:	109,177		25,798
TANGIBLE FIXED ASSETS			
Land			
Structures on own ground	227 674		
Structures on someone else's ground	337,674		279,784
General facilities construction	953,455		5,390
Mechanical systems and industrial tooling	57,668		17,988
General facilities, plant and tooling			17,900
Shipping equipment			
Office equipment, computers And furniture			
Recoverable packaging and other	20,000		218,109
Assets under construction	20,000		
Advances and deposits			
TOTAL tangible assets	1,368,797		521,270
INVESTMENTS			
Investments in companies counted using the equity methodmises			
Other participating interests			1
Other investments			
Other long-term financial investments	682,481		377,212
<b>TOTAL Investments:</b>	682,481		377,213

TOTAL ASSETS 2,160,455 924,281

HEADINGS	Decreases through transfers	Decreases by disposals and retirements	Gross value year end	Legal revaluations
INTANGIBLE ASSETS				
Start-up and development costs Other intangible assets TOTAL intangible assets			134,975 <b>134,975</b>	
TANGIBLE FIXED ASSETS				
Land Structures on own ground Structures on someone else's ground General facilities construction Technical systems, industrial equipment and infrastructure General facilities, tools and other Shipping equipment Office equipment, computers and furniture Recoverable packaging and other Tangible fixed assets under development	125,629		617,457 958,845 75,656 112,480	
TOTAL tangible assets	125,629		1,764,438	
INVESTMENTS Interests measured using the equity method Other participating interests Other investments			1	
Loans and other long-term financial  TOTAL Investments		600,770 <b>600,770</b>	458,923 <b>458,924</b>	

TOTAL ASSETS 125,629 600,770 2,358,337

2014 – Reference Document \_\_\_\_\_\_ ERYTECH

# Amortization

# ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

POSITIONS AND TRANSACTIONS IN THE FINANCIAL YEAR					
AMORTIZABLE ASSETS	Start of FY amount	Increased allocations	Decreases reversals	Amount end of financial year	
INTANGIBLE ASSETS					
Startup and development costs					
Other intangible assets	94,900	9,124		104,025	
TOTAL intangible assets:	94,900	9,124		104,025	
TANGIBLE FIXED ASSETS					
Land					
Structures on own ground					
Structures on someone else's ground					
General facilities construction					
Technical systems and industrial infrastructure	200.020	0 < 0.54		245200	
General systems, layouts, and other	308,028	36,371		346,398	
Shipping equipment	540,238	95,616		635,854	
Office and IT equipment and furniture	27,306	8,535		35,841	
Recoverable packaging and other	27,300	0,333		33,041	
TOTAL tangible assets	875,572	142,521		1,018,093	

TOTAL ASSETS	970,473	151,645	1,122,117
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BREAKDOWN OF PROVISIONS FOR DEPRECIATION FOR THE FINANCIAL YEAR			
FIXED ASSETS SUBJECT TO AMORTIZATION	Straight-line depreciation	Declining balance depreciation	Exceptional amortizations
INTANGIBLE ASSETS Startup and development costs Other intangible assets  TOTAL intangible assets:	104,025 <b>104,025</b>		
TANGIBLE FIXED ASSETS			
Land Structures on own ground Structures on someone else's ground General facilities construction Mechanical systems and industrial tooling General facilities, plant and tooling	346,398 635,854		
Shipping equipment Office equipment, computers And furniture Recoverable packaging and other	35,841		
TOTAL tangible fixed assets:	1,018,093		
Acquisition costs for participating interests			

GENERAL TOTAL	1,122,118		
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**Amortizations (cont.)** 

Period from 01/01/14

to 12/31/14

ERYTECH PHARMA

TRANSACTIONS AFFECTING PROVISIONS FOR DEPRECIATION TO BENEFIT FROM TAX LAW					
FIXED ASSETS SUBJECT TO AMORTIZATION		Provisions	Reversals		
INTANGIBLE ASSETS Start-up and development costs Other intangible assets	ntangible assets				
TANGIBLE FIXED ASSETS	intaligible assets				
Land Buildings on own land Buildings on others' land Buildings general systems Technical systems and industrial infrastructure General facilities, plant and tooling Shipping equipment Office equipment, computers And furniture Recoverable packaging and other					
TOTAL	tangible assets				
Acquisition costs for participating interests					

# TOTAL ASSETS

MOVEMENTS DURING THE FINANCIAL YEAR AFFECTING EXPENSES DISTRIBUTED OVER MULTIPLE FINANCIAL YEARS					
HEADINGS	Net amount at year start	Increases	Allocations to amortizations during the financial year	Net amount year end	
Debt issuance costs to be spread out  Bond redemption premiums					

# Details of changes in inventory and works in progress

Period from 01/01/14

to 12/31/14

ERYTECH PHARMA

HEADINGS	At end of	At start of financial	Change in	inventory
HEADINGS	financial year	year	Increases	Decreases
Goods for resale				
Inventory resold as is				
Goods for resale				
Provisions				
Provisions inventory				
Raw materials	122,936		67,088	< 070
Other provisions	75,420	82,391		6,970
TOTAL I	198,356	138,238	60,118	
Intermediate goods Finished goods By-products				
TOTAL II				
	1			
Work in progress – production				
Income				
Works				
Studies				
Delivery of services				
TOTAL III				

PRODUCTION TRANSFERRED	TO INVENTORY	(or production removed from
inventory)		II+ III

The line "Raw materials" concerns the inventory of products dedicated to the production of batches for clinical usage. The increase in activities in 2014 led to a large increase in the related inventory.

The line "Other supplies" concerns the inventory of products dedicated to pre-clinical research.

# **Statement of Maturities for Receivables and Debts**

Period from 01/01/14 to 12/31/14

## ERYTECH PHARMA

STATEMENT OF RECEIVABLES	Gross amount	At 1 year or less	At greater than 1 year
NONCURRENT ASSETS			
Receivables relating to participating interests			
Loans			
Other long-term financial investments	458,923	377,109	81,814
TOTAL of capital assets:	458,923		81,814
CURRENT ASSETS			
Doubtful clients or disputes			
Other client receivables			
Receivables representing shares loaned or delivered as collateral	104,870	104,870	
Personnel and associated accounts			
Social security and other social welfare entities	167	167	
Statement – Income taxes	1 502 600	4 700 500	
Statement – value-added tax	1,523,688 457,513	1,523,688	
Statement - Other taxes, duties, and similar payments	45,369	457,513 45,369	
Statement- Miscellaneous	,	75,507	
Group and partners	80,847	80,847	
Sundry debtors	21,378	21,378	
TOTAL current assets:	2,233,832	2,233,832	
Prepayments	216,779	216,779	

TOTAL ASSETS	2,909,534	2,827,720	81,814
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STATEMENT OF DEBT	Amount gross	At 1 year or less	At greater than 1 year and less than 5 years	At greater than 5 years
Convertible bonds				
Other bonds				
With lending institutions:				
- at 1 year maximum from origin				
- at more than 1 year from origin				
Miscellaneous other loans and advances				
Trade payables and related accounts	2,096,901	2,096,901		
Personnel and associated accounts	453,484	453,484		
Social security and other bodies	466,594	466,594		
Income taxes	17.624	17.624		
Value-added tax	17,634	17,634		
Guaranteed bonds	50,719	50.710		
Taxes (other than corporate taxes)	30,719	50,719		
Liabilities on fixed assets and related accounts				
Group and partners	500,593	500,593		
Other payables Debts representing borrowed securities	500,595	500,595		
Deferred income	368,436	368,436		
Deterred medine	300,130	200,120		

TOTAL ASSET	3,954,360	3,954,360		
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#### Research tax credit

The Company has benefited, since its creation in 2004, from the research tax credit (Crédit d'Impôt Recherche - CIR) as defined in Article 244, quater B I of the French General Tax Code.

It is recognized in the results, less the income tax, with a tax receivable contra-entry.

The amount of the company's CIR for the last three financial years totaled:

2014: €1,523,688
2013: €1,366,356
2012: €812,570

# Tax credit for competition and jobs ("credit d'impot pour la competitivite et l'emploi" - CICE)

The company benefits from a tax credit for competition and jobs (CICE) created under article 66, law no. 2012-1510 of December 29, 2012, the amending finance law for 2012.

The amount for 2014 totaled €42,835.62 and was recorded minus salary expenses, with a tax receivable contraentry in the statement of financial position.

# **Sundry debtors**

Sundry debtors concern credit notes with suppliers having provided services within the context of the ADR program, and for which the Company will be reimbursed a portion of expenses.

# Liquidity

The Company's cash position totaled €36,655,100.94, of which €32,000,000 was placed in term deposits, stipulated:

- in the amount of €1,000,000, with Société Générale, 1-month maturity tacitly renewable,
- in the amount of €26,000,000, with Banque Populaire, 18-month maturity, mobilized on demand.
- in the amount of €5,000,000, with Banque CIC, 18-month maturity, mobilized on demand.

The cash position was therefore divided based on the following categories:

Total	€36,655,100.94
Money market funds	€3,000,583.15
Accrued interest	€112,962.38
Term deposits	€32,000,000.00
Current accounts	€1,541,555.41

# **Prepaid Expenses and Deferred Income**

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

HEADINGS	Charges	Income
Operating charges or income	216,779	368,436
Financial charges or income		
Non-recurring charges or income		

TOTAL 216,779 36	8,436
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The prepaid expenses primarily concern maintenance contracts, as well as lease agreements on movable and immovable property.

The deferred income is the portion of the grant from the TEDAC project for which associated costs have not yet been sustained.

# **Income Receivable**

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

AMOUNT OF INCOME TO RECEIVE INCLUDED IN THE FOLLOWING BALANCE SHEET ENTRIES	Amount
- Investments	
Receivables relating to participating interests	
Other long-term financial investments	
Receivables	
Trade receivables	2,465
Staff	
Social security and similar	
Statement	45,369
Miscellaneous, income to receive	
Other receivables	12,355
Marketable securities	
Cash at bank and in hand	

TOTAL 60,188

# Composition of the share capital

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

SHARE CLASSES	Number	Nominal value
1 - Shares or stock comprising the share capital at the start of the financial year	5558952	0.1
2 - Shares or stock issued during the financial year	1323809	0.1
3 - Shares or stock redeemed during the financial year		
4 - Shares or stock constituting the share capital at financial year end	6882761	0.1

The Company proceeded with the admission, on the EURONEXT market, of 1,224,489 new shares in October 2014.

The exercise of BSA<sub>2012</sub> and BSPCE<sub>2012</sub> created 99,320 new shares during the financial year.

# Table of variations in shareholders' equity (in Euros, French regulations)

	Number of shares	Share capital	Issue premium	Reserves & carried forward	FY profit(loss)	Regulatory provisions	Total Shareholders' Equity
Balance as of Dec. 31, 2013	5,558,952	€555,895.20	€42,335,338.33	(€22,295,938.09)	(€6,478,994.29)	- €	€14,116,301.15
Allocation of earnings 2013				(€6,478,994.29)	€6,478,994.29 €		
Capitalization of convertible bond							
Bond conversions							
Admission of new shares	1,224,489	€122,448.90	€29,877,531.60				
Charging of costs associated with			(€1,558,417.27)				
Share Warrants & Founder Warrants Conversion	99,320	€9,932.00	€721,261.84				
Financial year profit (loss) 2014					(€7,283.237.28)		
Balance as of Dec. 31, 2014	6 882 761	€688,276.10	€71,375,714.50	(28,774,932.38)	(€7,283.237.28)	- €	€36,005,820.94

## **Conditional advances**

The conditional advances, totaling €580,107, were divided as follows at 12/31/2014:

BPI FRANCE INNOVATION (advance 1): €485,000
BPI FRANCE FEDER (advance 2): €32,500
BPI FRANCE ISI (advance 3): €62,607

1. Assistance granted by <u>BPI FRANCE INNOVATION (€735,000)</u>: program for the "development of a new treatment against pancreatic cancer through the administration of allogenic red blood cells incorporating L-asparaginase".

This assistance was distributed in 3 phases:

- €294,000 upon signature of the agreement (paid in 2008)
- €294,000 upon calls for funds (paid in 2010)
- balance upon completion of work with end of program identified by BPI FRANCE.

The repayment of this conditional advance will be made according to a fixed payment schedule that will end at the latest on 06/30/2016. To this end, the company repaid its first maturity of €100,000 in 2013, and its second of €150,000 in 2014.

2. Assistance granted by <u>BPI FRANCE FEDER (€135,000)</u>: program for the "preclinical validation of the encapsulation of interfering RNA for therapeutic use in red blood cells, notably to limit inflammation of the cirrhotic liver and/or prevent the development of hepatocellular carcinomas".

This assistance was distributed in 4 phases:

- €40,500 upon signature of the agreement (paid in 2009)
- €40,500 upon calls for funds (paid in 2010)
- €27,000 upon calls for funds
- balance upon completion of work with end of program identified by BPI FRANCE.

The repayment of this conditional advance will be made according to a fixed payment schedule that will end at the latest on 06/30/2016.

As the program was interrupted early, only the first two calls for funds were paid, for a total of  $\in 81,000$ . To date, the company has repaid  $\in 48,500$ .

3. Assistance granted by <u>BPI FRANCE (€4,895,052):</u> TEDAC project.

This assistance is distributed upon completion of the following key milestones:

- the remainder upon calls for funds in function of the key milestones.

The company undertakes to repay BPI FRANCE a sum of  $\in$ 5,281,000 upon achieving a cumulative amount of before-tax sales revenue equal to or greater than 10 million Euros and, where applicable, an annuity equal to 50% of the income generated by the sale of intellectual property rights resulting from the project. In a second phase, where the cumulative sales revenue reaches  $\in$ 60,000,000, the company undertakes to pay BPI FRANCE a sum of 2.5% of the sales revenue generated by development of the products resulting from the project, within the limit of a total repayment of  $\in$ 15M over 15 years.

# Provisions recognized on the Balance sheet

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

HEADINGS	Start of FY amount	Increased allocations	Decreases reversals	Amount year end
Provision for restoring deposits Provisions for investment Provisions for price increases Depreciation benefiting from tax law Including exceptional increases of 30% Tax provisions for establishment abroad, established prior to 01/01/1992 Tax provisions for establishment abroad, established subsequent to 01/01/1992 Provisions for facilities loans Other regulated provisions				
REGULATED PROVISIONS				
Provisions for disputes. Provisions for guarantees given to clients Provisions for losses on futures markets Provisions for fines and penalties Provisions for exchange losses Provisions for pensions and similar obligations Provisions for taxes Provisions for building renovation Provisions for large-scale maintenance and major overhauls Provisions for social security and tax expenses on holidays owing				
Other provisions for liabilities and charges				
PROV. FOR LIABILITIES AND CHARGES				
Prov. for intangible assets Prov. for tangible assets Provisions for blocked securities counted by the equity method Provision for blocked participating interests Provision for other non-current financial assets Provisions for inventory and works in progress Provisions for client accounts Other provisions for depreciation	100 607		100 607	
PROVISIONS FOR DEPRECIATION	100 607		100 607	
TOTAL ASSETS	100 607		100 607	

At the end of 2013, the company recorded a provision for impairment associated with company securities purchased under mandate, within the scope of liquidity. The company's share price having significantly increased during the period, the establishment of this provision was no longer considered necessary and formed the object of a reversal.

#### 6. ADDITIONAL INFORMATION RELATIVE TO THE RESULTS

## **SALES REVENUE**

By way of reminder, in 2012, the Company stipulated an exclusive distribution agreement for its product in the indication of acute lymphoblastic leukemia with Orphan Europe.

The Company likewise entered into a contract with the Recordati Group to financially support clinical trial of GRASPA AML 2012 01 in AML, in the amount of €5 M.

To this end, the Company continues to re-invoice, with no margin and on a monthly basis, the costs relative to the trial, which totaled €791,853 in 2014.

Amounts re-invoiced are recorded in the books under sundry income.

## **OPERATING GRANT**

The Company recorded the portion of the TEDAC grant associated with the program's annual expenses, totaling €271,230.72.

## REMUNERATION OF EXECUTIVE OFFICERS

The total compensation paid to executive corporate officers was €715,943.83.

The securities held giving the right to a future portion of the capital are presented in the detailed table "Subscription warrants."

# **Details of Non-recurring Income and Non-recurring Expenses**

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

NON-RECURRING INCOME	Amount	Reported in account
for insurance adjustment	(2,749)	77200000
gifts received	2,950	77180000

NON-RECURRING CHARGES	Amount	Reported in account
adjustment differences	(4)	67180000
loss of security	770	67500000
for insurance adjustment	6,165	67200000
adjustment of contributions	9,420	67200000
adjustment differences	24	67200000

TOTAL	17.055	
TOTAL	16,375	
10112	20,0:0	

# **DEFERRED TAX EFFECTS**

	Amount
FY profit(loss)	(€7,283,237)
Income tax	(€1,523,688)
Before-tax results	(€8,806,925)
Profit (loss) excluding exceptional that tax assessments pre-tax	(€8,806,925)
Taxable income (loss) for the financial year	(€8,831,602)
Deficits remaining to be carried forward the previous financial year	€34,298,815
Total deficits remaining to be carried forward	€43,130,417

# **INCOME TAX**

# BREAKDOWN OF TAX BETWEEN CURRENT RESULTS AND EXCEPTIONAL RESULTS

	Amount	Current profit (loss)	Exceptio nal results
FY profit(loss)	(€7,283,237)	(€7,267,063)	(€16,174)
Income tax	(€1,523,688)	( €1,523,688)	
Before-tax results	(€8,806,925)	(€8,790,751)	(€16,174)

The income tax amount corresponds to the research tax credit. Its basis corresponds to research costs excluded from the exceptional results.

## 7. OTHER INFORMATION

# **CLINICAL TRIALS**

The costs associated with clinical trials are recognized as expenses as and when they are sustained.

Each patient included results in an obligation for ERYTECH to sustain certain costs whether or not the study continues, and to do so in addition to the expenses already incurred. When a patient is recruited, the company establishes a provision to cover all the costs sustained to continue the clinical trial over a one-year horizon.

The remainder of the costs sustained leading up to the end of the clinical trial (patients not yet recruited) are monitored off-balance sheet.

12/31/2014 in	K Euros	ERYTECH contractual commitment		
Clinical trial name	Accrued payables, tax incl.	Definite accrued Uncertain (Off- balance sheet, net of taxes)		Comment
2007/04	-	-	-	Trial ended
2008/02	-	-	-	Trial ended
2009/06	200	-	-	Trial ended
2012/09	41	-	1,014	Recruitment begun
2012/10	4	-	-	Recruitment begun
2013/03	256	-	4,526	Recruitment begun
	Accr	rued payables	off-balance sheet	
		501	5,539	

12/31/2013 in	K Euros	ERYTECH contractual commitment		
Clinical trial name	Accrued payables, tax incl.	Definite accrued payables	Uncertain (Off- balance sheet, net of taxes)	Comment
2007/04	-	-	-	Trial ended
2008/02	-	-	-	Trial ended
2009/06	347	-	<u>-</u>	Recruitment ended
2012/09	-	-	-	Recruitment not begun
2012/10	-	-	-	Recruitment not begun
2013/03	-	-	<del>-</del>	Recruitment not begun
		Acc	off-balance sheet	
		rue	-	

#### RETIREMENT INDEMNITY

In consideration of the company data, for actuarial assumptions adopted, i.e., primarily a gross discount rate of 1.49%, the total commitment relating to retirement indemnities measured at 12/31/2014 totals 88,594 Euros.

No provision for liabilities was recognized in relation to this financial year.

# **COMMITMENTS TO DIRECTORS**

By way of reminder, on May 24, 2013, the Board of Directors authorized severance indemnities to the benefit of:

- Gil Beyen. This commitment stipulates that, in the event of Mr. Beyen's departure from the company, i.e., in the event of:
  - expiry of his mandate (save where renewal is rejected by Mr. BEYEN) or
  - revocation (except due to serious misconduct or gross negligence, as understood pursuant to case law resulting from the corporate chambers of the Court of Cassation),

Mr. BEYEN may claim an indemnity equal to:

- twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office, or
- the fixed annual remuneration established by the Board of Directors, in the event of revocation decided within twelve months following the appointment of Mr. Beyen.
- Pierre-Olivier Goineau. This commitment stipulates that, in the event of Mr. Goineau's departure from the company, i.e., in the event of:
  - expiry of his mandate (save where renewal is rejected by Mr. GOINEAU) or
  - revocation (except due to serious misconduct or gross negligence, as understood pursuant to case law resulting from the corporate chambers of the Court of Cassation),

Mr. Goineau may claim an indemnity equal to twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office.

- Yann Godfrin. This commitment stipulates that, in the event of Mr. Godfrin's departure from the company, i.e., in the event of:
  - expiry of his mandate (save where renewal is rejected by Mr. GODFRIN) or
  - revocation (except due to serious misconduct or gross negligence, as understood pursuant to case law resulting from the corporate chambers of the Court of Cassation),

Mr. Godfrin may claim an indemnity equal to twelve times his average monthly remuneration (bonuses included) effectively received during the twelve months prior to the revocation decision or expiry of his term of office.

Within the context of his resignation, we specify that Pierre-Olivier GOINEAU did not receive any indemnities.

## **AUDITORS' FEES**

For the 2014 financial year, the external auditor fees paid on the financial year totaled:

- within the scope of its legal term of office: €95,000, excluding out-of-pocket expenses,
- in relation to the capital increase: €12,000

#### **SUBSCRIPTION WARRANTS**

Share options have been allocated to the directors, to certain employees, as well as to members of the Board of Directors in the form of share subscription warrants ("BSA") or founder subscription warrants ("BSPCE").

# "2012 Plan"

Types of securities	Founder subscription warrants BSPCE2012	Share subscription warrants BSA2012
Number of warrants authorized for issue	33,788	30,034
Number of warrants that the shares authorized to issue, for all types of shares	45,0	050
Total number of warrants issued	33,788	11,262
Total number of warrants Allocated	33,788	5,025
Number of warrants exercised	6,807	5,025
Date of General Meeting	May 21	, 2012
Exercise price per new share subscribed	€ 7,;	362
Final date for exercising warrants	May 20	), 2020
Parity General conditions of exercise	1 warrant fo	or 10 shares
	Warrant holders can only exercise their subsetion of the Company shares for trading on a refrance or the European Union, or a foreign on one single occasion, or on multiple occasions, within a limit of twice warrant holders shall only be able to exercise subscribed or Allocated but not yet subscribe operations occurs:  (i) acceptance, by shareholders representing (66.67%) of the shares constituting the Compoffer pertaining to control of the Company (of Commerce).  (ii) the formation of a merger agreement processed of the shares constituting the Company.  The securities to which the warrants give right to ten (10) capital.  The new shares resulting from the exercise of (BSPCEs) shall form the object of periodic the regulated market NYSE Euronext.	efinitive operation involving the initial egulated or unregulated stock market, in securities exchange;  e a year and at least 100 warrants.  se the entirety of their warrants, already led, in the event that one of the following  g at least sixty-six point six seven percent pany's capital, of a firm, definitive buyback as pursuant to Article L. 233-3 of the Code providing for absorption of the  ghts are common shares.  I shares in the Company's share
Maximum number of new shares that can be		100
issued	332	180

Within the scope of the  $BSA_{2012}$  and  $BSPCE_{2012}$  plans, the Board of Directors' meeting of July 17, 2014 defined the additional list of beneficiaries, as well as the number of warrants to which each employee may subscribe within the scope of the  $BSA_{2012}$  and  $BSPCE_{2012}$ , in relation to the period of June 1<sup>st</sup>, 2013 to May 31, 2014. As such, 1,000 additional  $BSA_{2012}$  and 13,176 additional  $BSPCE_{2012}$  were allocated to Erytech employees.

At the end of 2014, the subscription warrants for the 2012 plan were broken down as follows:

BSA / BSPCE (Share warrants/founder warrants) reference	GAB reference	Parity	Period of exercise	Number of warrants issued	Number of warrants allocated	financial year	Number of warrants remaining to be exercised	Number of warrants remaining to be allocated
BSPCE 2012	21/05/2012	1 warrant = 10	20/05/2020	33,788	33,788	6,807	26,981	-
BSA 2012	21/05/2012	1 warrant = 10	20/05/2020	11,262	5,025	5,025	-	6,237
			Total	45,050	38,813	11,832	26,981	6,237

## "2014 Plan"

On January 22, 2014, the Board of Directors used the delegation granted by the combined general shareholders' meeting of April 2, 2013, in its twenty-fifth resolution, to decide on a plan for the free allocation of 22,500 founder share subscription warrants (hereinafter entitled BSPCE<sub>2014</sub>) to the benefit of Erytech directors (12,000 warrants) and to a category of "employees with management status" not yet identified by name (10,500 warrants).

The plan's characteristics are as follows:

Types of securities	Founder subscription warrants (BSPCE)2014			
Number of warrants issued	22,500			
Number of warrants awarded	12,000			
Number of warrants exercised	0			
Board of Directors Date	Jan. 22, 2014			
Exercise price per new share subscribed	€12,250			
Final date for exercising warrants	Jan. 22, 2024			
Parity	1 warrant for 10 shares			
General conditions of exercise	In the event of the beneficiary's death, it is stipulated that, pursuant to the provisions of article 163 bis G of the general tax code, the decedent's heirs may exercise the warrants within six months starting from the death.  The founder subscription warrants (BSPCE)2014 can be exercised: - on one single occasion, or - except in the event of an M&A operation, at most four (4) times per year, and for the exercise of a minimum of fifty (50) founder subscription warrants (BSPCE)2014.  In the event of a so-called M&A operation, holders of BSPCE20124 shall have five (5) business days starting from notice by the Company of the occurrence of such an event to exercise all of their BSPCE20124. However, the exercise of the BSPCE2014 may be canceled in the event of the ultimate non-performance of the takeover or the merger operation, for any reason whatsoever.			
Maximum number of new shares that can be issued	120,000			

In the event of a beneficiary's departure from the Company for any reason whatsoever, this beneficiary shall retain the BSPCE<sub>2014</sub> to which he subscribed prior to his departure. However, in the event of a beneficiary's departure from the Company, for any reason whatsoever, prior to subscription of the BSPCE<sub>2014</sub> to which the beneficiary has a right, the BSPCE<sub>2014</sub> shall be considered invalid vis-a-vis this beneficiary. Within this hypothesis, the BSPCE<sub>2014</sub> not subscribed may be re-allocated to other beneficiaries within the same category and/or replacing the person who left the company.

In any case, the BSPCE<sub>2014</sub> not exercised at January 22, 2024 shall become duly and fully expired.

Moreover, the board of directors' meeting of December 4, 2014 transformed 3,000 BSPCE<sub>2014</sub> into 3,000 BSA<sub>2014</sub> for a Medical Director at the subsidiary ERYECH PHARMA INC., in accordance with Annex IV-BSA<sub>2014</sub> Regulations, as recorded in the minutes.

#### INDIVIDUAL RIGHT TO TRAINING

Within the scope of the individual right to training established by Law 2004-391 of May 4, 2004 relative to life-long professional training, at 12/31/2014, the volume of cumulative training hours relative to rights acquired and not exercised was 2,431.58 hours.

It should be noted that, in accordance with:

- Law no. 2014-288 of March 5, 2014 relative to professional development, jobs, and social democracy,
- Decree no. 2014-1120 of October 2, 2014 relative to methods of funding and mobilizing the CPF (personnel training account),

the DIF (individual right to training) system has been replaced by that of the personnel training account (CPF) as of January 1st, 2015. The transferable DIF will likewise disappear as of January 1st, 2015.

# Leasing-purchase agreements

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

HEADINGS	Land	Buildings	Systems equipment infrastructure	Other	Total
Original value				973,877	973,877
Amortization: - totals from prior financial years - allocations from the financial year				654,154 98,593	654,154 98,593
TOTAL				221,129	221,130
ROYALTIES PAID: - totals from prior financial years - allocations from the financial year				753,675 89,587	753,675 89,587
TOTAL				843,262	843,262
ROYALTIES REMAINING TO  PAV.  - up to one year  - from one year up to five years  - over five years				80,702 149,481	80,702 149,481
TOTAL				230,183	230,183
RESIDUAL VALUE  - up to one year  - from one year up to five years  - over five years				143,279 3,009	143,279 3,009
TOTAL				146,288	146,288
Amount reported for the financial year					
Note: Lease concessions					89,587

This table includes the leases financing equipment for R&D and Production. The most distant maturity is December 2018.

2014 – Reference Document \_\_\_\_\_\_ ERYTECH

# **Average Staff**

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

STAFF	Staff salaried	Personnel made available to the company
Management	21	
Chargehands and technicians		
Employees	17	
Laborers		

TOTAL	38	
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During the financial year, the company hired 12 employees and had 6 employees leave.

# **Financial commitments**

ERYTECH PHARMA

Period from 01/01/14 to 12/31/14

COMMITMENTS MADE	Amount
Discounted notes not yet matured Deposits and guarantees	
Pension, retirement, and compensation commitments  Other commitments made:	88,595

TOTAL	88,595
-------	--------

COMMITMENTS RECEIVED	Amount
Deposits and guarantees and securities	
Other commitments received:	3,724,182

TOTAL	3,724,182
-------	-----------

The Recordati commitment on the GRASPA-AML study contractually totals €5,000,000 and was valued at €3,724,182.23 at the end of 2014, the difference corresponding to 2013 and 2014 re-invoicing.

#### **MARKET RISK**

The Company uses the Euro as a reference currency for its financial information and communication activities. However, a significant portion, in the amount of 10% of its operating expenses, is denominated in US dollars (agency office in Philadelphia, collaborations relating to the production of clinical batches with the American Red Cross, business development consultants, consultants for the development of clinical trials in the United States, and various collaborations around tests and clinical projects in the United States).

To date, the company has not opted to use active hedging techniques, and has not made recourse to derivative instruments to this end. Unfavorable exchange rate fluctuations between the euro and the dollar that are difficult to predict could affect the financial position of the Company.

This dependency will increase, as the company will perform clinical trials in the USA and, in the longer term, sell on this market. The Company will opt for exchange rate hedging techniques.

Expenses in US Dollars (USD) totaled \$949,232 during the 2014 financial year. The counter-values recorded in the accounts totaled  $\[ \in \]$  714,807 in relation to the receipt of invoices and price fluctuations. This represents an average annual rate of \$1.328 per  $\[ \in \]$  (\$1.324/ $\[ \in \]$  on average in 2013).

However, the EUR/USD rate fell considerably at the period end, reaching \$1.2141 per €1 at December 31, 2014.

The Company purchased 1 million dollars at a rate of \$1.2197 per €1 during December 2014.

The exchange rate differences are not significant for the periods presented.

# 20.3 Statutory auditors' report on the financial statements prepared in accordance with IFRS standards for the year ended December 31, 2014

(The corporate financial statements prepared in accordance with IFRS standards for the 2012 financial year are addressed in the external auditor's report under Section 20 of the Reference Document registered on April 17, 2013 by the AMF under visa no. 13-166.)

(The corporate financial statements prepared in accordance with IFRS standards for the 2013 financial year are addressed in the external auditor's report under Section 20 of the Reference Document registered on June 4, 2014 by the AMF under visa no. R14-038.)

# **Erytech Pharma SA**

Headquarters: 60 avenue Rockefeller – Bâtiment Adénine – 69008 Lyon

Share capital: € 688,276

## Statutory auditors' report on the consolidated financial statements

Financial year ended December 31, 2014

Dear shareholders,

In fulfillment of the assignment that was entrusted to us by your general meeting, we hereby present you our report pertaining to the financial year ending December 31, 2014 concerning:

- the audit of the consolidated financial statements for Erytech Pharma S.A., as attached to this report;
- the basis for our appraisals;
- the specific verifications required by law.

The financial statements were issued by the Board of Directors. Our task, on the basis of our audit, is to express an opinion on these financial statements.

#### OPINION ON THE CONSOLIDATED FINANCIAL STATEMENTS

We conducted our audit in accordance with professional standards applicable in France; these standards require that certain diligence reviews be performed so as to obtain a reasonable assurance that the consolidated financial statements do not contain significant errors. An audit consists of verifying, by sampling or other selection methods, elements that will support the amounts and statements found in the consolidated financial statements. It also consists of evaluating the accounting principles followed, any significant estimates used, and the presentation of the financial statements as a whole. We believe that the information that we collected is sufficient and appropriate on which to base our opinion.

We certify that the consolidated financial statements are, with regard to IFRS standards as adopted by the European Union, complete and truthful and provide a faithful reflection of the assets, the financial position, and the results of the group, composed of the persons and entities included in the consolidation.

### **BASIS FOR OUR ASSESSMENTS**

In application of the provisions of Article L.823-9 of the Code of Commerce pertaining to the basis for our appraisals, we direct your attention to the following elements.

#### **INCOME FROM REGULAR OPERATIONS**

Note 5.15 "Income from regular operations" in the annex to the consolidated financial statements outlines the accounting rules and methods relative to the recognition of subsidy-related revenue and income.

As part of our assessment of the accounting rules and principles that your group followed, we verified the appropriate nature of the above-referenced accounting methods and the information provided in the annex to the consolidated financial statements and we assured ourselves of their correct application.

## **CLINICAL TRIALS**

Note 9 "Off-balance sheet commitments" in the annex to the consolidated financial statements outlines the accounting rules and methods relative to the recording of clinical trial figures.

As part of our assessment of the accounting rules and principles that your group followed, we verified the appropriate nature of the above-referenced accounting methods and the information provided in the annex to the financial statements and we assured ourselves of their correct application.

The assessments thus performed took place within the context of our audit of the consolidated financial statements, considered as a whole, and thus contributed to the establishment of our opinion as expressed in the first part of this report.

# SPECIFIC VERIFICATIONS

In accordance with the applicable standards for professional conduct in France, we also conducted those specific verifications required by law on the information provided in the group's management report and on the information relative to the group as provided in the annual report.

We have no observations to formulate regarding their accuracy and consistency with the consolidated financial statements.

The auditors

Lyon, March 30, 2015 Lyon, March 30, 2015

KPMG Audit Rhône Alpes Auvergne RSM CCI Conseils

Sara Righenzi de Villers Gaël Dhalluin

Auditor Deputy auditor

# 20.4 Statutory auditors' report on the corporate financial statements for the year ended December 31, 2014

(The corporate financial statements prepared for the 2012 financial year were discussed in a statutory auditors' report on the annual financial statements in Section 0 of the Reference Document registered with the AMF on April 17, 2013 under No. 13-166.

The corporate financial statements prepared for the 2013 financial year were discussed in a statutory auditors' report on the annual financial statements in Section 0 of the Reference Document registered with the AMF on June 4, 2014 under No. R.14-038.)

## **Erytech Pharma SA**

Headquarters: 60 avenue Rockefeller – Bâtiment Adénine – 69008 Lyon

Share capital: € 688,276

# Statutory auditors' report on the annual financial statements

Financial year ended December 31, 2014

Dear shareholders.

In fulfillment of the mission that was entrusted to us by your general meeting, we hereby present you our report pertaining to the financial year ending December 31, 2014 concerning:

- the audit of the annual financial statements for Erytech Pharma S.A., as attached to this report;
- the basis for our appraisals;
- the inspections and specific statements provided by law.

The financial statements were issued by the Board of Directors. Our task, on the basis of our audit, is to express an opinion about these financial statements.

## OPINION ON THE ANNUAL FINANCIAL STATEMENTS

We conducted our audit following the professional standards applicable in France; the standards require that certain verifications be made so as to obtain a reasonable assurance that the restated financial statements do not contain significant errors. An audit consists in verifying, whether through spot-checks or other selection methods, elements that will support the amounts and statements found in the financial statements. It also consists in evaluating the accounting principles followed, any significant estimates used, and the presentation of the financial statements as a whole. We believe that the information that we collected is sufficient and appropriate on which to base our opinion.

We certify that the annual financial statements are complete and truthful and a faithful reflection of the result of operations during the past financial year, as well as the Company's financial condition and that of its assets as of the end of the financial year.

## **BASIS FOR OUR ASSESSMENTS**

In application of the provisions of Article L.823-9 of the Code of Commerce pertaining to the basis for our appraisals, we direct your attention to the following elements.

The notes "Recognition of proceeds and subsidies" and "Clinical trials" present the accounting methods and rules pertaining to the treatment on the profit and loss statement of any subsidies and the cost of clinical trials.

As part of our assessment of the accounting rules and principles that your company followed, we verified the appropriate nature of the above-referenced accounting methods and the statements provided in the appendix to the financial statements and we assured ourselves of their correct application.

The assessments thereby made are part of our approach to auditing annual financial statements, taken as a whole, and thus contributed to the formation of our opinion expressed in the first part of this report.

#### SPECIFIC VERIFICATIONS AND DISCLOSURES

In accordance with the applicable standards for professional conduct in France, we also conducted those specific verifications provided by law.

We have no comments to make about the accuracy and consistency of the information provided in the Board of Director's management report and in the documents sent to the shareholders about the financial circumstances and the annual financial statements.

Concerning the information provided in application of the provisions of Article L.225-102-1 of the Code of Commerce concerning remuneration and benefits paid to corporate officers as well as commitments made it to them, we have verified that they are consistent with the financial statements or with the data which were used to produce these financial statements and, as applicable, with the information collected by your company from companies controlling your company or controlled by it. On the basis of such work, we certify the accuracy and veracity of this information.

As required by law, we have assured ourselves that the various information pertaining to the identity of the shareholders has been provided to you in the annual report.

Lyon, March 30, 2015 Lyon, March 30, 2015

KPMG Audit Rhône Alpes Auvergne RSM CCI Conseils

Sara Righenzi de Villers Gaël Dhalluin

Auditor Deputy auditor

# 20.5 Date of last financial information

December 31, 2014

# **20.6 Table of results for the last five financial years** (Erytech Pharma SA, annual financial statements prepared in accordance with French accounting standards)

				1	
	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014
CAPITAL AT END OF YEAR					
Number of common shares outstanding	315,355	315,355	315,355	5,558,952***	6,882,761
Number of existing priority dividend shares Maximum number of future shares to be created	315,355	315,355	315,355	5,558,952***	6,882,761
- by conversion of bonds		67,916*	135,833*	-	-
- by subscription right exercise	147,027	172,876**	244 855	22,736	452,180
OPERATIONS AND RESULTS					
Revenue excluding taxes Income before tax, employee sharing and depreciation of amortization and provisions	(5,373,958)	(6,605,757)	(2,149,309)	483,964 (7,592,464)	
Income taxes Employee sharing for financial year	(721,327)	(798,967)	(812,570)	(1,366,656)	(1,523,688)
Income before tax, employee sharing and depreciation of amortization and provisions Retained earnings	(4,822,357)	(5,983,691)	(2,011,394)	(6,478,994)	(7,283,237)
EARNINGS PER SHARE					
Results after taxes, employee profit-sharing, but before					
allocations to amortizations and provisions	(14.75)	(18.41)	(4.23)	(1.12)	(1.05)
Income before tax, employee sharing and depreciation					
of amortization and provisions	(15.29)	(18.97)	(6.38)	(1.17)	(1.06)
Dividend per share					
Staff					
Average number of employees during the year	41	41	38	36	38
Amount of payroll for the financial year	1,715,167	1,847,841	1,718,300	2,504,423	2,402,291
Amount of sums paid in relation to company benefits during the financial year	463,122	833,826	827,736	1,164,033	1,168,792

<sup>\*</sup>the assumption of a raising of funds of 18 million euros with a valuation of 73.62 euros per share

# 20.7 Dividend distribution policy

# 20.7.1 Dividends paid during the last three financial years

None.

# 20.7.2 Dividend distribution policy

No plan exists to initiate a dividend policy in the short term, given the Company's stage of development.

# 20.8 Legal and arbitration proceedings

At the registration date of this Reference Document, no government, legal, or arbitration proceedings existed, including any proceedings of which the Company has knowledge, that are suspended or with which it is threatened, such as will have or had during the last 12 months a significant effect on the financial position, activity, or results of the Company and/or of its subsidiary.

<sup>\*\*</sup>not including share subscription warrant lapsed at 12/31

<sup>\*\*\*</sup> division of the nominal share value by 10 in 2013

# 20.9 Significant changes in the financial or commercial situation

To the knowledge of the Company, no significant changes have taken place in the Company's financial or commercial situation since December 31, 2014.

# **20.10Report on the economic and financial results** (annual financial statements prepared in accordance with French accounting standards)

The before-tax sales revenue totaled 791,852 Euros following the re-invoicing, with no margin, of the GRASPA-AML clinical trial to Orphan Europe/Recordati Group, as compared to 483,964 Euros in 2013.

The total operating income was equal to 1,113,132 Euros, as compared to 911,804 Euros in the previous financial year. This increase is associated with the progress of the AML clinical trial re-invoiced to Orphan Europe.

The year's operating expenses totaled 10,297,787 Euros, as compared to 8,767,638 Euros in the previous financial year, therefore a +17.4% variation. This variation in operating expenses is explained in the very significant increase in purchases and external expenses associated with the clinical and pre-clinical developments of ERY-ASP/GRASPA®, as well as personnel expenses.

The operating results totaled a loss of 9,184,655 Euros, as compared to a loss of 7,855,834 Euros in the previous financial year, therefore a variation of +17%.

The average employee numbers remained stable at 38, as compared to 36 in the previous financial year, therefore an insignificant variation.

The financial results totaled 393,903 Euros, as compared to -4,222 Euros in the previous financial year, primarily resulting from reversal of the provision for impairment of securities, totaling 100,607 Euros, as well as the performance of investments in term deposits and the decrease in interest following conversion of the convertible bonds in 2013.

The current results before tax for the year totaled a loss of 8,790,751 Euros, against a loss of 7,860,056 Euros for the previous financial year, therefore a variation of +11.8%.

In consideration of the preceding information,

- of the exceptional results of -16,174 Euros, as compared to 14,406 Euros for the previous financial year,
- of the research tax credit of 1,523,688 Euros.

The financial year's results total a loss of 7,283,237 Euros, as compared to a loss of 6,478,994 Euros in the previous financial year, therefore a variation of 12.24%.

At December 31, 2014, the Company's balance sheet total was 40,540,288 Euros, as compared to 18,245,790 Euros in the previous financial year, i.e., a variation of +22.3%.

# **20.11Report on the economic and financial results** (financial statements consolidated in accordance with IFRS framework)

The ERYTECH PHARMA Group is composed:

- of the company ERYTECH PHARMA SA (headquarters: 60 av Rockefeller, Bioparc Bat Adénine, 69008 LYON, FRANCE)
- of the company ERYTECH PHARMA Inc. (headquarters: 185 Alawife Brook Parkway Ste 410, CAMBRIDGE, MA 02138, USA), 100% held by the company ERYTECH PHARMA SA.

The Group's financial statements include consolidation of the American subsidiary. The financial statements for the ERYTECH PHARMA Group are prepared in conformity with the International Financial Reporting Standards (IFRS) published by the International Accounting Standards Board (IASB), as adopted by the European Union at the date of issue of the financial statements by the board of directors, as applicable at December 31, 2014.

The Group has recorded no sales revenue either in relation to the 2014 financial year or in relation to the 2013 financial year. The other income was primarily generated by the research tax credit, the grants associated with the pre-clinical research programs in partnership with BPI France. The Research Tax Credit totaled 1,523,688 Euros in 2014, as compared to 1,366,656 Euros, i.e., an increase of 11.50%. For 2014, the other income also includes the re-invoicing, to Orphan Europe, of 230,769 Euros in internal costs sustained by the Group within the context of the AML study.

Operating expenses increased by 23%, totaling 10,974,054 Euros in 2014, as compared to 8,915,188 Euros in 2013.

Excluding personnel costs, research and development costs decreased by 24% to 892,651 Euros in 2014, as compared to 1,171,016 Euros in 2013, the sub-contracting expenses having decreased by 273,746 euros. Clinical study expenses increased from 2013 to 2014 by 1,211,723 Euros, i.e., an increase of 74%, in line with the increase in the Group's activities. Intellectual property costs totaled 418,645 Euros in 2014, as compared to 265,371 Euros in 2013, the increase being primarily associated with intellectual property adviser fees. Lastly, general costs increased by 245,776 Euros between 2013 and 2014, primarily associated again with services, sub-contracting, and fees, this increase being 14% greater than the 2013 figure.

Personnel costs increased by 2% between 2013 and 2014, from 3,503,601 Euros in 2013 to 3,574,796 Euros in 2014, excluding the fair value impact of share-based compensation plans (IFRS 2).

The fair value of share-based compensation plans (IFRS 2) increased by 113%, from 580,621 Euros in 2013 for allocation of the  $2^{and}$  tranche of the BSPCE<sub>2012</sub> and BSA<sub>2012</sub> plan, as compared to 1,235,883 Euros for allocation of the  $3^{rd}$ tranche of the BSPCE<sub>2012</sub> and BSA<sub>2012</sub> plan, as well as for allocation of the BSPCE<sub>2014</sub> to Group directors.

The Group's financial results showed a profit of 68,173 Euros in 2014, as compared to a loss of 1,099,589 Euros in 2013, primarily caused by the financial cost of the convertible bonds issued by the Group. Income tax highlights income associated with revaluation of the liability relating to defined benefit plans (IAS 19), presented under Other items of the Group's comprehensive income.

The Group's consolidated statement of financial position shows total assets and liabilities of 40,606,639 Euros in 2014, as compared to 17,948,960 Euros in 2013, i.e., an increase of 22,657,679 Euros.

In October 2014, the Group performed a capital increase, making recourse to the market to obtain 29,172,757 Euros. Disinvestments within the scope of the liquidity agreement led to a variation of 650,675 Euros in shareholders' equity, the net results for the period showing a loss of 8,860,036 Euros, actuarial differences of 38,389 Euros, as well as the impact of the fair value valuation of 1,235,883 Euros for the compensation plans, which changed the Group's shareholders' equity by 22,237,669 Euros.

Financial liabilities decreased by 242,349 Euros between 2013 and 2014, the Group continuing to reduce its debt both in the conditional advances and in the financial debts associated with leases.

The variation in working capital requirements increased, in line with the growth in the Group's activities, totaling 1,874,169 Euros in 2014, as compared to 1,491,607 Euros in 2013.

# 20.12 Allocation of the results

It will be proposed to the General Assembly of Shareholders that it approve the annual financial statements (statement of financial position, statement of comprehensive income, and annex) as presented, and that the loss of 7,283,237 Euros be allocated to the "carry forward" account.

In consideration of this allocation, the Company's shareholders' equity would be 36,005,821 Euros.

# 20.13Luxury expenditures and non-deductible expenses

The financial statements for 2014 include expenses of 18,855 Euros corresponding to expenditures not tax deductible.

Consequently, the tax sustained by reason of these expenditures and expenses totals 6,285 Euros.

# 20.14Information on payment timeframes

The breakdown, at the end of the last two financial years, of the balance of debts to suppliers, by maturity date:

# 2014 financial year:

MATURED	TOTAL
Less than 1 month	345,332
Between 1 and 3 months	187,552
Between 3 and 6 months	107,799
More than 6 months	28,088
TOTAL =	668,771 euros
MATURING	TOTAL
MATURING Less than 1 month	TOTAL 1,224,565
Less than 1 month	1,224,565
Less than 1 month Between 1 and 3 months	1,224,565

I.e., a total of 1,926,602 Euros for the item supplier debts.

# 2013 financial year:

MATURED	TOTAL
Less than 1 month	351,861
Between 1 and 3 months	379,550
Between 3 and 6 months	97,639
More than 6 months	4,114
TOTAL =	833,163 euros
MATURING	TOTAL
Less than 1 month	407,904
Between 1 and 3 months	4,933
Between 1 and 3 months Between 3 and 6 months	4,933
	4,933 - -

I.e., a total of 1,246,000 Euros for the item supplier debts.

# 20.15 Regulated agreements

The agreements reached, where applicable, directly or through a third party, between, on one part, one of the members of the board of directors, the managing director, one of the delegated managing directors, or one of the shareholders holding a portion of the voting rights greater than 10% in the company ERYTECH Pharma and, on the other hand, another company in which the latter directly or indirectly holds more than half the capital are outlined in detail in the special auditors' report on the agreements outlined under Article L. 225-38 of the French Code of Commerce.

The agreements outlined under Article L. 225-38 of the Code of Commerce and stipulated during the financial year elapsed shall be submitted for the approval of the shareholders, it being specified that the auditor has been duly notified of these agreements, which it has described in its special report. (*See also Chapter 19 of this Reference document*).

#### 21 ADDITIONAL INFORMATION

# 21.1 Share capital

# 21.1.1 Amount of subscribed capital

At the date of the present Reference Document, the share capital, fully paid up, totaled 688,276.10 Euros, divided into 6,882,761 common shares with a nominal value of 0.10 Euro each, all in the same category.

# 21.1.2 Shares not representing the capital

None.

# 21.1.3 Acquisition of shareholder equity by the Company

The Company's combined general shareholders' meeting of June 17, 2014, modified as follows the authorization given to the Board of Directors by the combined general shareholders' meeting of April 2, 2013 to implement a buyback program on the Company shares, in conformity with the provisions of Article L. 225-209 of the Code of Commerce and the General Regulations of the Autorité des Marchés Financiers:

<u>Maximum number of shares that can be repurchased</u>: 5% of the number of shares constituting the Company's share capital at the performance date of these buybacks, as calculated in conformity with applicable legislative and regulatory provisions, it being nevertheless specified that the maximum number of shares held after these buybacks cannot exceed 10% of the capital.

# Objectives of the share buyback:

- Awarding shares to employees or corporate officers of the Company and French or foreign companies or groups that might be associated with it in the conditions and following the terms provided by law, particularly in the context of employee participation in the fruits of the company's expansion, employee shareholder plans, or company savings plans, the stock options plan, or by way of the allocation of free shares;
- To retain the shares for the purpose of using them for payment or exchange, namely as part of external growth operations, complying with recognized market practice by the Autorité des Marchés Financiers and within the limits provided by article L.225-209 of the Code of Commerce;
- Assuring liquidity in the market for shares by way of one or more providers of investment services acting independently, in the context of a liquidity contract, pursuant to a professional ethics charter recognized by the Autorité des Marchés Financiers, it being noted that the number of shares used to calculate the aforementioned 10% limit corresponds to the number of shares purchased, after deducting the number of shares resold during the term of this authorization;
- Reducing the Company's share capital in application of the twenty-first resolution of the present general assembly of shareholders, subject to its adoption;
- Delivering shares, when there is an exercise of rights associated with securities giving access to shares by any means, whether immediately or over time;
- Implementing any market practice which might be recognized by law or by the Autorité des Marchés Financiers.

<u>Maximum purchase price</u>: twenty (20) Euros (excluding purchase costs), it being specified that, in the event of a capital operation, notably by incorporation of reserves and allocation of free shares, or division or regrouping of shares, or even modification of the nominal value of shares, this price will be consequently adjusted.

During the financial year ended December 31, 2014, this buyback program was used exclusively within the scope of a liquidity agreement responding to the objective of market making or liquidation of the Company shares, stipulated with the company Bryan Garnier as investment service provider.

Securities purchased167 345Nominal share value€0.10Average share price19.487 Euros

Total amount paid for acquisition of securities 3,261,099.75 euros

Shares sold

Nominal share value

Average share price

Total amount received for the sale of shares

215 780

€0.10

18.129 Euros

3,911,775.10 Euros

Trading costs totaled 7,223.09 Euros for the 2014 financial year.

At December 31, 2014, the Company held 4,500 ERYTECH shares, valued at 125,100 Euros (0.07% of the share capital), reduced to 1,500 shares at March 20, 2015 (0.02% of the share capital).

# 21.1.4 Other securities giving access to the capital

All the securities giving access to the Company's capital and in circulation at April 20, 2015 are described in the table below.

		BSPCE <sub>2012</sub>	BSA <sub>2012</sub>	BSPCE <sub>2014</sub>				
Date of meeting		May 21	, 2012	April 2, 2013				
Number of shares that the to issue	Company is authorized	45,0	050	22,500				
Total number of subscript	tion warrants issued	38,5	312	0				
Number of warrants exerc	cised	12,4	0					
Number of warrants not y	et exercised	26,4	22,500					
Maximum number of share	res remaining to be issued	264,	225,000					
	Y. GODFRIN	75,080		30,000				
Of which the maximum number of shares that can be subscribed by:	P.O. GOINEAU	75,080		75,080		10,000		
	G. BEYEN	78,630		78,630		78,630 60,00		60,000

Number of shares issued	124,000	0
Starting point for exercise of subscription warrants	May 21, 2012	April 1, 2015
Expiry date of subscription warrants	May 20, 2020	Jan. 22, 2024
Warrant subscription price	€0.00	€0.00

# Founder subscription warrants ("BSPCE") and share subscription warrants ("BSA")

Types of securities	Founder subscription warrants BSPCE <sub>2012</sub>	Share subscription warrants BSA <sub>2012</sub>	Founder subscription warrants BSPCE <sub>2014</sub>	
Number of shares that the company is authorized to issue	45,050	2022	22,500	
Maximum number of warrants not yet exercised	26,412		22,500	
Number of warrants awarded	33,787	5,025	0	
Date of General Meeting	May 21, 2012	2	April 2, 2013	
Exercise price per new share subscribed	€7.362		€12.25	
Final date for exercising warrants	May 20, 2020	)	January 22, 2024	
Parity	1	warrant for 10 shares	S	
General conditions of exercise	Warrant holders can only exercivariants upon the occurrence of operation involving the initial shares for trading on a regulated market, in France or the European securities exchange:  (i) on one single occasion (ii) on multiple occasion twice a year and at less than the occurrence of the occurrence occurrence of the occurrence	The founder subscription warrants (BSPCE) <sub>2014</sub> can be exercised:  - on one single occasion, or  - except in the event of an M&A operation, at most four (4) times per year, and for the		
	Upon the occurrence of one operations:	of the following	exercise of a minimum of fifty (50) founder	

	<ul> <li>(i) acceptance, by shareholders representing at least sixty-six point six seven percent (66.67%) of the shares constituting the Company's capital, of a firm, definitive buyback offer pertaining to control of the Company (as pursuant to Article L. 233-3 of the Code of Commerce);</li> <li>(ii) the stipulation of a merger agreement providing for absorption of the Company;</li> <li>Warrant holders can exercise the entirety of their warrants</li> </ul>	subscription warrants (BSPCE) <sub>2014</sub> .  By way of exception, the possibility of early exercise was been established in the event of (i) a change of control as pursuant to article L. 233-3, par. 1 of the Code of Commerce, or (ii) a merger of the Company, and this without conditions on minimum threshold or frequency.
	The securities to which the warrants give rights are common shares.  Each warrant shall give the right to ten (10) shares in the Company's share capital.  The new shares resulting from the exercise of founder subscription warrants (BSPCEs) shall form the object of periodic requests for admission for trading on the regulated market NYSE Euronext.	The securities to which the warrants give rights are common shares.  Each warrant shall give the right to ten (10) shares in the Company's share capital.  The new shares resulting from the exercise of founder subscription warrants (BSPCEs) shall form the object of periodic requests for admission for trading on the regulated market NYSE Euronext.
Number of shares issued as of the date of the prospectus	124,000	0
Maximum number of new shares that can be issued*	264,120	225,000
Maximum dilution of shares and % resulting from the exercise of warrants	489,120 shares, i.e., a maximum dilution of approxima	tely 7.10%**

<sup>\*</sup> Post division of the nominal value of Company shares

At the date of the Reference Document, no "guarantee of value" (*ratchet*) share subscription warrants exist any longer. These 233,855 warrants previously in circulation were canceled by the general shareholders' meeting of April 2, 2013.

<sup>\*\*</sup> Based on the exercise of all diluting instruments (i.e., the BSA and BSPCE) and a share capital of €688,844.10

# 21.1.5 Authorized capital not issued

The general shareholders' meeting of May 21, 2012 decided on a maximum issue of:

 30,034 share subscription warrants (BSA<sub>2012</sub>) with suppression of the preferential subscription right to the benefit of corporate officers of the Company or its subsidiaries and/or to the employees of its subsidiaries and/or of the company Gil Beyen BVBA,

 33,788 founder share subscription warrants (BSPCE<sub>2012</sub>) with suppression of the preferential subscription right to Company employees and/or executive officers,

and delegated the Executive Board, for a duration of 36 months, the necessary powers to allocate these BSAs<sub>2012</sub> and BSPCEs<sub>2012</sub>.

The Board of Directors used this delegation:

- in its meeting of July 18, 2013 and proceeded to assign 459 BSA<sub>2012</sub> and 13,177 BSPCE<sub>2012</sub> to the Company's top managers and corporate officers;
- in its meeting of July 17, 2014 and proceeded to assign 1,000 BSA<sub>2012</sub> and 13,176 BSPCE<sub>2012</sub> to the Company's top managers and corporate officers.

The Company's combined general shareholders' meeting of April 2, 2013, in its twenty-fifth resolution, delegated its powers to the Board of Directors for the purpose of issuing shares and securities giving access, immediately or in future, to common shares existing or to be issued by the Company, with suppression of the preferential subscription right outlined, through offerings as established under no. II, Article L. 411-2 of the Monetary and Financial Code.

The Board of Directors used this delegation:

- in its meeting of January 22, 2014 and proceeded to issue 22,500 BSPCE<sub>2014</sub> to the benefit of the Company's top managers and corporate officers;
- in its meeting of December 4, 2014, to proceed with the transformation of 3,000 of the 22,500 BSPCE<sub>2014</sub> into BSA<sub>2014</sub> to the benefit of the medical director of its subsidiary, ERYTECH Pharma Inc.

At March 20, 2015, 28,738 warrants remained to be allocated, and 26,612 warrants allocated but not exercised, i.e., a total of 55,350 warrants to be exercised.

The general shareholders' meetings of April 2, 2013 and June 17, 2014 delegated to the Company's Board of Directors the power to issue securities in the proportions and for the amounts summarized in the table below.

Date of General Meeting	Nature of authorization	Maximum nominal amount of capital increase or issue of securities representing debt securities resulting from the issue	Cumulative ceiling	Preferential subscription right	Duration	Use	Maximum nominal amount remaining	
04/02/2013	Increase in share capital to the issuance of common stock and/or securities giving access to the share capital immediately or over time while maintaining the preferential subscription right (22nd resolution)	€500,000		yes	26 months 06/02/2015	N/A		
06/17/2014	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with suppression of the preferential subscription right to the benefit of categories of investors (10 <sup>th</sup> resolution)	€500,000		No	18 months 12/17/2015	10/22/2014 in the amount of 122,448.90 Euros	€377,551.10	
06/17/2014	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with suppression of the preferential subscription right to the benefit of categories of investors* (11th resolution)	€500,000	€500,000	No	18 months 12/17/2015	N/A		
04/02/2013	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares in the company, with suppression of the preferential subscription right, by way of a public offering (24th resolution)	€500,000 (Ceiling 13 <sup>th</sup> resolution of the Combined General Meeting of 06/17/2014)		No	26 months 06/02/2015	04/30/2013 in the amount of €148,711.40	€500,000	
04/02/2013	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares in the company, with suppression of the shareholders' preferential subscription right, by way of an offering as established under Article L. 411-2, II of the Monetary and Financial Code (25th resolution)	20% of the share capital (per 12-month period), within a limit of €500,000 (Ceiling 13 <sup>th</sup> resolution of the Combined General Meeting of 06/17/2014)	€500,000	No	26 months 06/02/2015	01/22/2014 in the amount of €22,500	€137,728.82	

Date of General Meeting	Nature of authorization	Maximum nominal amount of capital increase or issue of securities representing debt securities resulting from the issue	Cumulative ceiling	Preferential subscription right	Duration	Use	Maximum nominal amount remaining
04/02/2013	Increase in the number of shares to be issued in the event of a capital increase with or without suppression of the preferential subscription right	Limited to 15% of the initial issue in application of the 10th and 11th resolutions of the general meeting of June 17, 2014 (12th resolution Combined General Meeting of 06/17/2014)		Yes/No	18 months 12/17/2015	N/A	€75,000 Euros (15% of 500,000 Euros)
06/17/2014		Limited to 15% of the initial issuance in application of the 22 <sup>nd</sup> , 24 <sup>th</sup> , and 25 <sup>th</sup> resolutions of the general meeting of April 2, 2013(26 <sup>th</sup> resolution of the General Meeting of 04/02/2013)		Yes/No	26 months 06/02/2015	03/30/2013 in the amount of €3.722	€71,278 (15% of €500,000 – €3,722)
04/02/2013	Share capital increase through the incorporation of premiums, reserves, profits or bonuses (29th resolution)	€1 million		N/A	26 months 06/02/2015	N/A	€1 million

<sup>\*</sup> Legal entities or individuals traditionally investing in securities in the healthcare domain

The ceilings outlined in the 22<sup>nd</sup>, 24<sup>th</sup>, and 25<sup>th</sup> resolutions of the General Meeting of April 2, 2013, initially set at 1,000,000 Euros, were decreased to €500,000 by the General Meeting of June 17, 2014, it being specified that this ceiling was set without taking into consideration the capital realized up to June 17, 2014.

Lastly, the General Meeting of June 17, 2014 terminated:

- In its 10<sup>th</sup> resolution, the 23<sup>rd</sup> resolution of the General Meeting of April 2, 2013 (issue of shares and securities with suppression of the preferential subscription right to the benefit of a category of investors),
- In its 12<sup>th</sup> resolution, the (i) authorization granted for 18 months, under the 26<sup>th</sup> resolution of the General Meeting of April 2, 2013, for the issue decided on in application of the 23<sup>rd</sup> resolution and (ii) the authorization granted by the General Meeting of April 2, 2013, in its 28<sup>th</sup> resolution (overall limitation on authorizations).

## Use of these delegations:

In its meetings on April 12, 2013 and April 30, 2013, the Executive Board made use of the delegation granted to it under the twenty-fourth resolution by the Combined General Shareholders' Meeting of April 2, 2013 pertaining to a capital increase through the issue of shares and/or securities giving access to the Company's

<sup>\*\*</sup>on the basis of a share capital of €688,644.10.

capital, with suppression of the preferential subscription right, through a public offering, and thus proceeded to issue 1,487,114 shares at a unit price of 11.60 euros.

On April 30, 2013, the Executive Board made use of the delegation granted to it under the twenty-sixth resolution by the Combined General Shareholders' Meeting of April 2, 2013 pertaining to an increase in the number of securities to be issued in the event of a capital increase with or without suppression of the preferential subscription right, and thus proceeded to issue 37,220 shares at a unit price of 11.60 euros.

On January 22, 2014, the Board of Directors made usage of the delegation granted to it under the twenty-fifth resolution by the combined general shareholders' meeting of April 2, 2013 relative to a capital increase through the issue of shares and/or securities giving access to the Company's capital with suppression of the preferential subscription right, through offerings as established under ii, Article L. 411-2 of the Monetary and Financial Code, and thus proceeded with the issue of 22,500 BSPCE $_{2014}$ , to the benefit of the Company's top directors and managers with employment contracts.

The combined general shareholders' meeting of June 17, 2014, in its 10th resolution, delegated its powers to the Board of Directors for a duration of 18 months, for the purpose of proceeding, on one or more occasions, with the issue of shares, the subscription of which could be undertaken either in cash or through the offsetting of claims, for a maximum nominal amount of 500,000 Euros.

The Board of Directors made usage of this delegation of powers during its meeting of September 22, 2014, deciding in principle on a capital increase in accordance with certain conditions, and gave full powers to the Managing Director, who, holding the right to sub-delegate his powers to a Delegated Managing Director, used this delegation on October 8, 2014, giving Pierre-Olivier GOINEAU, in his capacity as Delegated Managing Director of the Company, the power to perform the above-described capital increase.

The Delegated Managing Director used this delegation on October 22, 2014 and decided to proceed with a capital increase in cash, with suppression of the preferential subscription right, for a nominal amount of 122,448.90 Euros through the issue of 1,224,489 new common shares with a nominal value of 0.10 Euros at a price set at 24.50 Euros per share (i.e., a nominal value of 0.10 Euro and an issue premium of 24.40 Euros), with a resulting capital increase in the amount, issue premium included, of 29,999,980.50 Euros and an issue premium in the amount of 29,877,531.60 Euros. The Delegated Managing Director acknowledged final completion of this increase on October 27, 2014.

The Board of Directors acknowledged the use of these delegations by the Chief Executive Officer and the Delegated Managing Director, and consequently modified the Company's articles of incorporation.

# 21.1.6 Company capital forming the object of an option or a conditional or unconditional agreement stipulating its placement under option

To the Company's knowledge, no call or put options or other commitments exist to the benefit of the Company shareholders or granted by the latter and pertaining to the Company shares.

# 21.1.7 Evolution of the share capital

The table below outlines the evolution of the Company's share capital during the last three financial years, it being specified (i) that no modification of the capital took place between 12/31/2010 and 12/31/2012, and (ii) that the Company proceeded, on October 27, 2014, with a cash-based capital increase with suppression of the preferential subscription right for a nominal amount 122,448.90 Euros through the issue of 1,224,489 new common shares with a nominal value of 0.10 Euros:

_	1	2/31/2013		12/31/2014			20/04/2015		
SHAREHOLDERS	SHARES	% of capital	% of the total voting rights <sup>1</sup>	SHARES	% of capital	% of the total voting rights <sup>1</sup>	SHARES	% of capital	% of the total voting rights <sup>1</sup>
MANAGEMENT	558,350	10.04%	13.16%	599,230	8.71%	13.94%	152,390	2.21%	3.65%
Gil Beyen				34,000	0.49%	0.41%	0	0.00%	0.00%
Pierre-Olivier Goineau	263,490	4.74%	6.20%	263,490	3.83%	6.36%	No longer p	part of man	agement <sup>2</sup>
Yann Godfrin	292,990	5.27%	6.90%	292,990	4.26%	7.07%	142,990	2.08%	3.53%
Jérôme Bailly				3,500	0.05%	0.04%	2,500	0.04%	0.03%
Other management	1870	0.03%	0.06%	5,250	0.08%	0.06%	6,900	0.10%	0.09%
FINANCIAL INVESTORS/PE FUNDS	2,827,284	10.04%	60.51%	1,069,742	15.54%	22.70%	1,069,742	15.53%	23.25%
AMORCAGE RHONE ALPES	109,200	1.96%	2.59%	0	0.00%	0.00%	0	0.00%	0.00%
IDINVEST Partners	1,221,392	21.97%	25.72%	51,530	0.75%	1.24%	51,530	0.75%	1.27%
AURIGA Partners	1,018,212	18.32%	20.94%	1,018,212	14.79%	21.46%	1,018,212	14.78%	21.97%
AXA	478,480	8.61%	11.26%	0	0.00%	0.00%	0	0.00%	0.00%
RECORDATI ORPHAN DRUGS	431,034	7.75%	5.07%	431,034	6.26%	5.20%	431,034	6.26%	5.32%
MEMBERS OF THE BOARD OF DIRECTORS	0	0.00%	0.00%	10,500	0.15%	0.13%	8,500	0.12%	0.10%
OTHER SHAREHOLDERS	67,502	1.21%	1.54%	61,263	0.89%	1.21%	274,083	3.98%	6.50%
SUB-TOTAL REGISTERED SHAREHOLDERS	3,884,170	69.87%	80.29%	2,171,769	31.55%	43.17%	1,935,749	28.10%	38.83%
SUB-TOTAL BEARER SHAREHOLDERS	1,674,782	29.18%	19.71%	4,710,992	68.45%	56.83%	4,952,692	71.90%	61.17%
TOTAL	5,558,952	100.00%	100.00%	6,882,761 <sup>3</sup>	100.00%	100.00%	6,888,441 <sup>3</sup>	100.00%	100.00%

<sup>&</sup>lt;sup>1</sup>See also Section 18.4 of the Reference Document

To its knowledge, the company has no pledges on its capital.

It should be noted that, on May 6, 2013, the Company adopted a double voting right to the benefit of shareholders holding registered shares for more than two years (*see Chapter 21.2.4*); as such, the number of voting rights may increase on May 6, 2015 and result in a dilution.

<sup>&</sup>lt;sup>2</sup>Pierre-Olivier GOINEAU resigned from his positions of Deputy Chairman, Delegated Managing Director, and Director at the end of the Board of Directors' meeting of January 11, 2015. Consequently, the number of shares held by Mr. GOINEAU (*see Chapter 18.1*) have been placed in the "Other shareholders" account.

<sup>&</sup>lt;sup>3</sup>Increase in the number of shares resulting from exercise of the BSPCE2012 and BSA2012. The capital increase will be recognized in a future Board of Directors' meeting, in conformity with Article L. 225-149 of the Code of Commerce.

The table below summarizes the operations occurring on the share capital during the last three financial years:

Date	Operation	Securities issued/exercised	Amount of capital increase (excluding issue premium)	Number of shares/securities issued	Nominal value	Issue premium per share	Number of shares after operation	Price per share (issue premium included)	Capital post operation
04/30/13	Capital increase	Compensation for bond interest	€8,375	83 750	€0.10	€11.50	3,237,300	€11.60	€323,730
04/30/13	Capital increase	New Shares	€144,058.40	1,440,584	€0.10	€11.50	4,677,884	€11.60	€467,788.40
04/30/13	Capital increase	Convertible bonds	86,206.80€	862 068	€0.10	€11.50	5,539,952	€11.60	€553,995.20
18/07/13	Capital increase	Share warrants (BSA) <sub>2012</sub>	€60,073.92	8 160	€0.10	€7,262	5,548,112	€7,362	€554,811.20
03/12/13	Capital increase	Share warrants (BSA) <sub>2012</sub>	€79,804.08	10 840	€0.10	€7,262	5,558,952	€7,362	€555,895.20
05/05/2014	Capital increase	$\begin{array}{c} BSA_{2012} \\ BSPCE_{2012} \end{array}$	€762.00	7 620	€0.10	€7,262	5,566,572	€7,362	€556,657.20
04/12/2014	Capital increase	BSA <sub>2012</sub> BSPCE <sub>2012</sub>	€9,170	91 700	€0.10	€7,262	5,658,272	€7,362	€565,827.20
04/12/2014	Capital increase	Issue of new shares	€122,448.90	1,224,489	€0.10	24,40	6 882 761	€24.50	€688,276.10

# 21.1.8 Evolution of the shares

The evolution of Company shares since the initial listing of its shares on the regulated market NYSE Euronext in Paris can be summarized in the table below:

Since listing							
highest price	Wednesday, October 1, 2014	€34.97	i.e., for	5 584 272	shares	a value of	€195.3 M
price at	Monday, April 20, 2015	€29.80	i.e., for	6 886 941	shares	a value of	€205.2 M
lowest price	Monday, December 16, 2013	€8.58	i.e., for	5 548 112	shares	a value of	€47.6 M
		number of	shares traded:	14 895 302			
2013							
highest price	Tuesday, May 7, 2013	€12.07	i.e., for	5 539 952	shares	a value of	€66.9 M
lowest price	Monday, December 16, 2013	€8.58	i.e., for	5 548 112	shares	a value of	€47.6 M
		number of	shares traded:	864 643			
2014							
highest price	Wednesday, October 1, 2014	€34.97	i.e., for	5 584 272	shares	a value of	€195.3 M
lowest price	Thursday, January 2, 2014	€10.16	i.e., for	5 558 952	shares	a value of	€56.5 M
		number of	shares traded:	10 136 876			
2015							
highest price	Tuesday, January 13, 2015	€32.99	i.e., for	6 882 761	shares	a value of	€227.1 M
lowest price	Tuesday, February 3, 2015	€25.20	i.e., for	6 882 761	shares	a value of	€173.4 M
		number of shares traded:		3 374 537			

# 21.2 Main provisions of the articles of incorporation

## 21.2.1 Corporate purpose (Article 3 of the articles of incorporation)

The Company has the purpose, in France and in any country, of:

- the research, manufacture, import, distribution, and marketing of experimental drugs, drugs, devices, and equipment;
- the provision of all advisory services associated therewith;

and generally, all financial, commercial, industrial, civil, property, or security-related transactions, such as may directly or indirectly relate to one of the purposes specified or such as may facilitate their fulfillment.

The Company may act directly or indirectly and perform all these operations in any country, on its own behalf and on behalf of third parties, either alone or with third parties in a joint venture, association, grouping, or company, through the creation of new companies, contributions, partnerships, subscription, purchase of company securities or rights, merger, alliance, joint venture companies, or the obtaining or provision, under lease or management, of any assets and rights or other items.

# 21.2.2 Administration and Senior Management (articles 17 to 24 of the articles of incorporation)

#### **BOARD OF DIRECTORS**

#### I. Appointment/removal of directors

The Company is governed by a Board of Directors composed of at least three members and at most eighteen members, without prejudice to the derogation established by law in the event of merger.

The Board of Directors is composed by seeking a balanced representation of women and men.

During the life of the company, directors are appointed, renewed, or removed in Ordinary General Meetings. They can always be re-elected.

The duration of a director position is three (3) years; this position ends at the end of the Ordinary General Meeting called to rule on the annual financial statements for the year just ended and held during the year in which their term of office expires.

A person cannot be appointed as director where, having surpassed sixty-five years of age, this person's appointment has the effect of bringing the number of Board members having surpassed this age to more than one-third of the number of directors. Where this limit has been surpassed, the oldest director shall be deemed as having duly resigned.

Directors can be shareholders or non-shareholders of the Company.

A Company employee cannot be appointed director where his/her employment contract corresponds to an effective job. The number of directors tied to the Company by way of an employment contract cannot exceed one third of the directors in position.

# II. Directors as legal persons

Directors can be natural persons or legal persons. In the latter case, upon its appointment, the legal person is required to designate a permanent representative, who is subject to the same conditions and obligations and who incurs the same civil and criminal liability as if this person was a director in his/her own name, without prejudice to the several liability of the legal person that he/she represents. The permanent representative of a director as a legal entity is subject to the age conditions pertaining to directors as natural persons.

The term of office of the permanent representative designated by the legal person appointed as director is given to him/her for the duration of the latter's term of office.

Where the legal person revokes the term of office of its permanent representative, he/she is required to provide the Company, without delay and by registered letter, this revocation as well as the identify of its new permanent representative. The same is applicable in the event of the death or resignation of the permanent representative. Designation of the permanent representative and discontinuation of his/her term of office are subject to the same publication formalities applicable as if he/she had been a director in his/her own name.

#### III. Vacancy, death, resignation

In the event of a vacancy, due to death or resignation, of one or more director positions, the Board of Directors may, between two general meetings, proceed with temporary appointments.

Where the number of directors has become lower than the legal minimum, the remaining directors shall immediately call an Ordinary General Meeting with a view to supplementing the Board's numbers.

Temporary appointments made by the Board are subject to ratification at the next Ordinary General Meeting. In default of such ratification, the resolutions made and acts performed by the Board prior to this meeting shall no longer be considered valid.

In the event of absence of a director at more than four consecutive Board of Directors' meetings, this director shall be considered as having duly resigned.

#### ORGANIZATION OF THE BOARD

The Board of Directors shall elect a Chairman from among its members, the Chairman being a natural person, on penalty of invalidity of this appointment. It shall determine the Chairman's remuneration.

Any person older than sixty-five years of age may not be appointed Chairman. Where the Chairman in office comes to surpass this age, he/she shall be deemed as having duly resigned.

The Chairman is appointed for a duration that cannot exceed that of his/her director term of office. He/she can be re-elected. The Board of Directors may remove the Chairman at any time.

The Board may likewise appoint a Vice President from among its members who are natural persons, and he/she shall preside over Board meetings in the Chairman's absence.

The Board may designate, within a maximum limit of two, one or more observers who are natural persons, directors or otherwise, and who are 65 years of age at most at the day of their appointment.

These observers are appointed for a duration of two years.

These observer positions shall be fulfilled free of charge. The observers shall be summoned to all meetings of the Board of Directors and shall take part in deliberations for consultation purposes only. With the Board of Directors, the observers shall perform a general mission of consultation and supervision.

#### **BOARD DELIBERATIONS**

The Board of Directors shall meet as often as the Company's interests so require, upon summons by its Chairman or the Chief Executive Officer. Where the Board has not met for more than two months, at least one third of the directors may request that the Chairman, who is bound by this request, summon a Board of Directors meeting on a specific agenda.

Summonses shall be given by any means, including verbally.

Meetings shall take place either at the headquarters or at any other location indicated in the summons.

The Board may only validly deliberate where half of its directors are present.

Decisions shall be made by the majority of members present or represented.

In the event of a tie, the meeting Chairman's vote shall carry the decision.

Pursuant to the provisions of internal rules established by the Board of Directors, for calculation of the quorum and the majority, the directors participating in a Board meeting by videoconference or other means of telecommunications allowing for identification of the participants and guaranteeing their effective participation shall be deemed present, in compliance with current regulations.

This provision is not applicable for decisions on the annual financial statements, the consolidated financial statements, and preparation of the annual report and the group's annual report.

# POWERS OF THE BOARD OF DIRECTORS

The Board of Directors determines the orientation of the Company's activities and oversees their implementation. Without prejudice to the powers expressly assigned by law to the shareholders and within the limit of the corporate purpose, the Board of Directors is responsible for all matters relating to the successful operation of the Company and governs matters concerning the Company, through its resolutions.

In relations with third parties, the Company is committed by the actions of the Board of Directors including where not pertaining to the corporate object, except where it can prove that the third party knew that such action fell outside this purpose or that it could not be ignorant of such fact, given the circumstances, mere publication of the articles of incorporation not being sufficient to constitute such proof.

The Board of Directors shall perform the controls and verifications that it deems appropriate. Each director may arrange for the communication to him/her of all documents and information necessary to the fulfillment of his/her mission.

The Board of Directors may decide on the creation of a study committee responsible for studying matters that the Board of Directors or its Chairman submits to it.

#### SENIOR MANAGEMENT

#### 1 - Operating methods

Senior Management is provided under its responsibility, by a natural person appointed by the Board of Directors and holding the title of Chief Executive Officer. This natural person can be the Chairman of the Board of Directors.

The Board of Directors chooses between two operating methods for the Senior Management.

The Board resolution pertaining to the choice of operating method for the Senior Management shall be carried by the majority of directors present or represented. Shareholders and third parties shall be informed of this choice in accordance with the conditions established by current regulations.

### 2 - Senior Management

The Chief Executive Officer shall be a natural person selected from among the directors or elsewhere.

The duration of the Chief Executive Officer's duties is determined by the board at the time of his/her appointment. However, where the Chief Executive Officer is a director, the duration of his/her duties cannot exceed that of the director term of office.

Any person older than seventy years of age cannot be appointed as Chief Executive Officer. When the Chief Executive Officer reaches this age limit, he/she shall be deemed as having duly resigned.

The Chief Executive Officer can be removed by the Board of Directors at any time. Where the removal is decided without just cause, it may result in the payment of damages, except where the Chief Executive Officer holds the position of Chairman of the Board of Directors.

The Chief Executive Officer is vested with the broadest of powers to act in all circumstances in the name of the Company. He shall exercise his powers within the limits of the corporate purpose and without prejudice to those that the law expressly assigns to the shareholders and to the Board of Directors.

He shall represent the Company in its relations with third parties. The Company is committed by the actions of the Chief Executive Officer including where not pertaining to the corporate object, except where it can prove that the third party knew that such action fell outside this purpose or that it could not be ignorant of such fact, given the circumstances, mere publication of the articles of incorporation not being sufficient to constitute such proof.

The Board of Directors may limit the powers of the Chief Executive Officer, but these limitations are not binding against third parties.

#### 3 – Delegated Managing Directors

Upon the proposal of the Chief Executive Officer that this position be assumed by the Chairman of the Board of Directors or by another person, the Board of Directors may appoint one or more natural persons assigned to assist the Chief Executive Officer, with the title of Delegated Managing Director.

The Board of Directors may choose the Delegated Managing Directors from among the directors or elsewhere, and cannot appoint more than five (5) persons.

The age limit is set at seventy (70) years. When a Delegated Managing Director reaches this age limit, he/she shall be deemed as having duly resigned.

The Delegated Managing Director can be removed at any time by the Board of Directors, upon such proposal by the Chief Executive Officer. Where such removal is decided on without just cause, it may result in the payment of damages.

Where the Chief Executive Officer ceases or is unable to perform his/her duties, the Delegated Managing Directors shall retain, except where decided otherwise by the Board, their duties and powers until the appointment of a new Chief Executive Officer.

In accordance with the Chief Executive Officer, the Board of Directors shall determine the extent and duration of powers granted to the Delegated Managing Directors. The Delegated Managing Directors shall have, in relation to third parties, the same powers as the Chief Executive Officer.

#### REMUNERATION OF DIRECTORS

1 - The General Meeting may allocate to the directors, in remuneration for their activity and in the form of attendance fees, a fixed annual sum, the amount of which is reported under operating expenses and shall be maintained until a decision is made to the contrary. Its distribution among the directors shall be determined by the Board of Directors.

2 - The Board of Directors shall determine the remuneration for the Chairman of the Board of Directors, the Chief Executive Officer, and the Delegated Managing Director. This remuneration can be fixed and/or proportional.

#### PLURALITY OF TERMS OF OFFICE

The limitation on the plurality of terms of office as director and Chief Executive Officer applies in accordance with the conditions and subject to the derogations established by law.

**REGULATED AGREEMENTS** (as this provision has been proposed to the General Meeting of June 23, 2015 for approval)

All regulated agreements taking place, directly or through a third party, between the Company and one of its directors, its managing director, one of its delegated managing directors, one of its shareholders holding a portion of the voting rights greater than 10% or, where relating to a shareholder company, the company controlling it as defined under Article L. 233-3 of the Code of Commerce, must be submitted for the prior authorization of the Board of Directors.

The same is likewise applicable for agreements in which one of the persons outlined in the previous paragraph has an indirect interest, and for agreements taking place between the Company and another company, where the managing director, one of the delegated managing directors, or one of the Company's directors is the owner, shareholder with unlimited liability, manager, director, member of the supervisory board, or generally any director of this company.

The prior authorization of the Board of Directors shall be supported by reasons justifying the Company's interests in stipulating the agreement, and shall notably specify the financial conditions associated with this agreement.

Agreements stipulated and authorized during previous financial years, the fulfillment of which was continued into the last financial year, shall be examined each year by the Board of Directors and disclosed to the external auditors as established under the law.

The provisions of the preceding paragraphs shall not be applicable either to agreements relating to day-to-day operations stipulated under normal conditions or to agreements stipulated between two companies where one of these companies directly or indirectly holds the entirety of the other's capital, where applicable after deducting the minimum number of shares required to satisfy the requirements of Article 1832 of the Civil Code and Articles L. 225-1 and L. 226-1 of the Code of Commerce.

The report outlined under Article L. 225-102 of the Code of Commerce mentions, save where these are agreements relating to day-to-day operations stipulated under normal conditions, agreements reached directly or through a third party and between, on one part and as applicable, the managing director, one of the delegated managing directors, one of the directors, or one of the shareholders holding a portion of the voting rights greater than 10% of the Company's capital and, on the other part, another company in which the Company directly or indirectly holds more than half the capital.

# 21.2.3 Rights, privileges, and restrictions attached to shares (Articles 9 to 16 of the articles of incorporation)

#### **CROSSING OF THRESHOLDS**

All shareholders who come to hold or cease to hold, directly or indirectly, alone or jointly with another person, a number of shares or similar securities representing a portion of the capital or voting rights established by law must inform the Company of this, in accordance with the conditions established by the law and regulations. Shareholders who have not respected these provisions shall be deprived of the voting rights attached to the shares exceeding the portion that should have been declared. The loss of voting rights shall apply to all shareholders' meetings held up to the expiry of a two-year period following the date on which the declaration was normalized.

#### **INCREASES IN SHARE CAPITAL**

The share capital shall be increased by any means and according to any methods established by law.

An Extraordinary General Meeting, acting on a report by the Board of Directors, is the sole entity with competency to decide on a capital increase. It may delegate such competency or powers to the Board of Directors.

The shareholders have, proportionately to the amount of their shares, a preferential right to the subscription of shares issued by way of a cash contribution to perform a capital increase, a right that they can waive individually. An Extraordinary General Meeting may decide to withdraw this preferential subscription right under legally established conditions.

The right to the assignment of new shares to shareholders, following an incorporation of reserves, income, or issue premiums into the capital, belongs to the bare owner, without prejudice to the rights of the usufructuary.

#### PAYMENT OF SHARES

All the original shares constituting the initial capital and representing cash contributions must be paid up in the amount of at least half their nominal value at the time of their subscription.

Shares subscribed during a cash-based capital increase must be paid up in the amount of at least one quarter of their nominal value at the time of their subscription and, where applicable, the entirety of the issue premium. Payment of the remainder must take place on one or more occasions on the decision of the Board of Directors within a period of five years, i.e., this period starting on the day of registration in the Trade and Companies Register or, for a capital increase, on the day on which the capital increase became final.

Calls for funds shall be brought to the knowledge of subscribers by registered letter with acknowledgment of receipt sent at least fifteen days prior to the date established for each payment. Payments shall be paid either at the headquarters or at any other location indicated to this end.

Any delays in the payment of sums owing on the share amount not paid up shall result, duly and without the need to proceed with any formalities whatsoever, in the payment of interest at the legal rate, starting on the due date, without prejudice to any personal action that the Company may exercise against the defaulting shareholder and the enforcement measures established by law.

## REDUCTION - AMORTIZATION OF THE SHARE CAPITAL

A reduction of the capital may be authorized or decided on in an Extraordinary General Meeting which may delegate to the board of directors all powers to perform such reduction. In no case shall this harm the equal treatment of the shareholders.

A reduction in share capital for an amount below the legal minimum can only be decided pursuant to the suspensive condition of a capital increase intended to return the share capital to an amount at least equal to this minimum amount, except where the Company is transformed into another form of company.

In the event of non-compliance with these provisions, any interested parties may seek dissolution of the Company through the courts.

Nevertheless, the court cannot order its dissolution where, on the date on which it rules based on grounds, the situation has been normalized.

The capital may be amortized in accordance with legal provisions. Amortization of the capital may be decided in an Extraordinary General Meeting and must be performed, through sums distributable in accordance with

article L. 232-11 of the Code of Commerce, by way of an equal reimbursement on each share of the same class. It shall not result in a reduction of the capital. Shares fully or partially amortized shall lose the right to reimbursement at their nominal value, up to the amount of this amortization. They shall retain all their other rights.

#### **SHARE TYPES**

The shares are nominal, up to their full payment. Where they are fully paid up, they can be nominal or bearer, as decided by the shareholders.

They shall give rise to the registration of an account opened pursuant to the conditions and methods established under current legal and regulatory provisions, by the issuing company or by a financial broker authorized by the French Minister of the Economy and Finance.

#### INDIVISIBILITY OF THE SHARES - BARE OWNERSHIP - USUFRUCT

The shares are indivisible in the eyes of the Company. Indivisible co-owners of shares shall be represented in General Meetings by one of the co-owners or by a joint representative of their choice. In default of an agreement between them on the choice of a representative, this representative shall be designated by order of the President of the Commercial Court, ruling in an interim order on the application of the co-owner first making such request.

The voting right attached to a share belongs to the usufructuary for Ordinary General Meetings and to the bare owner for Extraordinary General Meetings. However, the shareholders may agree amongst themselves on any other distribution for the exercise of a voting right in General Meetings. In this case, they must bring their agreement to the knowledge of the Company by registered letter sent to the headquarters, the Company being required to respect this agreement for any General Meetings held after the expiry of a one-month period following mailing of the registered letter, the postmark being considered proof of the mailing date.

The shareholder's right to obtain the communication of company documents or to consult these documents may likewise be exercised by each co-owner of an undivided share, by the usufructuary, and the bare owner of shares.

# ASSIGNMENT AND TRANSFER OF SHARES

Shares can be freely traded, without prejudice to legal and regulatory provisions.

The ownership of shares issued in nominal form shall result from their registration in the name of the owners on the registers held to this end. Shares that are registered as necessarily being nominal may only be traded on the market where they have first been placed in a management account with an authorized broker.

Shares that are not registered as necessarily being nominal may only be traded on the market where they are converted to bearer shares.

Ownership of bearer shares shall result from their registration in a bearer account with an authorized financial broker.

The assignment of nominal or bearer shares shall take place, with regard to third parties and the company, by an account-to-account transfer into the accounts of the issuing company or those of the authorized financial broker.

The transfer of shares, free or charge or following a death, shall likewise take place by an account-to-account transfer upon the provision of evidence supporting the change in legal conditions.

#### RIGHTS AND OBLIGATIONS ATTACHED TO THE SHARES

Each share gives right to the profits, the company assets in a share proportional to the proportion of capital that it represents.

All shareholders shall have the right to be informed of the Company's performance and to obtain the communication of certain company documents at the times and in accordance with the conditions established by the law and regulations.

Shareholders shall only sustain losses up to the amount of their contributions.

The possession of a share requires due adherence to the decisions of the shareholders in General Meetings and to these articles of incorporation. Assignments shall include all dividends matured and not paid or maturing in

future, as well as any share in the reserve funds, except where provisions to the contrary are reported to the Company.

Whenever it is necessary to hold a certain number of shares to exercise a right, in the event of an exchange, regrouping, or assignment of title, or at the time of a capital increase or reduction, a merger, or any other operation, the shareholders holding a number of shares less than that required can only exercise these rights on the condition that they personally arrange to obtain the number of shares required.

# 21.3.4 Actions requied to modify shareholders' rights

The rights of shareholders may be modified in accordance with legal conditions, by way of a modification of the Company's articles of incorporation, an operation that only the extraordinary general meeting is authorized to perform.

## 21.2.4 General Meetings (Articles 26 to 30 of the articles of incorporation)

# NATURE OF THE MEETINGS

Shareholder decisions shall be made in General Meetings.

Ordinary General Meetings are those that are called to make all decisions that do not modify the articles of incorporation.

Extraordinary General Meetings are those called to decide on or authorize direct or indirect modifications to the articles of incorporation.

The resolutions of General Meetings create an obligation on all shareholders, including those who are absent, dissenting, or incompetent.

**SUMMONSES AND MEETINGS OF THE GENERAL SHAREHOLDERS** (as this provision has been proposed to the General Meeting of June 23, 2015 for approval)

All shareholders have the right to participate in General Meetings or to arrange for their representation in accordance with the conditions established by law.

General Meetings are called either by the Board of Directors or by the statutory auditors, or by a representative designated by the President of the Commercial Court in an interim ruling on the application of one or more shareholders constituting at least one tenth of the capital or, in an emergency, on the application of the participative Management Committee.

Where the Company's shares are admitted for trading on a regulated market or where all its shares are not nominal, it is required, at least thirty-five (35) days prior to any meeting, to publish in the French Bulletin des Annonces Légales Obligatoires (BALO) a meeting notice containing the information outlined in current regulations.

The summons to a General Meeting is made by a notice in a newspaper authorized to publish legal notices in the French département where the headquarters is located, and a notice, furthermore, in the Bulletin des Annonces Légales et Obligatoires [French Bulletin of Compulsory Legal Notices] (BALO).

Nevertheless, the notices outlined in the previous paragraph can be replaced by a summons made, at the Company's expense, by simple or registered letter sent to each shareholder. This summons may likewise be sent by a means of electronic telecommunications implemented in accordance with regulatory conditions.

Meetings shall take place at the headquarters or at any other location indicated in the notice of summons.

General Meetings shall be composed of all the shareholders, whatever the number of shares they hold.

Participation in the General Meetings, in any form whatsoever, is subject to the recording of shares in accordance with the conditions and timeframes established under current regulations. The Board of Directors has the right to accept voting forms and proxies arriving at the Company after the deadline established under current regulations.

A shareholder may arrange for his/her representation at the General Meetings by any natural or legal person of his/her choice, in accordance with legal provisions. Shareholders who are legal persons shall participate in meetings through their legal representatives or through any representative designated to this end.

Shareholders may likewise vote remotely in accordance with the methods established by the law and regulations, sending their remote voting form either in paper format or, on the decision of the Board of Directors, by a means of telecommunications.

The Board of Directors has the right to decide, at the time a meeting is called, whether the shareholders may participate and vote in any meetings by videoconference or any other means of telecommunications or electronic transmission (including via the internet), in accordance with the conditions established by the law and regulations applicable at the time of its utilization. This decision shall be communicated in the meeting notice and the notice of summons published in the Bulletin des Annonces Légales Obligatoires (BALO).

The shareholders who use, to this end and within the required timeframes, the electronic voting form offered on the website established by the coordinator of the shareholders' meeting shall be considered equal to the shareholders present or represented. The submission and signature of the electronic form may be directly performed on this site through any process approved by the Board of Directors and meeting the conditions defined in the first sentence of paragraph two, article 1316-4 of the French Civil Code, i.e., the usage of a reliable identification process guaranteeing the link with the form, notably such as consists of an identifier and a password.

The proxy or the vote thus expressed prior to the meeting by any means of telecommunications or electronic transmission, as well as the acknowledgment of receipt that is given in such case, shall be considered a fully irrevocable and enforceable submission, it being specified that, in the event of an assignment of shares taking place prior to the second (2<sup>nd</sup>) business day preceding the shareholders' meeting at local Paris time, the Company shall consequently invalidate or modify, as applicable, the proxy or the vote expressed prior to the meeting by any means of telecommunications.

### **AGENDA**

The agenda for Meetings is provided by the person issuing the summons.

One or more shareholders, representing at least the portion of share capital required and acting in accordance with the conditions and timeframes established by law, have the right to request, by registered letter with acknowledgment of receipt or by electronic telecommunications, the inclusion of points or draft resolutions on a Meeting agenda.

The participative management committee may likewise request that draft resolutions be included on a Meeting agenda.

Meetings cannot deliberate on a matter that is not included on the agenda, which cannot be modified in the event of a second summons. It can nevertheless, in all circumstances, remove one or more members of the Board of Directors and proceed with their replacement.

#### **HOLDING OF MEETINGS - CHAIR COMMITTEE - MINUTES**

Meetings are presided over by the Chairman of the Board of Directors or, in his absence, by a Vice President or by a director specially delegated to this end by the Board. Failing this, the Meeting shall itself designate its Chairman.

In the event of a summons by a statutory auditor or by an agent appointed by the court, the Meeting shall be presided over by the person issuing the summons.

The two shareholders, present and accepting such duties, representing, both for themselves and as representatives, the largest number of votes shall act as scrutineers and vote counters.

The committee thus established shall designate a secretary, who may be taken from outside the members of the Meeting

An attendance sheet shall be kept, in accordance with the conditions established by law.

Deliberations and resolutions of the Meetings are recorded in minutes signed by the committee members and kept in a special register, in accordance with the law. Copies and extracts of these minutes shall be validly certified in accordance with the conditions established by law.

QUORUM – VOTE (as this provision has been proposed to the General Meeting of June 23, 2015 for approval

General Meetings, whether they are ordinary, extraordinary, or combined, shall deliberate in accordance with the conditions for a quorum and majority as established in the provisions governing them, and shall exercise the powers assigned to them by the law.

The voting right attached to capital or dividend shares is proportional to the portion of capital that they represent. Each share gives the right to one vote.

A double voting right is nevertheless assigned, in accordance with legal conditions, to all shares fully paid up for which evidence is provided, at the latest on the second day prior to the date of the shareholders' meeting,

of nominal registration for at least two years in the name of the same shareholder, or in the name of a person holding such rights following a succession, a sharing of the community of property between spouses, or an inter vivos gift granted by a shareholder to his/her spouse or to a relative in the direct line of succession, or following a transfer resulting from a merger or a division of a shareholder company.

In the event of a capital increase through the incorporation of reserves, income, or issue premiums, the double voting right is granted, upon their issue, to nominal shares assigned free of charge to replace the previous shares already receiving such benefit.

The double voting right shall be duly withdrawn from any share having been converted to a bearer share or been subject to a transfer of ownership, except where this transfer results from a succession, a sharing of the community of property between spouses, or an inter vivos gift granted by a shareholder to his/her spouse or to a relative in the direct line of succession, or following a transfer resulting from a merger or a division of a shareholder company.

# 21.2.5 Clauses of the articles of incorporation such as may have an effect on the occurrence of a change of control

No clauses of the articles of incorporation are such as may have the effect of delaying, deferring, or impeding a change of control in the Company.

## 21.2.6 Crossing of thresholds set by the articles of incorporation

The Company's articles of incorporation do not stipulate obligations other than those established by the law and regulations (Article 9 of the Company's articles of incorporation).

## 21.2.7 Special provisions governing modifications to the share capital

All modifications to the share capital are subject to legal requirements, the articles of incorporation not stipulating any specific provisions.

### 22 MAJOR CONTRACTS

The major contracts for the Company during the last two years, other than those stipulated in the normal course of business, are the following:

## 22.1 Partnership and cooperation agreements

#### 22.1.1 Financed agreements

# 22.1.1.1 Erytech/Inserm/Aphp/Diaxonhit

The parties have stipulated a cooperation agreement within the scope of the TEDAC project: "Therapeutic Enzymes to Deplete Amino acids to treat Cancers resistant to radio/chemotherapy."

This agreement entered into effect retroactively as of January 1<sup>st</sup>, 2012, for a duration of 8 years.

Within the scope of this project, OSEO will finance the Company in amount of 7 million euros, which shall be paid in multiple tranches, 4.9 million euros of which is in repayable advances and 2.1 million euros in non-repayable grants.

The OSEO assistance is composed of a grant, as well as repayable assistance, in accordance with the following structure:

	Project	Cost of elig	gible activities includ	led (in €)	Maximum assistance provided (in €)		
Beneficiary	amount		Experimental	Total	Grants	Repayable	Total
	(in €)		development	Total	Grants	advances	assistance

ERYTECH	1.4.2.62.050	4.550.560	0.700.000	1.4.2.62.0.50	2.050.104	4.005.050	6 0 5 0 0 4 6 th
Pharma	14,363,850	4,573,760	9,790,090	14,363,850	2,058,194	4,895,052	6,953,246*

<sup>\*</sup>That being 48% of the project amount

The project is monitored through a series of key milestones defined with a view to enabling OSEO to evaluate the progress of the project and determine the assistance to be paid. The key milestones are as follows (t0 having been established as July 1st, 2012):

Key Milestone	Stopwatch	Date	ERYTECH Condition
Key Milestone	t0 + 12 months	Jul-13	Provision of contract between ERYTECH and the enzyme supplier
Key Milestone 2	t0 + 24 months	Jul-14	Enzyme encapsulation capacity
Key Milestone	t0 + 36 months	Jul-15	Results of toxicology study, selection of therapeutic indication for Phase I/II
Key Milestone 4	t0 + 48 months	Jul-16	Design of study I/II, approval of regulatory authorities for Phase I/II
Key Milestone 5	t0 + 60 months	Jul-17	Intermediate results Phase I/II
Key Milestone 6	t0 + 72 months	Jul-18	Design of study II/III, approval of regulatory authorities II/III, results of I/II
Key Milestone 7	t0 + 84 months	Jul-19	Intermediate results Phase II/III
Key Milestone 8	t0 + 96 months	Jul-20	Final report

The estimated amount of payments is established in the following tables:

	First		Payments of non-repayable grants by key milestone (in €)							
	payment of non- repayable grants	Key Milestone 1	Key Milestone 2	Key Milestone 3	Key Milestone 4	Key Milestone 5	Key Milestone 6	Key Milestone 7	Key Milestone 8	Total grant payments (in €)
ERYTEC H Pharma	992,257	463,054	294,153	0	0	0	0	0	308,730	2,058,194

	First	Payments of repayable advances by key milestone (in €)								
	payment of repayable advances	Key Milestone	Key Milestone 2	Key Milestone 3	Key Milestone 4	Key Milestone 5	Key Milestone 6	Key Milestone 7	Key Milestone 8	Total payments of repayable advances (in €)
ERYTEC H Pharma	62,607	0	0	217,121	901,807	1,018,028	1,454,167	507,064	734,258	4,895,052

The first payment was made after signature of the Framework Agreement with OSEO. In May 2012, the Company therefore received the above-mentioned amounts, i.e., €992,257 in non-repayable grants and €62,607 in repayable advances.

These amounts were therefore received as an advance, and therefore correspond to the amount of expenses estimated for Key Milestone 1 to which the assistance rate is applied.

At the end of key milestone 1, as of June 30, 2013, the Company had incurred an expense volume which came to  $\[ \in \]$  438,674, which did not reach the volume for which it had received the advance of  $\[ \in \]$  992,257. Consequently, the Company was unable to sollicit payment of the advance for the milestone, namely  $\[ \in \]$  463,054. The Company had, furthermore, already recorded deferred revenues amounting to  $\[ \in \]$  943,004 as of December 2012.

The following payments are made after each review of a Key Milestone. The amount effectively paid has a ceiling at the amount of the Key Milestone in question, decreased by any overpayments at previous Key Milestones. The total amount of payments made prior to the final Key Milestone shall not exceed 85% of the anticipated amount of the assistance.

The final payment of an estimated amount of 15% of the total amount of assistance shall be made after the Key Milestone and the final review of the project R&D identifying the end of the project and acceptance by OSEO.

Within the context of closing its books on 31 December 2013, the Company did not realize all of the forecast expenses in key milestone 2, as the milestone will be completed in June 2014. Since subsidies are booked on a pro rated basis for costs incurred (corporate financial statements and IFRS), at the end of 2013, the company recorded deferred revenues of €648,854, (refer to note 5.10 in Section 0).

However, the Company is clearly within the planned schedule with regard to the TEDAC project. The expenses incurred are lesser than planned in the initially submitted budget, as, in the end it was not necessary to go beyond that in order to achieve the initial steps of the project.

The Financial Repayments shall be made in specific payment amounts, in function of the anticipated sales revenue generated by the direct or indirect development of products or services resulting from the Project, as listed below:

• Therapeutic products, simple or combined, used in the treatment of a solid tumor and composed of enzymes intended to break down a specific amino acid, encapsulated in the red blood cells.

The Financial Repayments include repayment of the Repayable Advance and the Additional Payments explained below. We specify that the amounts of the repayment maturities on the Repayable Advance take into account an annual discount rate of 3.05% (three point zero five percent), calculated according to the methods below.

The amounts M(m) of the advance payments and repayment payments arising in month (m) are thus based on the economic conditions of the month (m0) of signature of the agreement, according to the following calculation:

 $M(m0) = M(m) (1.0305)^{(-n/12)}$ 

Where n represents the number of months elapsed between (m0) and (m),

And the dates to be taken into consideration are:

- for a payment of the Repayable Advance, the date of disbursement by OSEO;
- for a repayment, the collection date identified by OSEO.

The Company undertakes to repay OSEO an amount of  $\[ \in \]$ 5,281,000 (five million, two hundred and eighty-one thousand Euros) upon achieving a cumulative amount of before-tax sales revenue equal to or greater than  $\[ \in \]$ 10,000,000 (ten million euros), entitled "trigger sales revenue", according to the following estimated lump-sum payment schedule:

Year 1 at the latest on June 30	€500,000 (five hundred thousand euros)
Year 2 at the latest on June 30	€750,000 (seven hundred and fifty thousand euros)
Year 3 at the latest on June 30	€1,500,000 (one million, five hundred thousand euros)
Year 4 at the latest on June 30	€2,531,000 (two million, five hundred and thirty-one thousand euros)

In the event of sales of the intellectual property rights resulting from the project, as well as the assignment of prototypes, test series, and models created within the scope of the project, an annuity equal to 50% (fifty percent) of the income generated shall be lowing to OSEO ISI.

Where repayment of the Repayable Advance has been made in accordance with the above provisions, the Company shall pay OSEO, for a duration of five consecutive years after the termination date of said repayment and insofar as it has achieved a cumulative amount of before-tax sales revenue equal to or greater than 60,000,000 (sixty million euros), 2.5% of the annual sales revenue generated by the development of products resulting from the Project.

#### In any case:

- the amount of the Additional Payments shall have a ceiling of €15,000,000,
- the total period for the lump-sum repayments and the profit-sharing payments is limited to 15 years.

Early repayment of the Repayable Advance may be required by OSEO, notably in the event of a change of control in the Company.

# 22.1.2 Partnership agreements

### 22.1.2.1 Erytech/Teva Group

On March 28, 2011, ERYTECH signed a partnership agreement with Abic Marketing Limited (Groupe Teva), a global player in the pharmaceutical industry based in Israel, to distribute GRASPA® in this country. With a sales revenue of more than \$20 billion in 2013, Groupe Teva is a diversified pharmaceutical group with a strong strategy in innovative and unusual specialty products in therapeutic areas such as the central nervous system, respiratory system, women's health, oncology, and pain.

In accordance with the terms of this agreement, Groupe Teva shall submit an application for approval of the drug in Israel and shall provide for its marketing and long-term distribution in this country. Groupe Teva shall make milestone payments and shall share the income.

Early termination of the agreement may be requested by either party in the event of a change of control in the other party.

# 22.1.2.2 Erytech/Orphan Europe (Recordati Group)

On November 23, 2012, ERYTECH signed a marketing agreement with Orphan Europe, a company specialized in the development, production, and marketing of drugs for orphan diseases. Orphan Europe is a subsidiary of Recordati, a major European pharmaceutical group that earned 942 million euros in sales revenue in 2013.

Orphan Europe holds a portfolio of orphan drugs already on the market in different areas, such as neonatology, pediatrics, and metabolic disorders. Orphan Europe is a leading player in the field of orphan diseases and has the medical, clinical, regulatory and commercial expertise to market and effectively sell GRASPA<sup>®</sup> in Europe. Orphan Europe is a strategic business for Recordati, which acquired the company in 2007 for €135 million and built it up further with the acquisition of a portfolio of rare and orphan disease drugs in the United States for \$100 million.

Orphan Europe will market GRASPA® in 38 European countries, including all the countries in the European Union for the treatment of ALL and AML. The parties have the opportunity to discuss the extension of this agreement to other areas around Europe and other indications.

ERYTECH is keeping the production of GRASPA® at its Lyon site and will supply Orphan Europe in the various European countries where the drug will be sold.

Under this agreement, Orphan Europe contributed €5 million upon signing. Orphan Europe will pay ERYTECH up to €37.5 million on future milestones in function of various clinical, regulatory, and commercial events. Orphan Europe will invest in the development costs for GRASPA® in AML and ERYTECH will receive a payment for product delivered and royalties on the sales made by Orphan Europe with GRASPA®, for a total of up to 45% of the sale price.

The Company considers, in particular, that withdrawal of the objection on the patent, initiated by the Company, allowed for a clause in the agreement to be automatically terminated, this clause stipulating that, where the intellectual property licensed is deemed to be counterfeited or invalid, the Company could be required to reimburse Orphan Europe for certain expenses, or even reduced milestone payments and/or the agreement, terminated in part.

Separately, another company in the Recordati Group has subscribed to bonds that were converted into an investment stake in the capital of ERYTECH for a value of €5M at the time of the IPO (see also Section 18.1 of the Reference Document).

# 22.2 License agreement

# 22.2.1 Erytech/National Institutes of Health (NIH)

The NIH has granted a license, pertaining to the intellectual property covering a diagnostic method to predict the efficacy of L-asparaginase in patients (*see also Chapter 11.2 Intellectual Property*). This license covers US territory and development in leukemias and solid cancers. It is exclusive for five years after FDA approval of the drug that will be developed by ERYTECH. This license is granted against the payment of an annual royalty. In the event of commercial use of this license, the Company will be required to pay an additional royalty proportionate to the net sale price.

# **22.3** Supply contracts:

# 22.3.1 Erytech/Établissement Français Du Sang (EFS)

The parties have entered into multiple agreements for the sale of packed red blood cells for therapeutic use intended for the manufacture of ERY-ASP/GRASPA®, notably on September 1<sup>st</sup>, 2009, within the context of the GRASPALL 2009-06 clinical study.

# 22.3.2 Erytech/American Red Cross (ARC)

The parties have stipulated a forward contract according to which the ARC undertakes to supply ERYTECH within the scope of its requirements for packed red blood cells in the United States.

This contract entered into effect on July 1<sup>st</sup>, 2009 and will expire on December 4, 2015.

## 22.3.3 Erytech/Medac

ERYTECH and Medac, a German company, have stipulated two exclusive supply contracts for asparaginase intended for the manufacture of ERY-ASP/GRASPA®.

- The first contract entered into effect on December 10, 2008 for a duration of 20 years, and concerns the native form of asparaginase currently used by ERY-ASP/GRASPA® for its European clinical trials in ALL and AML.
- The second contract covers any new formulations of asparaginase that Medac develops and that ERYTECH may potentially use. In particular, medac develops a recombinant asparaginase (in Phase III in Europe) and a pegylated asparaginase (in Phase I in Europe) (*see also Chapter* 6 of the Reference Document). For supplies for clinical usage, this contract entered into effect on April 6, 2011 for a duration of 10 years; for supplies for commercial usage, it will enter into effect on the date of commercial approval, for a duration of 5 years.

This second contract contains certain provisions according to which ERYTECH may be required to refrain from any form of promotion of ERY-ASP/GRASPA® where this product is manufactured using a new formulation of asparaginase registered and marketed prior to ERY-ASP/GRASPA® as first-line treatment. It is specified that any restriction against promotion shall only be applicable for the country or countries in which the new formulation is approved first and only for the indication or indications that it obtains, and shall not impede the prescription of ERY-ASP by a physician and its sale by ERYTECH.

It is reiterated that ERY-ASP/GRASPA® is currently manufactured in Europe using native asparaginase and therefore covered by the first supply contract, which contains no promotion-related restrictions. The Company may plan to manufacture ERY-ASP/GRASPA® in Europe using any new Medac formulation, in the event such new formulation is developed, but has no obligation to do so.

In any event, none of the provisions of contracts with medac are such as impede or restrict, in any country, a physician's ability to prescribe ERYTECH drugs.

# 22.3.4 Other supply contracts

The Company has stipulated a supply contract for the provision of "Osmocell" devices, as well as the know-how associated therewith. This contract entered into effect on September 10, 2013 for a duration of one year, with tacit renewal for subsequent one-year periods.

The Company has stipulated a supply contract for the provision of hemodialysis filters that the Company uses in its production system. The contract entered into effect on November 24, 2010 for a duration of 10 years.

# 22.4 Subcontracting agreements

## 22.4.1 Erytech/American Red Cross (ARC)

The parties have stipulated a subcontracting agreement for the production of batches of ERY-ASP for the Company's clinical trials in the United States.

The contract entered into effect on March 1<sup>st</sup>, 2009 for an initial duration of 3 years, and is renewable in one-year periods or, where applicable, until the end of the clinical trial for which ARC produces the batches.

## 22.4.2 Other subcontracting agreements

The Company has stipulated a subcontracting agreement for the production of Lysis/resealing solutions that the Company uses within the scope of its activities involving molecule encapsulation in red blood cells. The agreement entered into effect on March 8, 2011 for an initial duration of 2 years, and is renewable for one-year periods.

# 23 INFORMATION ORIGINATING FROM THIRD PARTIES, EXPERT DECLARATIONS, AND DECLARATIONS OF INTERESTS

None.

## 24 DOCUMENTS ACCESSIBLE TO THE PUBLIC

Copies of this Reference Document are available at no cost at the Company's headquarters, 60 avenue Rockefeller, 69008 Lyon, France. This Reference Document can likewise be found on the Company's web site (www.erytech.com) and on the AMF web site (www.amf-france.org).

The articles of incorporation, General Meeting minutes, and other Company documents, as well as the historical financial information and all evaluations or declarations made by an expert upon the request of the Company and made available to the shareholders in accordance with applicable legislation can be found, at no cost, at the Company's headquarters.

These documents are likewise available in paper format upon a simple request to the Company.

Further, pursuant to article 221-3 of the French Autorité des Marchés Financiers (AMF) General Rules, the information regulated under article 221-1 of the same Regulations is available on the Company's website (www.erytech.com).

# 25 INFORMATION ON INVESTMENT STAKES

At December 31, 2004, ERYTECH Pharma held 100% of the shares in ERYTECH Pharma Inc., an American company established in April 2014, the objective of which is to develop the Company's activities in the United States of America (see Chapter 20.1 Annexes 2.3 and 5.5 and the table of subsidiaries and investment stakes in the annexes to the corporate financial statements under Chapter 20.5).

# **26 GLOSSARY**

• **AFSSAPS** (now **ANSM**): The French Agency for the Safety of Health Products (now the French National Security Agency of Medicines and Health Products), is a French public institution whose mission is to assess the health risks posed by drugs and issue drug marketing approvals(MA). It is the sole authority for regulating biomedical research.

- American Red Cross (ARC): Organization whose mission is the collection, storage, processing and distribution of blood. It provides almost 44% of blood donations in the United States. It distributes its products in more than 3,000 hospitals and transfusion centers in the United States.
- MA: Marketing Approval is the approval given to a holder of operating rights for a drug manufactured industrially so that said holder can sell it.
- ANR: (L'Agence Nationale de la Recherche [National Research Agency]) is a funding agency for public and private research projects, in the form of contract research.
- Asparaginase: Specific enzyme capable of suppressing circulating asparagine, thus depriving cancer cells
  of a key nutrient, causing them to die. Its introduction as the standard treatment for acute lymphoblastic
  leukemia (ALL) dates back to the 1970s, in particular thanks to a purified version of the enzyme from
  bacteria (E. coli). Asparaginase gradually established itself as a pillar of anti-leukemia chemotherapy
- **GMP** (**Good Manufacturing Practice**): Set of mandatory standards governing the manufacture of industrial drugs that ensure the pharmaceutical quality of drugs and patient safety.
- PRBCs (Packed Red Blood Cells): Suspension of red blood cells aseptically obtained from a unit of whole blood after removing plasma.
- Half Life: Time required for the concentration of a drug present in tissue (e.g., blood) to decrease to half its initial value. In practice, a medicine is considered to no longer have a pharmacological effect after five to seven half-lives.
- **DSMB** (**Data Safety Monitoring Board**): a committee of independent experts responsible for monitoring the performance of clinical studies.
- **EMA**(European Medicines Agency) is a European Union agency based in London, which coordinates the evaluation and supervision of the development of new medicines in the European Union.
- Erythrocytes: Red blood cells
- **FDA** (**Food and Drug Administration**) is the US government agency responsible for the safety of food products as well as the control and regulation of drugs. Its responsibilities include assessing the safety and efficacy of drugs before issuing their marketing approval for the United States.
- ERY-ASP/GRASPA® or ERY-ASP or GRASPA® consists of an L-asparaginase encapsulated in a red blood cell. This medicine aims in particular to treat patients with acute leukemia. Encapsulation allows L-asparaginase to destroy asparagine, tumor growth factor, inside the red blood cell, while avoiding allergic reactions and reducing other side effects, thus providing prolonged therapeutic efficacy compared to other forms and a significantly improved safety profile, to treat fragile patients. The GRASPA® brand was licensed to Orphan Europe (Recordati Group) in order to market the product in ALL and AML in Europe and to the Teva Group in Israel.
- IND (Investigational New Drug Application) is an approval request to the FDA to administer an investigational drug or biological product to humans in the United States

• **Therapeutic Index**: Measurement of the relative safety of a drug, expressed as the ratio of toxic dose to therapeutically effective dose.

- **KOL** (**Key Opinion Leader**): an individual who, due to his/her reputation, expertise or intensive social activity, could influence the opinions or actions of a large number of individuals.
- **Orphan disease**: orphan diseases refer to diseases for which we do not have any effective treatment; proposed treatments for these diseases are limited to reducing symptoms. Orphan diseases are often rare diseases, i.e., low prevalence diseases, but there are highly prevalent diseases for which there is no treatment (such as Alzheimer's disease, which is an orphan disease that is not rare).
- **ODD** (**Orphan Drug Designation**): Legislation enacted to promote the research and commercialization of products that treat rare diseases. Pharmaceutical companies eligible for this status benefit from market exclusivity for ten years as well as scientific, financial and administrative support incentives for product development in these indications.
- **Phase I:** Clinical trials in healthy volunteers. They have two objectives: to ensure that the toxicity in humans is similar to that tested in animals during the preclinical stage and to analyze what happens to the drug in the body (pharmacokinetics).
- **Phase II:** During this phase, the optimal dose of the drug in terms of efficacy is determined. These trials are performed on a small homogeneous group of one hundred patients.
- **Phase II/III**: A study combining a Phase II and a Phase III, studying efficacy and the overall risk/benefit ratio at the same time.
- **Phase III**: This Phase Involves a large group of patients and is to compare the drug under development to another drug with proven effect or a placebo (a medicine devoid of therapeutic activity). The objective is to demonstrate effectiveness and assess the efficacy/safety ratio.
- **Pegylation Process**: non-toxic chemical processing of a molecule to increase its half-life in the body
- **Hypotonic solutions**: solution whose molecular concentration is lower than that of the reference environment (especially blood plasma). In a hypotonic solution, water tends to enter red blood cells through their semi-permeable membrane.
- **Reticuloendothelial system:** Set of cells scattered throughout the body with various functions including the production of blood components, the destruction of bodies considered foreign and immunity.
- **Companion Test**: test specific to a drug making it possible to predict patient response to the treatment and suggest the most effective and appropriate treatment and/or drug dosage.
- **Enzymatic therapy**: therapeutic treatment based on the specific activity of an enzyme. Enzymes are specialized proteins that each have a specific action such as causing chemical reactions, rearranging molecules, adding or subtracting components. Enzymes are not destroyed or changed during their action.

# APPENDIX 1 – Report by the statutory auditors on the chairman's report

## **Erytech Pharma SA**

Headquarters: 60 avenue Rockefeller – Bâtiment Adénine – 69008 Lyon

Share capital: €688,276.10

Statutory auditors' report, prepared in application of Article L.225-235 of the Code of Commerce, on the report by the chairman of the board of directors of the company Erytech Pharma SA

Financial year ended December 31, 2014

Dear Shareholders.

In our capacity as statutory auditors of ERYTECH Pharma SA, and in application of the provisions of Article L.225-235 of the Code of Commerce, we hereby present you our report on the report prepared by the Chairman of your company, in conformity with the provisions of Article L.225-37 of the Code of Commerce, for the financial year ending December 31, 2014.

It is the responsibility of the Chairman to prepare and submit, for the approval of the Board of Directors, a report summarizing the internal control and risk management procedures implemented within the company and providing the other information required by Article L.225-37 of the Code of Commerce, notably relative to the system of corporate governance.

#### Our task is:

- to provide you with any observations required of us based on the information contained in the Chairman's report respecting the internal control and risk management procedures relative to the preparation and treatment of accounting and financial information, and
- to certify that this report contains the other information required under Article L.225-37 of the Code of Commerce, it being specified that we are not responsible for verifying the accuracy of such other information.

We conducted our work in accordance with the professional standards applicable in France.

# 1. Information about internal control and risk management procedures pertaining to the development and processing of accounting and financial information

Professional standards require the implementation of diligence reviews intended to assess the accuracy of information with respect to internal control and risk management procedures relative to the preparation and treatment of the accounting and financial information contained in the Chairman's report. These verifications consisted specifically in:

- examining the internal control and risk management procedures relative to the preparation and treatment of
  accounting and financial information underlying the information presented in the Chairman's report, as well
  as existing documentation;
- examining the work that made it possible to prepare such information and the existing documentation;

• determining whether major deficiencies in internal control, relative to the preparation and treatment of the accounting and financial information, such as we have identified within the context of our mission, were appropriately disclosed in the Chairman's report.

On the basis of this work, we have no observations to formulate on the information concerning the Company's internal control and risk management procedures pertaining to the preparation and treatment of the accounting and financial information contained in the Chairman's report to the Board of Directors, prepared in accordance with the provisions of Article L.225-37 of the Code of Commerce.

#### 2. Other information

We hereby certify that the Chairman's report to the Board of Directors contains the other information required under Article L.225-37 of the Code of Commerce.

The statutory auditors Lyon, March 30, 2015

For KPMG Audit Rhône Alpes Auvergne

For RSM CCI Conseils

Sara RIGHENZI DE VILLERS Statutory Auditor Gaël DHALLUIN Associate

# **Erytech Pharma SA**

Headquarters: 60 avenue Rockefeller – Bâtiment Adénine – 69008 Lyon

Share capital: €688,276.10

Statutory auditors' report, prepared in application of Article L.225-235 of the Code of Commerce, on the report by the chairman of the board of directors of the company Erytech Pharma SA

Financial year ended December 31, 2014

Dear Shareholders,

In our capacity as statutory auditors of ERYTECH Pharma SA, and in application of the provisions of Article L.225-235 of the Code of Commerce, we hereby present you our report on the report prepared by the Chairman of your company, in conformity with the provisions of Article L.225-37 of the Code of Commerce, for the financial year ending December 31, 2014.

It is the responsibility of the Chairman to prepare and submit, for the approval of the Board of Directors, a report summarizing the internal control and risk management procedures implemented within the company and providing the other information required by Article L.225-37 of the Code of Commerce, notably relative to the system of corporate governance.

#### Our task is:

• to provide you with any observations required of us based on the information contained in the Chairman's report respecting the internal control and risk management procedures relative to the preparation and treatment of accounting and financial information, and

• to certify that this report contains the other information required under Article L.225-37 of the Code of Commerce, it being specified that we are not responsible for verifying the accuracy of such other information.

We conducted our work in accordance with the professional standards applicable in France.

1. Information about internal control and risk management procedures pertaining to the development and processing of accounting and financial information

Professional standards require the implementation of diligence reviews intended to assess the accuracy of information with respect to internal control and risk management procedures relative to the preparation and treatment of the accounting and financial information contained in the Chairman's report. These verifications consisted specifically in:

- examining the internal control and risk management procedures relative to the preparation and treatment of accounting and financial information underlying the information presented in the Chairman's report, as well as existing documentation;
- examining the work that made it possible to prepare such information and the existing documentation;

determining whether major deficiencies in internal control, relative to the preparation and treatment of the
accounting and financial information, such as we have identified within the context of our mission, were
appropriately disclosed in the Chairman's report.

On the basis of this work, we have no observations to formulate on the information concerning the Company's internal control and risk management procedures pertaining to the preparation and treatment of the accounting and financial information contained in the Chairman's report to the Board of Directors, prepared in accordance with the provisions of Article L.225-37 of the Code of Commerce.

#### 2. Other information

We hereby certify that the Chairman's report to the Board of Directors contains the other information required under Article L.225-37 of the Code of Commerce.

The statutory auditors Lyon, March 30, 2015

For KPMG Audit Rhône Alpes Auvergne

For RSM CCI Conseils

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Sara RIGHENZI DE VILLERS Statutory Auditor Gaël DHALLUIN Associate

# APPENDIX 2 - POLICY WITH REGARD TO ENVIRONMENTAL, SOCIAL, AND SOCIETAL RESPONSIBILITY

ERYTECH Pharma is a biopharmaceutical company which wishes to become an international leader in customized medicine in the field of cancer.

ERYTECH Pharma Company aspires to conduct each of its actions as a Socially Responsible Enterprise.

Placing the patient at the heart of our priorities, demonstrating ethics and respect towards each person are shared values within ERYTECH Pharma and they form the basis for its approach as a socially responsible enterprise.

The employees are the ones who promote these values and develop business on a day-to-day basis. The Company has made a particular commitment to train them and offer them a healthy and safe work setting so that they can continue to form a team that is motivated by the Company's success.

ERYTECH Pharma has made a sustained investment in R&D to meet the challenges of public health and to offer innovative and radical therapeutic responses particularly in the field of cancer.

Its current activities thus are concentrated in research and development and production for clinical trials. They are being developed in close collaboration with health professionals, particularly physicians and pharmacists, whose expectations guide ERYTECH Pharma.

The Company holds regulated status as a Pharmaceutical Company.

This report is intended to present the Company's stakeholders with its contribution in terms of Sustainable Development.

# 1 Employment and social security responsibilities

The table below summarizes the numerical indicators used to describe jobs at ERYTECH Pharma over the last three years:

_	nnel and the distribution of employees by gender and	2012 I	2013	2014
by age	Personnel at the end of the financial year (headings)	37	36	42
	Staff distribution M/W (%)	32/68	32/68	40/60
	Mean age (years)	35	36	35
	Employees 45 years of age or greater (employees, %)	8%	14%	12%
Hires and d	ismissals  Net number of jobs created	1	-1	6
Remunerati	ion and its evolution			
	Mean gross remuneration	47,072	52,852	55,325
	Annual increase ratio (comparable personnel)	nd	7%	5%

## • Total personnel and the distribution of employees by gender and by age

ERYTECH Pharma's personnel has remained stable between the 2013 financial year and the 2014 financial year. All personnel is located at a single site in Lyon, in the eighth district. The Men/Women distribution as well as the average age are generally stable. The rate of collaborators more than 45 years of age is nearly stable: 5 in 2014, as compared to 3 in 2013.

Staff are highly qualified: managers represented 48% of the personnel in 2014. At the end of the year, the personnel included 9 employees holding a doctorate in science, medicine, or pharmacy and 16 employees holding a degree in engineering or a master's degree, i.e., respectively 21% and 38% of the total staff.

#### • Hires and dismissals

In 2014, twelve new employees joined the company under different contracts: 6 permanent contracts and 6 fixed-term contracts.

Four employees working under permanent contracts left the company during the year, one as part of a dismissal, one within the context of a mutually agreed departure, and two through resignations. Two employees with fixed-term contracts reached the end of their contracts in 2014.

ERYTECH Pharma receives interns coming from schools or universities. In 2013 and 2014, interns received an indemnity that was above the legal minimum. As with any employee, they receive meal tickets and their transportation costs are reimbursed at a rate of 50%. Periods of internship are considered for purposes of seniority for those interns hired at the end of their internship. One intern was hired at the start of 2014 under a fixed-term contract, at the end of his internship.

ERYTECH Pharma also allows young diploma-holders to benefit from Volontariat International en Entreprise [International Volunteers in Business] (VIE). Additionally, the Company will be entrusting one of its employees with an 18-month professional assignment in Philadelphia (USA).

#### • Remuneration and its evolution

The Company applies an individual system for evolution in remuneration. There are two components to bonuses: individual and collective based on reaching objectives (quality, personal, department, company). Personnel working under fixed-term contracts receive payment of the bonus for at-risk employment should their contract not be renewed.

## a. Organization of work

ERYTECH Pharma complies with current law and has set the hours of the standard workweek to be 35 hours. These terms apply on prorated basis to part-time employees.

The table below summarizes the indicators used to describe the organization of work at ERYTECH Pharma over the last three years:

	2012	2013	2014
Organization of time at work			
Rate of part-time employees (%) <b>Absenteeism</b>	9.86%	6.69%	8.58%
Rate of absenteeism	2.40%	2.40%	1.75%

The rate of part-time work increased; there were four people working part-time (80%) at the end of 2014, versus three at the end of 2013.

Employees working part-time do so at their request; this is due primarily, but not exclusively, to parental leave. In effect, in order to find a just articulation between professional activity and personal and family life for men and women, the Company examines each request seeking to adapt the organization of work.

The absenteeism rate (excluding maternity, paternity, or parental leave) is stable; in the main, days of absence are days of absence due to illness (97%) and "sick child" days. No absence has been associated with a jobrelated illness.

#### **b.** Internal relations

Given the size of its personnel (fewer than 50 employees), the Company has one employee representative and one deputy. Meetings with the employee representative are held regularly, in accordance with legal procedures and even beyond that, since all questions are considered, even those that do not lie within the purview of powers awarded to the employee representative.

Agreements signed or commitment in the company are as follows:

- The individual right to training: and enterprise-level agreement respecting the exercise of the Droit Individuel à la Formation [individual right to training] (DIF) was signed on April 27, 2009.
- <u>Incentive</u>: an incentive agreement for the company's staff was signed on November 29, 2013. This took effect as of January 1<sup>st</sup>, 2014. For 2014, the Company granted a supplementary profit-sharing and stipulated an amendment to contributions on employee savings plans such as PEE and PERCO (the management costs are borne 100% by the Company).
- Remuneration for "sick child" days: unilateral commitment by the employer, who decides to pay for "sick child days" subject to certain limits and conditions.
- Work on weekends/public holidays and annual leave: Personnel in the Quality Assurance, Research and Development, Quality Control, and Production departments may be required to work on weekends and/or public holidays. The memo of July 16, 2013 was modified on October 28, 2014 with a view to equalizing the remunerations established between departments and to propose remunerations equivalent to or greater than those that were previously established. The memo entered into effect on November 17, 2014.
- On-call weekends and public holidays: Personnel in the Quality Assurance, Quality Control, Production, and Research and Development departments may be required to work on weekends and/or public holidays through on-call duty. The memo of March 30, 2012 was modified on October 28, 2014 with a view to equalizing the remunerations established between departments and to propose remunerations equivalent to or greater than those that were previously established. The memo entered into effect on November 17, 2014.

#### • Internal communications

The life of the company is based on active internal communication and participatory management. The company regularly organizes meetings within the departments about the various projects. Inter-departmental meetings have been implemented. Moreover, some informational meetings with employees, managers, or all categories put together, are organized thematically (for example during the IPO), so as to preserve dialogue and encourage employees to express themselves.

Each quarter, a meeting is organized with HR in which widely ranging themes are discussed such as training programs, end-of-year interviews, company insurance, incentives, etc.

Twice a year, ERYTECH Pharma offers "corporate days" which are essential for building cohesion among the teams.

## c. Health and safety

The company's activities are conducted in a particularly strict setting with regard to authorizations and approvals, and safety of the personnel is a fundamental element for the company's sustainable development.

Additionally, from the beginning, the company has deployed a policy of management through quality with ISO 9001: 2008 certification covering all of its processes. Within this framework, ERYTECH has a general health and safety procedure governing the practices of personnel in relation to the two following risks: biological and chemical.

Finally, problems pertaining to the personnel's hygiene and safety are followed and managed by the implementation of a Single Document, which identifies and evaluates work-related risks.

Within this context, ERYTECH Pharma supplemented its team of workplace first-aid rescue workers in 2014 by adding a new member.

The table below summarizes the indicators used to monitor health and safety at ERYTECH Pharma over the last three years:

Workplace accidents, particularly their frequency and their severity, as well as work-related illnesses	2012	2013	2014
Number of workplace accidents which resulted in work stoppage	1	0	2
Frequency rate* of workplace accidents resulting in stoppage	18/1000000	0	33/1000000
Severity level** of workplace accidents	0,02%	0	0,26%
Number of workplace accidents without stoppage	0	1	0
Frequency rate* of workplace accidents without stoppage	0	17/100000	0
Number of incidents	1	1	0
Frequency rate* of incidents	18/1000000	17/100000	0
Number of work-related illnesses	0	0	0

<sup>\*</sup>Frequency rate of workplace/commuting accidents = (Number of accidents involving an absence from work) x 1,000,000/Number of theoretical annual hours worked

The number of accidents resulting in an absence from work was two for 2014. ERYTECH Pharma files the necessary declarations if there is a workplace accident or an accident during transit, whether or not they result in stoppage of work. They are monitored in the incident log maintained by ERYTECH Pharma.

In terms of Hygiene and Safety, the Company complies with the legal and contractual provisions and, currently, has not signed any additional agreements either with a collective bargaining organization or with the employee representative.

## d. Training

The table below summarizes the indicators used to describe training at ERYTECH Pharma over the last three years:

	2012	2013	2014
Total number of hours of training  Total number of hours of training	400	474	600,5
Mean volume of hours of training/employee/year	11	13	14
Proportion of personnel 45 years or older who has received training actions (%) (Number of persons concerned)	100% 3/3	40% 2/5	40% (2/5)
Training expenditure ratio*	2.13%	2.22%	2.31%

<sup>\*</sup> Training expenditure ratio: Training expenses/wage and salary bill. Considering the size of ERYTECH Pharma, the company is required to comply with a minimum legal training expenditure ratio of 1.6%.

## • The policies implemented in terms of training

The company continued its training policy within a long-term perspective, on the basis of actions intended to strengthen collective and individual skills and abilities.

<sup>\*\*</sup>Severity rate = (Number of days of absence associated with workplace/commuting accidents) x 1,000/Number of hours worked

<sup>\*</sup>Frequency rate of incidents = (Number of incidents) x 1,000,000/Number of theoretical annual hours worked

ERYTECH Pharma has moreover defined the following areas of focus in relation to professional development, for 2014 and 2015:

- Excellence of experience and competencies;
- Better communication to work better together;
- The initiation of external professional practices;
- Communication in English.

These areas of focus have been defined in function of economic outlook and the evolution of jobs, investments, and technologies within the business, and notably, for 2014:

- Internationalization;
- Improvement of the organization ("ERYTECH 2.0");
- The needs of a pharmaceutical company.

For this reason, the training expenditure rate has been maintained above the legal obligations (1.6% of the wage and salary bill, according to the French Labor Code).

## e. Equality of treatment

# Measures taken to promote equality between men and women

During the Board of Directors' meeting of December 4, 2014, ERYTECH Pharma proposed continuing the measures initiated in 2014 with a view to consolidating equality between men and women possessing equal qualifications and skills, and more particularly to give preference to the hiring of women at the "director" level and to give preference to the hiring of men at other levels.

In conformity with the transitional provisions of Law no. 2011-103 of January 27, 2011 relative to the balanced representation of women and men on boards of directors and supervisory boards and relative to professional quality, the proportion of directors of each gender was greater than 20% at December 31, 2014.

#### Measures taken to promote employment and integration of handicapped personnel

Recruitment procedures at ERYTECH Pharma provide for the possible inclusion of disabled persons. Despite the publication of 2014 job offers on the site Handi EM (specialized in job insertion and retention for disabled persons in the pharmaceutical industry), no applications have been received from disabled persons.

#### • Steps taken to fight discrimination

The external recruitment procedure reviews the regulatory requirements in terms of nondiscrimination when hiring. The procedure illustrates these requirements through a list of "prohibited questions."

f. Promotion and compliance with the stipulations of the fundamental conventions of the International Labor Organization as pertains to the respect for freedom of association and the right to collective bargaining, the elimination of discrimination in terms of jobs and professions, the elimination of forced or mandatory work, and the effect of abolition of child labor

The Company's employees conduct their activities in France.

The company complies with the current regulations in this country, namely in terms of:

- freedom of association; The Company's internal rules allow employees to participate in associative
  activities. Indeed, no restrictions or penalties are imposed where its employees are members of
  associations.
- collective bargaining: the Company may negotiate and stipulate one or more collective agreements pursuant to the conditions established under the Labor Code, where the object of such agreement is not covered by the collective agreement applicable to the Company and/or is subject to collective bargaining in compliance with labor law.

• elimination of forced or compulsory work, and the effective abolition of child labor: The Company has no activities in a country in which such practices exist.

• elimination of job-related and professional discrimination.

#### 2 Environmental information

The activities implemented include contract industrial production. These activities therefore result neither in a massive use of raw materials, nor in significant energy consumption, nor any significant discharge of greenhouse gases into the environment, nor use of soil. Furthermore, the activities inherent to the Company do not generate particular auditory nuisances for its employees or neighbors.

Activities are localized within the Bioparc, a health, safety, and environment-focused business park developed as part of the Rockefeller Health Center in Lyon. The Company possesses quantitative elements which allow it to monitor practically all of its consumption in water and electricity (except for consumption pertaining to the common areas due to the ways the building is managed).

The Company has not identified any significant environmental risks associated with its activity such as could lead to establishing a provision against these risks or specifically training its employees with regard to these issues.

To date, the Company has not identified any opportunities for taking steps to protect biodiversity and adapting to the consequences of climate change.

In this setting, the following environmental indicators were chosen as being relevant:

- General environmental policy;
- Sustainable use of resources: energy consumption and water volume;
- Pollution and waste management: quantity of waste sent to a specific treatment center.

#### a. General environmental policy

Despite an environmental impact deemed to be low, the Company and its employees are involved, in terms of sustainable development, in the maintenance of the following actions:

- Destruction and recycling of all unused documents (since the second half of 2013) by a specialized company. Additionally, the company has changed the default settings on its printers to double-sided black-and-white printing. Finally, the company has an electronic document management system and educates staff, by tracking printouts, for the purpose of limiting internal printouts;
- Recycling its packaging, through the use of a collective arrangement within the building;
- Implementation of energy-saving devices: widespread use of timers for lights and air-conditioning.
- Preference given to teleconferences over travel;
- Encouraging employees to give preference to mass transit over personal vehicles.

ERYTECH Pharma chose its location in Lyon, at the heart of a center for health, which is well-served by mass transit, rather than outside of the city so as to limit travel by car.

#### b. Sustainable use of resources

The only energy source used by the Company is electric energy. The following table presents the evolution in annual electricity consumption:

	2012	2013	2014
Electricity consumption (kWh)	283,798	279,558	301,825

For information purposes, 301,825 kWh consumed in 2014 represent 23.5 tons of CO<sub>2</sub>\*.

\* Application of the emissions factor (indirect energy) from the ADEME (French Environment and Energy Management Agency) (carbon base).

Water consumption corresponds to the pharmaceutical company's activities. Water discharged after use is water that comes from washing cycles (sinks, washing machines). Water that has been contaminated by biological or chemical waste is reprocessed.

	2012	2013	2014
Consumption of water (m <sup>3</sup> )	8.37	8.21	8.21

The Company outsources the logistics associated with its activities.

It does not have all the quantitative information enabling it to ensure the exhaustive monitoring of associated  $CO_2$  emissions. Further, the information known is presented in the table below:

	2012	2013	2014
CO <sub>2</sub> emissions associated with professional travel (train & airplane) (T)	44.4	65.8	99.3
CO <sub>2</sub> emissions associated with the transportation of mail and packages (planes & road transportation) (T)	Not Available	Not Available	0.91
CO <sub>2</sub> emissions associated with the shipment of drugs (planes, trains & road transportation) (T)	Not Available	Not Available	Not Available

Intercontinental business trips are frequently necessary due to the international nature of the Company since 2013.

Despite multiple attempts, information relative to CO<sub>2</sub> emissions associated with the shipment of drugs has not been successfully obtained.

## c. Pollution and waste management

Within the context of its SRE activities, ERYTECH focuses the awareness of employees on the rigorous management of their consumables and waste. As such, in 2014, a very large decrease in the volume of expired reagents eliminated (in "Sécuribag") was recorded, reflecting good governance in the management of reagents used.

Further, within the objective of limiting the environmental impact of its waste, the Company arranges for the systematic removal and treatment of its waste resulting from laboratory activities, by a specialized company, with a view to ensuring full traceability through the treatment processes used.

In terms of volumes, quantities picked up and sent to the processing center are as follows:

	2012	2013	2014
Barrels and cans (in liters)	17,085	29,410	34,940
"Securibag" (in Kg)	78	90	1

The desire to align development of the business with that of our region of origin is a key value for the group.

## **3** Information on business practices

## a. Territorial, economic, and social impacts from the company's activity

In 2014, 41.55% of the outlays made when conducting the development of its research projects were external expenditures.

Indeed, the Company has a desire to align development of the business with that of our region, notably by subcontracting certain pre-clinical studies to regional entities, and by creating partnerships with Ecole Vétérinaire de Lyon [the Veterinary School of Lyon] and Université Claude Bernard in Lyon. It also calls on numerous consulting firms in the region (patents, finance, attorneys). Further, in 2014, the Company decided to add a program offered by the Chamber of Commerce and Industry through the Espace Numérique Entreprises [digital business space] for small and medium-sized companies, with a view to changing its information system.

ERYTECH Pharma has chosen to collaborate with ERAI (Entreprise Rhône Alpes International), a structure created by the Rhône Alpes Region, with a view to pursuing its economic development internationally. This choice arose naturally from the Company's volition to foster a strengthening of the attractiveness of Rhône-Alpes, one of the missions of ERAI.

ERYTECH Pharma is also an active member:

- <u>Nationally:</u> in three professional organizations in the field of health and/or biotechnology: Les Entreprises du Médicament (LEEM) [medicinal products companies], France Biotech, and the Société Française des Sciences et Techniques Pharmaceutiques (SFSTP) [the French company for pharmaceutical sciences and technologies].
- <u>At the regional level</u>: of the competition-focused Lyonbiopôle and of Cancéropôle Lyon Auvergne Rhône Alpes, but also joined the Association des Fabricants de l'Industrie Pharmaceutique de la Région Rhône-Alpes (Association of Pharmaceutical Industry Manufacturers in the Rhône-Alpes Region AFIPRAL) in 2014 with the objective of growing the performance of member companies by mobilizing a regional network involving the sharing of industrial know-how.

ERYTECH PHARMA seeks to create close relationships with training institutions and universities, and allows its employees to teach courses during their work time and within their field of expertise.

ERYTECH Pharma regularly participates in symposia, congresses, and annual conferences, notably including, in 2014:

- BIO International Convention in San Diego;
- AACR (American Association for Cancer Research) Annual Meeting in San Diego;
- ISCT (International Society of Cellular Therapy) Annual Meeting in Paris;
- ASH (American Society of Hematology) Annual Meeting in San Francisco.

These meetings allow the Company to meet health care professionals and key opinion leaders with a view to pursuing its areas of development in innovative products and to satisfying unmet medical needs.

# b. Relationships with stakeholders

#### Relationships with its shareholders and investors

All shareholders have access to fall, transparent, and clear information, adapted to the needs of each person and useful for an objective assessment of the Company's growth strategy and results. This financial communications policy is intended to ensure that all shareholders have information in compliance with the practices of the financial marketplace.

A very wide variety of public documents, including those distributed as regulated information, covers the Company's activity, strategy, and financial information and are accessible on the Company's website under the Investors heading, in French and in English. There is also a dedicated email address for investors (erytech@newcap.fr).

In terms of regulated information, the Company releases the annual information required of a listed company. The financial information is supplemented by periodic information and press releases intended for the financial community and more broadly the public, concerning subjects of significant importance for an understanding of the Company's activities and strategy.

The success of the reserved capital increase in the amount of 30 million Euros on October 23, 2014 attests to the Company's influence not only on the European market, but also on the American market. This operation indirectly enhances the visibility of French biotechnology companies and regional know-how in France and abroad. Lastly, the funds raised during this capital increase will ensure the completion of a portion of the biomedical research for which ERYTECH Pharma is the sponsor, and will launch a new clinical study on a therapeutic indication in oncology or hematological oncology. This biomedical research is performed with the goal of providing a tailored response to unmet medical needs in the indications studied.

In 2014, ERYTECH Pharma participated in two trade fairs, in order to meet small shareholders:

- The first, the Village des Actionnaires, took place in Lyon on June 12, 2014,
- And the second, the Actionaria trade fair, took place in Paris on November 21 and 22, 2014.

## • Relationships with its partners

At least once a year, steering committees are organized between the Company and its primary partners, for the purpose of discussing strategy and progress in joint projects.

# • Partnership or sponsorship actions

Through its sponsorship activities, ERYTECH supports associations and projects in the health care field, and notably in the fight against cancer. Their areas of common interest: consistency with our values and our desire for building strong roots in the region.

During 2014, after the sponsorship of Journées Nationales contre la Leucémie [national days against leukemia] on March 29 and 30, employees organized various sales and collections with a view to sponsoring the participation of 2 colleagues in the Course des Héros, in support of the Association Laurette Fugain.

Further, during the company's 10 years of existence, ERYTECH has sought to provide its financial support and show its thanks to the Centre Léon Bérard, its historical partner, which offered it the possibility of producing its first drug candidates upon creation of the company.

# c. Subcontractors + suppliers

ERYTECH Pharma desires to share its values with its suppliers and subcontractors, and encourages regular collaborations, insofar as possible, with a view to building client-supplier and client-subcontractor relationships of trust. This aspect is strengthened by the strategic nature of certain suppliers. As such, the stakes surrounding strategic supplier relationships allow for a closer dialog. These suppliers are specifically monitored internally by dedicated teams, and a single contact person is identified.

The Company also has a supplier selection and monitoring procedure for its business relationships with suppliers for certain critical elements (clinical trials, non-clinical trials, pharmacovigilance, and production unit suppliers). Given the regulatory aspects of the Company's activities, most service providers and suppliers must also comply with the Best Laboratory and/or Clinical and/or Manufacturing Practices.

ERYTECH undertakes to apply SRE principles to its purchasing, selecting goods and services produced and provided in compliance with rigorous environmental, social, and ethical principles. We pursue our involvement in the monitoring of SRE criteria compliance by suppliers, as specified in our internal procedures, giving preference to suppliers who have an SRE policy that complies with the requirements of Grenelle II during the pre-selection stage, all other factors being equal. Indeed, ERYTECH Pharma updated its supplier evaluation questionnaire in 2014, in order to learn about the SRE activities undertaken by its partners. However, no selections have been made since this criterion was added.

The Company's procedures provide for supplier audits based on the type of purchases (pharmaceutical business supplier, new supplier, critical nature, etc.). as well as follow-up audits. However, supplier audits do not incorporate the SRE aspects given the structure of the upstream market.

#### d. Fair dealing

Various policies have been implemented to reinforce the approach to ethics:

- Procurement policy:
  - a limit of €20,000, net of taxes, on authorizations to enter into contracts. Above that limit, authorization from the quality department is mandatory;
  - separation of duties for payments;
  - software barriers and traceability.
- Guide pertaining to the prevention of insider crimes and misconduct;
- Procedure for the management of health relations for the purpose of complying with the "Bertrand law";
- Management procedure for the handling of personal data and designation of an IT and freedoms correspondent on August 29, 2014;
- Travel charter: listing the maximum amount allowed for travel costs.

# e. Measures to promote patient health and safety

At the current stage of its development, none of the medicinal products being developed by the Company today has been marketed or received marketing approval. The development of medicinal products is highly controlled by strict regulation. The various phases in the development of medicinal products require animal tests at the outset (preclinical development) then tests with humans (clinical development). Each of the development phases requires prior authorization delivered by the oversight authorities following approval by the ethics committees.

As part of the research and development activities, the Company implements preclinical studies within a strict framework. For these phases, the Company may make use of service providers who conduct animal experiments. The latter must follow a national procedure pertaining to the protection of animals used for scientific purposes, in conformity with Decree no. 2013-118 of February 1, 2013, which contains, in particular, an obligation to obtain approval prior to conducting any project involving the performance of one or more experimental procedures using animals.

# f. Other actions undertaken to promote human rights

The Company has not undertaken any additional action to promote human rights.