

Translated from French for convenience purposes only



A limited liability company (société anonyme) with capital of €690,953.10
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UPDATE TO THE 2014 REFERENCE DOCUMENT CONTAINING THE HALF-YEAR FINANCIAL REPORT AS OF JUNE 30, 2015



This document was filed with the French *Autorité des marchés financiers* (“AMF”) on December 3, 2015 under number D. 15-0497-A01, in accordance with Article 212-13 IV of its General Regulations (*Règlement Général*). It supplements ERYTECH PHARMA’s 2014 reference document registered with the AMF on June 4, 2015 under number R.15-048 (the “**2014 Reference Document**”).

The 2014 Reference Document and its update may not be used in the context of any securities offering unless completed by a securities note in respect of which the AMF has granted a visa.

This document has been prepared by ERYTECH PHARMA (the “**Company**”) and its signatory therefore assumes responsibility for its contents.

This does not imply that AMF has verified the accounting and financial information presented herein.

This document in a free non binding translation, for information purpose only, of the French language “Actualisation du Document de Référence 2014” as submitted to and registered with the AMF on December 3, 2015 under number D. 15-0497-A01. 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 interim activity report and the interim financial statements.

Copies of the 2014 Reference Document and of this update to the 2014 Reference Document (the “**Update**”) are available free of charge at the registered office of ERYTECH Pharma, Bâtiment Adénine, 60, Avenue Rockefeller 69008 in Lyon, and an electronic version is available on the websites of ERYTECH Pharma (www.erytech.com) and of the AMF (www.amf-france.org).

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PREAMBLE

The sole purpose of the Update is to bring up to date the information reported in the 2014 Reference Document.

The information and data provided in the 2014 Reference Document registered with the AMF on June 4, 2015 under number R.15-048 remain valid subject to the supplements and updates included herein.

Therefore and with respect to the information not requiring any updates since the registration of the 2014 Reference Document, we invite you to refer to the concordance table listing the main sections required by Regulation (EC) 809/2004 implementing the Prospectus Directive, provided on pages 162 to 170 of the Update.

1 RESPONSIBLE PARTIES

1.1 Person Responsible for the Update

Gil Beyen
Chairman and Chief Executive Officer

1.2 Certification by the responsible party for the Update

“I hereby certify that, after having taken all reasonable measures to this effect, that the information contained in this update to the 2014 reference document is, to the best of my knowledge, in accordance with the facts and does not contain any omission likely to affect its import.

I hereby certify that, to the best of my knowledge, the half-year financial statements for the past six months of fiscal year 2015 have been prepared in accordance with applicable accounting standards and present fairly the assets, financial position and results of operations of the Company and of all of the companies included in the consolidation, and that the interim activity report included in Chapter 3 of this update to the 2014 reference document is a fair presentation of the important events that occurred during the first six months of the fiscal year 2015, of their impact on the financial statements, of the main related party transactions and a description of the main risks and uncertainties for the remaining six months of the fiscal year.

I have obtained from the statutory auditors a letter of completion of their work (*lettre de fin de travaux*), in which they state that they have verified the information relating to the financial situation and accounts presented in the update to the 2014 reference document and have read this update to the 2014 reference document in its entirety.

The half-year financial information presented in this update to the 2014 reference document was subject to a report by the statutory auditors included in Chapter 3 of this update to the 2014 reference document.”

December 3, 2015

Gil Beyen

2 SELECTED FINANCIAL INFORMATION

For the purpose of the Update, selected financial information as of December 31, 2014 presented below are extracted from the consolidated financial statements of ERYTECH PHARMA Group under IFRS and selected financial information as of June 30, 2015 and 2014 are extracted from the interim condensed consolidated financial statements of ERYTECH PHARMA Group prepared in accordance with IAS 34 "Interim Financial Reporting".

These selected accounting and operational data should be read in conjunction with the information contained in Chapter 3, "Half-Year Financial Report" of the Update.

- **Consolidated statements of financial position**

ASSETS (amounts in k€)	December 31, 2014	June 30, 2015
NON-CURRENT ASSETS	1,080	994
Intangible assets	31	44
Property, plant, and equipment	967	860
Other non-current financial assets	82	90
Deferred tax assets	-	-
CURRENT ASSETS	39,526	35,107
Cash and cash equivalents	36,988	31,046
TOTAL ASSET	40,607	36,101
TOTAL SHAREHOLDERS' EQUITY	35,824	30,715
TOTAL NON-CURRENT LIABILITIES	525	236
TOTAL CURRENT LIABILITIES	4,258	5,149
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	40,607	36,101

- **Consolidated statements of net income (loss)**

(amounts in k€)	June 30, 2014	June 30, 2015
	(6 months)	(6 months)
Total operating income	722	1,474
Revenues	-	-
Operating loss	(3,183)	(6,863)
Financial income	4	325
Net loss	(3,184)	(6,533)

- **Condensed statements of cash flow**

(amounts in k€)	June 30, 2014	June 30, 2015
Change in working capital	(371)	(873)
Net cash flow used in operating activities	(3,307)	(5,957)
Net cash flow used in investing activities	(162)	(47)
Net cash flow used in financial activities	641	62
Capital increases, net of transaction costs	56	48
Decrease in net cash and cash equivalents	(2,827)	(5,942)

3 HALF YEAR FINANCIAL REPORT

I. KEY FACTS OVER THE PERIOD

- Results and Cash burn in line with expectations
- Cash position of € 31M as of June 30th, 2015
- Resignation of Pierre-Olivier GOINEAU, co-founder & Deputy Chief Executive Officer on January 11, 2015
- ERYTECH initiated a Level 1 ADR program in U.S. and announced plans to conduct a registered initial public offering in the United States
- ERYTECH presented 3 posters at the American Association for Cancer Research (AACR) Annual Meeting from April 18 to 22, 2015 in Philadelphia (United States), including an oral presentation of the full Graspas® phase III clinical trial for patients with ALL and also an overview of the phase IIb for patients with AML.
- IP portfolio reinforced in the United States with a newly granted patent and also the extension of the patent term protection, for its patent entitled “*Medicament for the Treatment of Cancer of the Pancreas*” which was issued by the U.S. Patent and Trademark Office (USPTO) as U.S. Patent No. 8974802
- The Company received the EnterNext Tech 40 label and announced that it was admitted into the Tech 40 index
- ERYTECH announced that its independent data safety monitoring board (DSMB) has conducted the first tolerance analysis of its Expanded Access Program in the ALL and has recommended to continue the enrollment of patients in the EAP without changes to the protocol
- ERYTECH announces two positive safety reviews after the completion of the first cohort in the Company’s US Phase I study with ERY-ASP in Acute Lymphoblastic Leukemia (ALL), and following the treatment of the first three patients with ERY-ASP in combination with Folfox in its Phase II study in pancreatic cancer
- ERYTECH announced the appointment of Iman El-Hariry as Chief Medical Officer, responsible for global medical, clinical and regulatory affairs
- ERYTECH announced the appointment of Eric Soyer as Chief Financial and Chief Operating Officer (CFO/COO) as a replacement for Pierre-Olivier GOINEAU

II. ACTIVITY REPORT

A. Company's situation and results from activities

a. Clinical Trials

➤ GRASPA® in Europe (ERY-ASP)

The Data and Safety Monitoring Board, or DSMB, in charge of monitoring the Phase II / III clinical trial of GRASPA® in relapsed adults and children with ALL met and issued a favourable opinion related to the conduct of this phase III clinical trial according to the original protocol with a total of 80 patients. Based on the results of the completed clinical trials in ALL Phase III, the Company plans to submit a Marketing Authorization Application before the EMA in the second half of 2015.

The European Union has granted GRASPA® an orphan drug designation in the AML.

The Company received the authorization from ANSM (French Medicine Agency) to begin a Phase II B clinical trial in AML. The first patient was enrolled in March.

The independent Data and Safety Monitoring Board (DSMB) in charge of the safety assessment of the Company's Phase IIb study of GRASPA® in Acute Myeloid Leukemia (AML), and after the first positive analysis on the first 30 patients, recommended continuation of the trial without modification.

The Company received the authorization from several European countries for the AML clinical study allowing the enrollment of a larger number of patients.

The Company announced the launch of a Phase 2 clinical trial of ERY-ASP™ for patients with pancreatic cancer.

The Company announced the addition of a new product development candidate, ERY-MET, to the Company's "tumor starvation" dedicated oncology product pipeline.

➤ ERY-ASP in the United States

The Company received the authorization from The United States Food and Drug Administration (FDA) to initiate a Phase Ib clinical trial of its product ERY-ASP®, in the ALL. The principal patient recruitment centers opened are: Chicago, Duke, Columbus.

The US patent office (USPTO) issued a patent protecting ERYTECH's technology in the USA with an exclusivity term until 2029, which can be further extended to 2034.

Internationally, a new U.S. patent was issued to the Company.

b. Research & Development

➤ TEDAC

Erytech has led different experiences over various tumor types testing their sensitivity to L-Asparaginase with the objective to launch a Phase II clinical trial in solid cancer. The induced study results would lead to the selection of a first therapeutic indication in which there will be a Phase II clinical study.

Other trials with other therapeutic enzymes are being conducted following the defined step-plan. The objective to develop a group of products capable of inducing tumor starvation combined with the selection of patients is taking form. The first proof-of-concept on tumor sections are underway. By maintaining the speed of development, and subject to positive results, a first clinical trial could be considered at the very end of 2015.

As of June 30, 2015, the TEDAC program has reached key step n°3 which will allow the Company to qualify for a new portion of the subsidies granted on this program.

➤ Other on-going projects

Alongside the development of ERY-ASP/GRASPA®, Erytech has conducted extensive research to identify additional therapeutic enzymes that could induce tumor starvation and whose encapsulation in red blood cells would be relevant. The Company has received a € 7M funding from BPI France for this research program.

This research program enabled the Company to identify a new drug candidate, ERY-MET, which consists of methionine- γ -lyase (MGL) encapsulated in red blood cells.

In addition to the use of our ERYCAPS platform to encapsulate enzymes to increase their circulating activity and reduce their toxicity, Erytech believes that it can expand the use of its ERYCAPS technology to develop cancer vaccines.

c. Industrial Property

As at June 30, 2015, Erytech owns 12 patent families, in France and in the rest of the world. The Company also has a license from the U.S. National Institutes of Health (USA) on the rights to a diagnostic method in order to determine the effectiveness of L. Asparaginase in a patient.

d. Employees

As at June 30, 2015, the Company has 45 full-time employees.

e. Finance

Comparisons for the Six-Month Periods Ended June 30, 2014 and 2015

Operating Income

We generated operating income of €1,474,406 and €721,980 in the six-month periods ended June 30, 2015 and 2014, respectively, an increase of 104.2%.

The components of our operating income are set forth in the table below. Other income was primarily generated by the CIR and by subsidies received from BPI France for our research projects.

	FOR THE SIX-MONTH PERIOD ENDED JUNE 30,	
	2015	2014
Revenues	€ -	€ -
Other income		
- Research Tax Credit	1,092,097	607,390
- Subsidies	270,440	99,876
- Other income	111,869	14,713
Total Operating Income	1,474,406	721,980

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

The amounts recognized as CIR income represents the expected reimbursement of 30% of qualifying costs incurred by us. The increase in CIR income for the six-month period ended June 30, 2015 compared to the six-month period ended June 30, 2014 is the result of increased costs we incurred in relation to our research projects.

Grants recorded in operating income represent non-reimbursable subsidies. The amounts recorded for the six-month periods ended June 30, 2014 and 2015 relate to grants associated with the TEDAC programs in partnership with BPI France.

Other income totaled €14,713 and €111,869 for the six-month periods ended June 30, 2014 and 2015 respectively. The amount for 2015 represents the sum of internal costs borne by us within the context of the AML study and re-invoiced to Orphan Europe.

Research and Development Expenses

The total amount recorded by us for research and development activities increased from €1,913,985 for the six-month period ended June 30, 2014 to €5,231,340 for the six-month period ended June 30, 2015, an increase of 173.3%.

Our research and development expenses are broken down by nature in the table below:

FOR THE SIX-MONTH PERIOD ENDED JUNE 30,			
	2015	2014	% CHANGE
ERY-ASP	868,010	206,051	321%
TEDAC (ERY-MET / ERY-ADI)	545,111	115,940	370%
Total direct research and development expenses	1,413,121	321,991	339%
Consumables	360,610	142,777	153%
Rental and maintenance	216,316	147,989	46%
Services, subcontracting, and consulting fees	1,049,384	429,361	144%
Personnel expenses ⁽¹⁾	2,053,387	743,039	176%
Depreciation and amortization expense	114,841	101,225	13%
Other	23,680	27,603	-14%
Total indirect research and development expenses	3,818,218	1,591,994	140%
Total R&D expenses⁽²⁾	€5,231,339	€1,913,985	173%

⁽¹⁾ Includes €0 and €657,803 related to the share-based compensation expense for the six-month periods ended June 30, 2014 and 2015, respectively.

⁽²⁾ Of which €766,993 and €3,253,081 related to clinical studies for the six-month periods ended June 30, 2014 and 2015, respectively.

The increase in total research and development expenditures for the six-month period ended June 30, 2014 compared to the six-month period ended June 30, 2015 was primarily the result of a €620,023 increase in third-party services, subcontracting and consulting fees paid to CROs and other service providers for our manufacturing and clinical trials conducted in the first half of 2015 and a €1,310,348 increase in personnel expenses due to increasing headcount and share-based compensation issued to research and development personnel. We also experienced a €217,233 increase in consumables, which was primarily the result of increased purchases of clinical products such as enzyme and blood samples for use in clinical development. We have also experienced a €1,091,130 increase in direct research and development expenses related to ERY-ASP, namely as a result of clinical trials performed in relation to pancreatic cancer and TEDAC, which is expected to continue in future periods given our intention to commence a Phase 1 clinical trial of ERY-MET in 2016.

General and Administrative Expenses

Our general and administrative expenses increased from €1,991,388 for the six-month period ended June 30, 2014 to €3,106,512 for the six-month period ended June 30, 2015, an increase of 56%. The increase of €1,115,124 in general and administrative expenses was primarily due to an increase of €627,563 in services, subcontracting, and fees, associated with the development of

our regulatory and commercialization strategy in the United States, as well as consulting fees and third-party fees in connection with the recruitment of our Chief Medical Officer and Chief Financial Officer in 2015. We also experienced an increase of €558,265 in other costs, primarily the result of share-based warrants issued to board members.

Our general and administrative expenses are broken down by nature as follows:

FOR THE SIX-MONTH PERIOD ENDED JUNE 30,			
	2015	2014	% CHANGE
Consumables	€ 37,029	€ 15,042	146%
Rental and maintenance	196,984	201,540	-2%
Services, subcontracting, and consulting fees	1,123,995	496,432	126%
Personnel expenses ⁽¹⁾	507,665	682,211	-26%
Depreciation and amortization expense	99,122	12,720	679%
Other ⁽²⁾	1,141,718	583,443	96%
Total general and administrative expenses	€3,106,512	€1,991,388	56%

⁽¹⁾ Includes €79,488 and €643,599 related to the share-based compensation expense for the six-month periods ended June 30, 2014 and 2015, respectively.

⁽²⁾ Includes €0 and €512,010 related to the share-based compensation expense to directors for the six-month periods ended June 30, 2014 and 2015, respectively.

Financial Income (Loss)

Our net financial income increased by €321,568 in the six-month period ended June 30, 2015 compared to the six-month period ended June 30, 2014 and is broken down as follows:

FOR THE SIX-MONTH PERIOD ENDED JUNE 30,		
	2015	2014
Financial expense	€(17,937)	€(33,839)
Financial income	343,015	37,349
Net financial income (loss)	€325,078	€3,510

The increase is primarily due to interest income earned on interest-bearing accounts. The increase is due to the investment of the amounts raised during the capital raise on the Euronext market in October 2014.

Cash Flows

	FOR THE SIX-MONTH PERIOD ENDED JUNE 30,	
	2015	2014
Net cash flows used in operating activities	€(5,956,904)	€(3,306,518)
Net cash flows used in investing activities	(46,694)	(161,919)
Net cash flows from financing activities	61,583	641,437
Net decrease in cash and cash equivalents	€(5,942,015)	€(2,827,000)

Our net cash flows used in operating activities were €3,306,518 and €5,956,904 in the first halves of 2014 and 2015, respectively. For the six-month period ended June 30, 2015, our net cash flows used in operating activities increased due to our continued efforts in advancing our research and development programs such as TEDAC as well as increased general and administrative expenses.

Our net cash used in investing activities were €161,919 and €46,694 in 2014 and 2015, respectively. This decrease mainly reflects the fact that our investments in relation to acquiring property and plant equipment for our headquarters in Lyon are now fully completed.

Our net cash flows from financing activities decreased from €641,437 in 2014 to €61,583 in 2015 as a result of the decrease in the number of treasury shares held within the scope of the liquidity agreement.

B. Forecasts

The second half of 2015 will be a major semester regarding the clinical developments with:

- i. The filing of the Marketing Authorization Application (MAA)
- ii. The on-going clinical study and final patients' enrollment in the AML
- iii. The continuation of patient enrollment in the United States for the ALL clinical study with the use of ERY-ASP for adult patients

C. Major events happening from July 1, 2015, to the publication of this report

On July 20, 2015, the Company announced a positive DSMB safety review following the treatment of the first twenty-four patients with ERY-ASP in its Phase 2 study in pancreatic cancer.

D. Information concerning related parties

Relations with related parties during the first half of 2014 are available in the notes to interim condensed consolidated statements issued in compliance with IAS 34 hereafter.

E. Risks & Uncertainties

All risks and uncertainties likely to have a material effect on the company's financial situation and results are presented in the company's Prospectus, which received the visa of the French *Autorité des Marchés Financiers* on June 4, 2015, under the number R.15-048.

Over the period, no changes in the Risk Factors have occurred, neither in their nature nor in their form, and at the date of the publication of this report no other risks nor uncertainties exist for the previous six months of the financial year.

III. INTERIM CONDENSED CONSOLIDATED STATEMENTS FOR THE SIX-MONTH PERIOD ENDED JUNE 30, 2015

CONSOLIDATED STATEMENTS OF NET INCOME (LOSS) AND CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	<i>Notes</i>	<i>SIX MONTHS ENDED JUNE 30,</i>	
		<i>2015</i>	<i>2014</i>
		<i>€</i>	<i>€</i>
<i>Revenues</i>			
<i>Other income</i>	<i>4.1</i>	<i>1,474,406</i>	<i>721,980</i>
<i>Total operating income</i>		<i>1,474,406</i>	<i>721,980</i>
<i>Operating expenses</i>			
<i>Research and development</i>	<i>4.2 to 4.3</i>	<i>(5,231,340)</i>	<i>(1,913,985)</i>
<i>General and administrative</i>	<i>4.2 to 4.3</i>	<i>(3,106,512)</i>	<i>(1,991,388)</i>
<i>Operating loss</i>		<i>(6,863,446)</i>	<i>(3,183,393)</i>
<i>Financial income</i>	<i>4.5</i>	<i>343,015</i>	<i>37,349</i>
<i>Financial expenses</i>	<i>4.5</i>	<i>(17,937)</i>	<i>(33,839)</i>
<i>Financial income (loss)</i>		<i>325,078</i>	<i>3,510</i>
<i>Pre-tax income (loss)</i>		<i>6,538,368</i>	<i>3,179,883</i>
<i>Income tax</i>		<i>5,142</i>	<i>(4,173)</i>
<i>Net loss</i>		<i>(6,533,226)</i>	<i>(3,184,056)</i>
<i>Elements that may be reclassified subsequently to income (loss)</i>			
<i>None</i>			
<i>Elements that may not be reclassified subsequently to income (loss)</i>			
<i>Remeasurement of defined benefit liability (asset)</i>		<i>16,698</i>	<i>(12,121)</i>
<i>Tax effect</i>		<i>(5,749)</i>	<i>4,173</i>
<i>Other comprehensive income</i>		<i>10,949</i>	<i>(7,948)</i>
<i>Total comprehensive loss</i>		<i>(6,522,277)</i>	<i>(3,192,004)</i>
<i>Basic / diluted loss per share (€/share)</i>		<i>(0.95)</i>	<i>(0.57)</i>

CONSOLIDATED STATEMENTS OF FINANCIAL POSITIONS

	Notes	AS OF	
		JUNE 30, 2015	DECEMBER 31, 2014
		€	€
ASSETS			
<i>Non-current assets</i>			
<i>Intangible assets</i>	5.1	44,115	30,951
<i>Property, plant and equipment, net</i>	5.1	860,071	967,474
<i>Other non-current financial assets</i>	5.1	89,784	81,814
<i>Deferred tax assets</i>			
<i>Total non-current assets</i>		993,970	1,080,239
<i>Current assets</i>			
<i>Inventories</i>		184,622	198,356
<i>Trade and other receivables</i>	5.2	266,648	104,870
<i>Other current assets</i>	5.3	3,609,109	2,234,738
<i>Cash and cash equivalents</i>	5.4	31,046,421	36,988,436
<i>Total current assets</i>		35,106,800	39,526,400
TOTAL ASSETS		36,100,770	40,606,639
LIABILITIES AND SHAREHOLDERS' EQUITY			
<i>Shareholder's equity</i>			
<i>Share capital</i>	5.5	688,679	688,276
<i>Premiums related to the share capital</i>	5.5	72,538,487	72,426,817
<i>Reserves</i>	5.5	(35,978,441)	(28,430,754)
<i>Net loss for the period</i>		(6,533,226)	(8,860,036)
<i>Total shareholders' equity</i>		30,715,498	35,824,303
<i>Non-current liabilities</i>			
<i>Long-term provisions</i>	5.6	91,946	88,594
<i>Financial liabilities—non-current portion</i>	5.7	144,459	436,035
<i>Deferred tax liabilities</i>			
<i>Other non-current liabilities</i>			
<i>Total non-current liabilities</i>		236,406	524,629
<i>Current liabilities</i>			
<i>Short-term provisions</i>			
<i>Financial liabilities—current portion</i>	5.7	575,660	333,502
<i>Trade and other payables</i>		3,840,222	2,084,546
<i>Other current liabilities</i>	65.8	732,983	1,839,658
<i>Total current liabilities</i>		5,148,865	4,257,706
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		36,100,770	40,606,639

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(Amounts in euros)

	SHARE CAPITAL	PREMIUMS RELATED TO THE SHARE CAPITAL	RESERVES	INCOME (LOSS)	TOTAL SHAREHOLDERS' EQUITY
At December 31, 2013.....	550,602	42,741,059	(21,560,305)	(8,144,721)	13,586,634
Issue of ordinary shares	762				762
Share premium increase.....		55,336			55,336
Treasury shares	4,704	644,275			648,980
Allocation of prior period loss			(8,144,721)	8,144,721	
Net loss.....				(3,184,056)	(3,184,056)
Actuarial gain (loss)			(7,948)		(7,948)
IFRS 2 expenses			79,488		79,488
At June 30, 2014.....	556,068	43,440,671	(29,633,486)	(3,184,056)	11,179,196
At January 1, 2015.....	688,276	72,426,817	(28,430,754)	(8,860,036)	35,824,303
Issue of ordinary shares	653				653
Share premium increase.....		47,421			47,421
Treasury shares	(250)	64,250			64,000
Allocation of prior period loss			(8,860,036)	8,860,036	
Net loss.....				(6,533,226)	(6,533,226)
Actuarial gain/(loss)			10,949		10,949
IFRS 2 expenses			1,301,402		1,301,402
At June 30, 2015.....	688,679	72,538,487	(35,978,441)	(6,533,226)	30,715,498

CONSOLIDATED STATEMENTS OF CASH FLOW

	<i>SIX MONTHS ENDED JUNE 30</i>	
	<i>Notes</i>	
	<i>2015</i>	<i>2014</i>
	€	€
<i>Net loss</i>	(6,533,226)	(3,184,056)
<i>Expenses (income) with non-cash impact</i>		
<i>Amortization and depreciation</i>	132,963	113,945
<i>Increase in long-term provisions</i>	18,122	25,196
<i>Expense related to share-based payments</i>	1,301,402	79,488
<i>Interest expense</i>	2,392	25,750
<i>Income tax expense (due and deferred)</i>	(5,142)	4,173
<i>Operating cash flow before change in working capital</i>	(5,083,489)	(2,935,504)
<i>Increase/decrease in inventories</i>	13,735	(21,645)
<i>Increase in trade and other receivables</i>	(161,778)	(19,622)
<i>Increase/decrease in other current assets</i>	(1,374,373)	305,357
<i>Increase in trade and other payables</i>	1,755,676	18,958
<i>Decrease in other current liabilities</i>	(1,106,675)	(654,062)
<i>Change in working capital</i>	(873,415)	(371,014)
<i>Net cash flow used in operating activities</i>	(5,956,904)	(3,306,518)
<i>Cash flows from investing activities:</i>		
<i>Acquisition of property, plant and equipment</i>	(20,850)	(154,340)
<i>Acquisitions of intangible assets</i>	(18,644)	(8,777)
<i>Acquisition of other non-current financial assets</i>	(7,200)	—
<i>Disposal of property, plant and equipment</i>		
<i>Disposal of intangible assets</i>		
<i>Disposal of non-current financial assets</i>	—	1,197
<i>Net cash flow used in investing activities</i>	(46,694)	(161,919)
<i>Cash flows from financing activities:</i>		
<i>Capital increases, net of transaction costs</i>	48,074	56,098
<i>Proceeds from borrowings</i>	—	—
<i>Costs of borrowings</i>		
<i>Repayment of borrowings</i>	(50,489)	(63,641)
<i>Treasury shares</i>	63,998	648,980
<i>Net cash flow from financing activities</i>	61,583	641,437
<i>Decrease in cash and cash equivalents</i>	(5,942,015)	(2,827,000)
<i>Cash and cash equivalents at the beginning of the period</i>	36,988,436	15,112,523
<i>Cash and cash equivalents at the close of the period</i>	31,046,421	12,285,523
<i>Net Decrease in cash and cash equivalents</i>	(5,942,015)	(2,827,000)
<i>Supplemental disclosure of cash flows information:</i>		
<i>Cash paid for interest</i>	15,545	7,738

IV. NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The notes are an integral part of accompanying interim consolidated financial statements as of June, 30, 2015. The financial statements were approved by the Board of Directors on September 8, 2015.

The Group comprises the parent company, Erytech Pharma S.A., and a wholly owned subsidiary located in the United States, Erytech Pharma Inc.

I. Description of the company's business

The main activity of the Company is research and development in the treatment of acute leukemia and other orphan diseases.

Since its inception, the Company has focused on:

- The development of a patented technology based on the encapsulation of molecules into red blood cells, offering an innovative approach to the treatment of acute leukemia and other solid tumors. The development of the main product, Graspas®, initiated at the inception of the Company resulted in the issuance of 12 patent families held in its own name. The Company also developed a patented industrial process capable of producing clinical batches of Graspas®, and able to meet demand when the products are commercialized.
- The implementation of clinical programs in order to validate Graspas® initially in terms of safety of use and toxicology through a phase I clinical study in acute lymphoblastic leukemia (ALL) in adult and pediatric patients with relapsed LAL. Based on the results obtained, the Company completed a clinical Phase II study which also demonstrated the safety of use and efficacy of the products in more than 55 patients in ALL. The Company has completed a Phase III clinical trial at the end of which Erytech plans to file a marketing approval application in Europe for Graspas® in the LAL. The Company has also initiated a Phase II study in acute myeloid leukemia (AML).

The business model of the Company is to develop its products until it obtains a marketing approval in Europe then in the United States. Commercial partnerships concluded by Erytech will ensure the distribution of Graspas® in Europe first and then in the United States and the rest of the world. Erytech has the capacity to manufacture products for the sales of Graspas® during the first years of commercialization in Europe through its production unit in Lyon.

II. Major events of the period

Pierre-Olivier Goineau, co-founder of the Company and Deputy Chief Executive Officer, resigned from his positions during the Company's Board of Directors meeting held on January 11, 2015. Pierre-Olivier Goineau remains treasurer and secretary of the Company's U.S. subsidiary, ERYTECH Pharma, Inc.

Iman El-Hariry joined the Company as Chief Medical Officer of the Company's subsidiary, ERYTECH Pharma, Inc., located in Boston, and will be responsible for medical, clinical and regulatory affairs.

During the six-month period ended June 30, 2015, additional warrants (*bons de souscription d'actions*) have been allocated as follows (see note 4.3):

- The Board of Directors meeting held on April 29, 2015 allocated 2,150 BSA2012 to independent members of the Board of Directors;
- In accordance with the 2014 Plan, the Board of Directors meeting held on June 23, 2015 allocated the first tranche of the plan and granted 2,500 BSPCE2014 to a category of Erytech employees with management

status and 3,000 BSA2014 to Dr. El-Hariry working for the Company's subsidiary, ERYTECH Pharma, Inc., located in the United States.

Finally, the Company has not received the research tax credit (*Crédit d'Impôt Recherche* or "CIR") for 2014 as of June 30, 2015 for an amount of €1,523,688; the receivables in the balance sheet as of June 30, 2015 therefore correspond to the research tax credit of the six-month period ended June 30, 2015 and the balance for 2014.

III. Significant accounting policies and methods

According to European regulation 1606/2002 dated July 19, 2002, the consolidated financial statements of the company are prepared in accordance with IFRS (International Financial Reporting Standards) published by the IASB (International Accounting Standards Board) as adopted by the European Union on June 30, 2015.

These standards are available on the European Commission website at the following address (http://ec.europa.eu/internal_market/accounting/ias/index_fr.html).

The interim financial statements, presented in a summary form, have been prepared in accordance with International Financial Reporting Standard IAS 34 ("Interim Financial Reporting").

The interim financial statements do not include all information and notes as presented in the annual financial statements. Therefore, they must be read in conjunction with the financial statements of the Company as of December 31, 2014.

The financial statements are presented in euros which is the functional currency of the Company. All amounts mentioned in the notes to the financial statements are expressed in euros unless otherwise indicated.

Except for the standards applicable as of January 1, 2015 described below, the accounting policies and methods applied in the preparation of interim financial statements are the same as those applied to prepare the financial statements as of December 31, 2014.

Standards, amendments and interpretations effective within the European Union from the period beginning on January 1, 2015

The Group has adopted the following standards, amendments and interpretations applicable as of January 1, 2015:

- IFRIC 21: "Duties and taxes": this interpretation clarifies that tax must be accounted for in accordance with their triggering event as defined by the law regardless of their cost bases. The application of this standard has no effect on the annual financial statements.
- Amendments to IAS 16 (property, plant and equipment) and IAS 38 (Intangible assets) on acceptable depreciation methods. The IASB has indicated that using an amortization method based on revenues is not appropriate because it does not reflect the consumption of economic benefits of an intangible asset. This presumption can be rebutted in certain circumstances.
- Amendments to IFRS 11 "Joint Arrangements" concerning the acquisition of an interest in a joint venture;
- Amendments to IAS 19 "employee benefits" that applies to contributions by staff members or third parties to define benefit plans. Some contributions can now be deducted from the service cost in the period in which the service is provided;
- Annual Improvements to IFRS (December 2013) applicable as of July 1, 2014: these amendments relate mainly to the information on related parties (IAS 24), more specifically clarifications on the concept of performance provided by the "key" staff members of the management, the share-based payments (IFRS 2), including a clarification of the concept of "vesting conditions", segment reporting (IFRS 8) and the information to be provided on grouping criteria and the reconciliation of assets by segment with all the assets of the entity, clarification of the concept of fair value for receivables and short-term debt and the possibility of offsetting of

financial assets and liabilities (IFRS 13 fair value) and, the recognition of contingent consideration in business combinations (IFRS 3).

These new texts have had no material impact on the results and financial position of the group. The standards and interpretations of optional application as of June 30, 2015 have not been applied in advance. However, the group does not anticipate significant impacts related to the implementation of these new texts.

Presentation

The statements of income (loss) classify expenses and income by function.

The comparative information is presented using an identical classification.

The statements of cash flows were prepared according to the indirect method.

The financial statements are prepared in accordance with the accounting principles of going concern and the permanence of accounting methods.

Use of estimates

Preparation of the financial statements in accordance with the rules prescribed by the IFRS requires the use of estimates and the formulation of hypothesis having an impact on the financial statements. 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 main estimates used are described in the annual financial reports.

Segment reporting

In accordance with IFRS 8 Operating Segments, reporting by operating segment is derived from the internal organization of the Company'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 allocate resources and to assess performance.

The current reporting of the company has identified a single operating segment.

The operating segment is subject to individual monitoring for internal reporting purposes, according to performance indicators.

IV. Notes related to the consolidated statements of net income (loss)

4.1 Other operating income

Other operating income consists in the following:

<i>(Amounts in euros)</i>	<i>FOR THE SIX-MONTH PERIOD ENDED JUNE 30,</i>	
	<i>2015</i>	<i>2014</i>
<i>Research Tax Credit</i>	<i>1,092,097</i>	<i>607,390</i>
<i>Subsidies</i>	<i>270,440</i>	<i>99,876</i>
<i>Other income</i>	<i>111,869</i>	<i>14,713</i>
<i>Other operating income</i>	<i>1,474,406</i>	<i>721,980</i>

The operating income is primarily generated by the CIR research tax credit, and the subsidies associated with the pre-clinical research programs in partnership with BPI France.

Other income totaled €14,713 and €111,869 for the six-month periods ended June 2014 and June 2015, respectively. For the six-month period ended June 30, 2015, the other income represents the recharge to Orphan Europe of the internal costs borne by the Company within the context of the AML study in 2015.

The increase in the research tax credit and the grants for the six-month period ended June 30, 2015 compared to the same period in 2014 is due to the increased research and development activity over the two periods.

4.2 Operating expenses by nature

FOR THE SIX MONTH PERIOD ENDED JUNE 30, 2015 (Amounts in euros)	OTHER R&D EXPENSES	CLINICAL STUDIES	INTELLECTUAL PROPERTY	RESEARCH AND DEVELOPME NT EXPENSES	GENERAL AND ADMINISTRATIVE EXPENSES	TOTAL
Consumables	149,485	353,260	—	502,745	37,029	539,774
Rental and maintenance	110,638	158,283	—	268,921	196,984	465,905
Services, subcontracting, and fees	612,608	1,201,881	205,577	2,020,066	1,123,995	3,144,061
Personnel expenses	805,296	1,197,987	50,104	2,053,387	507,665	2,561,052
Other	29,824	240,443	1,112	271,379	1,141,718	1,413,097
Depreciation and amortization expense	13,614	101,227	—	114,841	99,122	213,963
Total	1,721,465	3,253,081	256,793	5,231,340	3,106,512	8,337,852

FOR THE SIX MONTH PERIOD ENDED JUNE 30, 2014 (Amounts in euros)	OTHER R&D EXPENSES	CLINICAL STUDIES	INTELLECTUAL PROPERTY	RESEARCH AND DEVELOPME NT EXPENSES	GENERAL AND ADMINISTRATIVE EXPENSES	TOTAL
Consumables	162,532	40,654	—	203,186	15,042	218,228
Rental and maintenance	69,186	80,626	—	149,812	201,540	351,352
Services, subcontracting, and fees	220,513	246,749	173,611	640,873	496,432	1,137,305
Personnel expenses	460,398	249,979	32,662	743,039	682,211	1,425,250
Other	11,713	64,137	—	75,850	583,443	659,293
Depreciation and amortization expense	16,377	84,848	—	101,225	12,720	113,945
Total	940,719	766,993	206,273	1,913,985	1,991,388	3,905,373

The increase in the “other” caption is due to the granting of BSA2012 to members of the board of directors for an amount of €512,010.

4.3 Personal expenses

The personal expenses are broken down as follows:

FOR THE SIX MONTH PERIOD ENDED JUNE 30, 2015 (Amounts in euros)	OTHER R&D EXPENSES	CLINICAL STUDIES	INTELLECTUAL PROPERTY	GENERAL AND ADMINISTRATIVE EXPENSES	TOTAL
Wages and salaries	451,255	464,499	20,767	248,361	1,184,882
Share-based payments	133,486	505,715	18,602	131,589	789,392
Social security expenses	220,556	227,772	10,735	127,714	586,777
Total Personnel expenses	805,297	1,197,986	50,104	507,664	2,561,051

FOR THE SIX MONTH PERIOD ENDED JUNE 30, 2014 (Amounts in euros)	OTHER R&D EXPENSES	CLINICAL STUDIES	INTELLECTUAL PROPERTY	GENERAL AND ADMINISTRATIVE EXPENSES	TOTAL
Wages and salaries	323,675	173,678	21,268	435,332	953,953
Share-based payments	—	—	—	79,488	79,488
Social security expenses	136,724	76,301	11,394	167,391	391,810

Total Personnel expenses.....	460,399	249,979	32,662	682,211	1,425,251
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As mentioned in the above paragraph “Major events of the period” the following warrants have been allocated during the period:

Allocation of BSA₂₀₁₂ to independent members of the Board of Directors

The Board of Directors meeting held on April 29, 2015 granted 2,150 BSA₂₀₁₂ to independent members of the Board of Directors. In accordance with IFRS 2, the Company performed a valuation of the BSA₂₀₁₂ granted and used the Black-Scholes measurement model to perform this valuation.

The primary assumptions used to determine the fair value of the BSA₂₀₁₂ allocated to senior management are:

- Risk-free rate: 0.07% (according to the zero coupon government bond rates curve);
- Expected dividends: 0%;
- Volatility: 20.5% based on the historical volatility observed on the NextBiotech index;
- Expected maturity: 2.5 years.

The fair value of the BSA₂₀₁₂ was estimated at €512,010 and was fully recorded as of June 30, 2015 in the “other” caption of general and administrative expenses.

“2014 Plan”

In 2014, the Shareholders’ Meeting of the Company allocated 12,000 BSPCE₂₀₁₄ to senior management. In accordance with IFRS 2, this allocation was valued during fiscal year 2014 due to the fact that all the conditions were met at that date, except for a service condition. Consequently, the fair value of this plan of €372,059 is recorded gradually over the duration of the 3-year plan in conformity with IFRS 2. For the six month period ending on June 30, 2015 an expense was recognized for an amount of €59,418 as personnel expenses. The Board of Directors meeting held on June 23, 2015 granted, in accordance with the conditions of the 2014 Plan, the following warrants:

- Completion of the allocation of the first tranche of the BSPCE₂₀₁₄ to a category of employees with management status by identifying the beneficiaries of these warrants. 2,500 warrants were allocated. In accordance with IFRS 2, the Company performed a valuation of the BSPCE₂₀₁₄ granted to these people and used the Black-Scholes measurement model to perform this valuation.

The primary assumptions used to determine the fair value of these BSPCE₂₀₁₄ are:

- Risk-free rate: 0.27% according to the tranche (according to the zero coupon government bond rates curve);
- Expected dividends: 0%;
- Volatility: 20.75% based on the historical volatility observed on the NextBiotech index;
- Expected maturity: 4.3 years according to the tranche.

The fair value of the BSPCE₂₀₁₄ was estimated at €516,735 and was fully recorded as of June 30, 2015 as personnel expenses split as follows: €424,758 for the research and development personnel costs and €91,977 for the general and administrative personnel costs.

Following the recruitment of Dr. EI-Hariry and in accordance with Annex IV-BSA₂₀₁₄ Regulations, all the conditions required to fully allocate the 3,000 BSA₂₀₁₄ were met at the date of recruitment, with the exception of a service condition for tranche 2 and 3. In accordance with IFRS 2, the Company performed a valuation of the BSA₂₀₁₄ granted to Dr. EI-Hariry and used the Black-Scholes measurement model to perform this valuation.

The primary assumptions used to determine the fair value of these BSA₂₀₁₄ are:

- Risk-free rate: between 0.27% and 0.45% according to the tranches (according to the zero coupon government bond rates curve);
- Expected dividends: 0%;
- Volatility: between 19.59% to 20.75% according to the tranches based on the historical volatility observed on the NextBiotech index;
- Expected maturity: between 4.3 and 5.3 years according to the tranches allocated.

The fair value of the BSA₂₀₁₄ was estimated at €622,244. This expense will be recorded gradually over the duration of the 3-year plan in conformity with IFRS 2 (graded vesting method). An expense of €213,234 was recognized under personnel expenses (research and development personnel costs only), for the period ended June 30, 2015.

4.4 Depreciation and amortization expenses

	FOR THE SIX MONTH PERIOD ENDED JUNE 30,	
	2015	2014
(Amounts in euros)		
Clinical studies	101,227	84,848
Research and development expenses	13,614	16,377
Intellectual property expenses	-	-
General and administrative expenses	18,122	12,720
Total depreciation and amortization expenses.....	132,963	113,945

4.5 Financial income and expense

	FOR THE SIX MONTH PERIOD ENDED JUNE 30	
	2015	2014
(Amounts in euros)		
Interest on leases.....	(2,599)	(3,681)
Other finance expenses	(15,338)	(30,158)
Total finance expense	(17,937)	(33,839)
Income from short term investments	256,585	—
Other finance income.....	86,430	37,349
Total finance income	343,015	37,349
	325,078	3,510

Revenues from short-term investments correspond to accrued interest on term deposits as at June 30, 2015. Other financial incomes consist in foreign exchange gains recognized on June 30, 2015.

V. Notes related to the unaudited interim condensed consolidated statements of financial position**5.1 Non-current assets***Intangible assets*

For the six month period ended June 30, 2015, investments related to intangible assets correspond to the acquisition of software licenses.

Property, plant and equipment

The changes in the gross value of the property, plant and equipment are mainly due to the acquisition of office equipment and computers.

Other non-current financial assets

The other non-current financial assets correspond to the deposit paid for the leasing of the Boston office.

There are no new leasing agreements signed over the period.

5.2 Trade and other receivables

	AS OF	
	JUNE 30, 2015	DECEMBER 31, 2014
(Amounts in euros)		
Trade receivables.....	266,648	104,870
Other receivables	—	—
Total trade and other receivables.....	266,648	104,870

As the company does not sell its product candidates, the trade receivables relate exclusively to the re-invoicing of research and development expenses incurred for the AML clinical trial to Orphan Europe.

5.3 Other current assets

	AS OF	
	JUNE 30, 2015	DECEMBER 31, 2014
(Amounts in euros)		
Research Tax Credit	2,615,785	1,523,688
Tax receivables (VAT, etc.) and other receivables	551,623	494,271
Accruals and prepaid expenses.....	441,701	216,779
Other subsidies to be received	-	-
Total.....	3,609,109	2,234,738

The payment of the 2014 research tax credit amounting to €1,523,688 had not been received by the Company as of June 30, 2015. The research tax credit asset as of June 30, 2015 includes the balance for 2014 and 2015 research tax credit.

5.4 Cash and cash equivalents

	AS OF	
	JUNE 30, 2015	DECEMBER 31, 2014
(Amounts in euros)		
Cash and cash equivalents.....	31,046,421	36,988,436
Total cash and cash equivalents as reported in statement of financial position	31,046,421	36,988,436
Bank overdrafts.....	—	—
Total cash and cash equivalents as reported in statement of cash flow	31,046,421	36,988,436

At June 30, 2015, the cash position is composed of the following items: (i) €1.2 million in current accounts and (ii) €29.5 million in term deposits (available subject to an approximately 30-day notice).

At December 31, 2014, the cash position is composed of the following items: (i) €3.0 million in monetary UCITS, (ii) €1.9 million in current accounts and (iii) €32.0 million in term deposits (available subject to an approximately 30-day notice).

5.5 Shareholder's equity

At December 31, 2014, the share capital is composed of a total of 6,882,761 fully paid shares with a nominal value of €0.1 per share.

As the Company listed on NYSE Euronext on May 6, 2013, certain holders of BSPCE₂₀₁₂ wanted to exercise BSPCE₂₀₁₂ subscribed by them. On June 23, 2015, the Board of Directors, acting under the delegations of authority granted by the Extraordinary General Meeting held on 21 May 2012 and on the basis of a list provided by Société Générale, acting as securities registrar, noted that 6,530 new shares were fully subscribed and paid for a total amount of €48,073.86 with €653 corresponding to the nominal value of the shares and €47,420.86 to the premium.

The share capital was increased by a total amount of €653 from €688,276.10 to €688,929.10, divided into 6,889,291 shares with a nominal value of €0.1 each.

5.6 Long-term provisions

The long-term provisions are broken down as follows:

	AS OF	
	JUNE 30, 2015	DECEMBER 31, 2014
(Amounts in euros)		
Provision for retirement indemnities	91,946	88,594
Provisions for litigations	-	-
Total	91,946	88,594

Financial liabilities

Financial liabilities by type

	AS OF	
	JUNE 30, 2015	DECEMBER 31, 2014
(Amounts in euros)		
Financial liabilities		
Financial liabilities related to leases	180,209	220,376
Bank overdrafts	-	-
Reimbursable advances	539,911	549,161
Convertible bonds	-	-
Other	81,000	-
Total financial liabilities	801,119	769,119

Maturity dates of financial liabilities as of June 30, 2015 are as follows:

	LESS THAN ONE YEAR	MORE THAN ONE YEAR	TOTAL
(Amounts in euros)			
Financial liabilities			
Loans			-
Conditional advances.....	508,250	31,661	539,911
Liabilities related to leases.....	67,410	112,798	180,208
Convertible bonds.....			-
Bank overdrafts			-
Total financial liabilities.....	575,660	144,459	720,119

Maturity dates of financial liabilities as December 31, 2014 are as follows:

	LESS THAN ONE YEAR	MORE THAN ONE YEAR	TOTAL
(Amounts in euros)			
Financial liabilities			
Loans			-
Conditional advances.....	257,500	291,661	549,161
Liabilities related to leases.....	76,002	144,374	220,376
Convertible bonds.....			-
Bank overdrafts			-
Total financial liabilities.....	333,502	436,035	769,537

5.7 Other current liabilities

	AS OF	
	JUNE 30, 2015	DECEMBER 31, 2014
(Amounts in euros)		
Taxation and social security	554,873	970,629
Deferred revenue	97,996	368,436
Other payables	80,115	500,593
Total other current liabilities.....	732,983	1,839,658

The Company was given notice in June 2015 to reimburse a subsidy received for the GR-SIL program from BPI France. The amount of the subsidy from inception is €81,000.

The dispute relates to ending of the program by the Company. BPI France considers that the Company has not fulfilled all its declarative requirements relating to this subsidy. The Company has requested further information from BPI France as it considers that the required declarations have been filed.

As of June 30, 2015, a provision of €81,000 has been recorded.

The taxation and social security costs decrease is related to bonuses and the social security charges for the senior management which were accrued as of December 31, 2014.

The decrease of the deferred revenue is mainly due to the subsidy received from BPI France for the TEDAC program. As of June 30, 2015 the Company incurred additional expenses which reduced the deferred revenue related to the subsidy.

The other payables are provisions for the invoices of the PANC 2013-03 program which were not received as at December 31, 2014.

5.8 Related parties

Gil Beyen and Yann Godfrin are senior executives of the Company; Jérôme Bailly is the Company's chief pharmacist. The other related parties are members of the board of directors.

There have been no significant changes since December 31, 2014 in the types of transaction undertaken with related parties.

The Company has no further related parties.

5.9 Financial instruments recorded in the unaudited interim condensed consolidated statements of financial

AS OF JUNE 30, 2015	CARRYING AMOUNT ON THE STATEMENT OF FINANCIAL POSITION	FAIR VALUE THROUGH P&L	LOANS AND RECEIVABLES	DEBT AT AMORTIZED COST	FAIR VALUE
<i>(Amounts in euros)</i>					
Non-current financial assets ⁽¹⁾	89,784		89,784		89,784
Other current assets ⁽¹⁾	3,609,109		3,609,109		3,609,109
Trade and other receivables	266,648		266,648		266,648
Cash and cash equivalents ⁽²⁾	31,046,421	31,046,421			31,046,421
Total financial assets	35,011,962	31,046,421	3,965,541	—	35,011,962
Financial liabilities—Non-current portion ⁽¹⁾ ..	144,459			144,459	144,459
Financial liabilities—Current portion ⁽¹⁾	575,660			575,660	575,660
Trade payables and related accounts ⁽¹⁾	3,840,222			3,840,222	3,840,222
Total financial liabilities	4,560,341	—	—	4,560,341	4,560,341

AS OF DECEMBER 31, 2014	CARRYING AMOUNT ON THE STATEMENT OF FINANCIAL POSITION	FAIR VALUE THROUGH P&L	LOANS AND RECEIVABLES	DEBT AT AMORTIZED COST	FAIR VALUE
<i>(Amounts in euros)</i>					
Non-current financial assets ⁽¹⁾	81,814		81,814		81,814
Other current assets ⁽¹⁾	2,234,738		2,234,738		2,234,738
Trade and other receivables	104,870		104,870		104,870
Cash and cash equivalents ⁽²⁾	36,988,436	36,988,436			36,988,436
Total financial assets	39,409,858	36,988,436	2,421,422	—	39,409,858
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 and related accounts ⁽¹⁾	2,084,546			2,084,546	2,084,546
Total financial liabilities	2,854,083	—	—	2,854,083	2,854,083

⁽¹⁾ The carrying amount of these assets and liabilities is a reasonable approximation of their fair value.

⁽²⁾ Level 2 fair value

5.10 Off balance sheet commitments

There have been no significant changes since December 31, 2014. The company has no other off balance sheet commitments as compared to the year ended December 31, 2014.

5.11 Events after balance sheet date

The company announced on July 20, 2015 a positive DSMB safety review following the treatment of the first 24 patients with ERY-ASP in its Phase 2 study in pancreatic cancer.

5.12 Notes regarding the change in presentation of consolidated financial statements

As part of its initial public offering project in the United States on the Nasdaq, ERYTECH Pharma submitted half-year financial statements whose presentation differs from the historical presentation of the financial statements previously filed with the AMF. For the sake of harmonization, the Company decided to apply the same presentation in the consolidated financial statements filed with the AMF.

These changes relate exclusively to the presentation of net consolidated income statements and the consolidated cash flows.

5.12.1 Consolidated statement of net income

- a) Combination of research and development expenses

All expenditures on R&D costs were combined as a single line item of the consolidated statement of net income. Detailed information is given in the notes.

- b) Removal of the aggregate "current operating income"

The company had decided to present the aggregate "current operating income" in accordance with Recommendation CNC2009-R03 relating to the format of financial statements of companies under international accounting standards. This aggregate was removed.

There is no difference between current operating income and operating income historically presented in the financial statements filed with the AMF.

- c) Change in presentation of the net financial income

The Company's net financial income presented the cost of net financial debt and other financial income and expenses. In the financial statements as at June 30, 2015, the net financial income has been broken down between financial expenses and financial income.

This change in presentation has no significant impact given the fact that the amount of financial expenses mainly correspond to the cost of net financial debt.

This treatment had not been applied for the interim financial statements as at June 30, 2014 previously submitted. The comparative information for the six months ended June 30, 2014 included in these financial statements has been restated. The restatements are presented below:

(amounts in euros)	June 30, 2014 (6 months)		June 30, 2014 (6 months)
	Non-restated		restated
Operating income		Operating income	
Other income	721,980	Other income	721,980
Total Operating income	721,980	Total Operating income	721,980
Research and development expenses	(940,719)		
Clinical trials	(766,993)	Research and development expenses	(1,913,985)
Intellectual property costs	(206,273)		
General and administrative expenses	(1,991,388)	General and administrative expenses	(1,991,388)
Current operating loss	(3,183,393)		
Other operating income and expenses			
Operating loss	(3,183,393)	Total operating	(3,183,393)
Cost of net financial debt	(29,781)	Financial income	37,349
Other income and financial expenses	33,292	Financial expenses	(33,839)
Financial income	3,510	Financial income	3,510
Pre-tax income (loss)	(3,179,883)	Pre-tax income (loss)	(3,179,883)
Income tax	(4,173)	Income tax	(4,173)
Net loss	(3,184,056)	Net loss	(3,184,056)

5.13 Consolidated cash flow

a) Change in presentation of operating grants

The Company decided to change the presentation of subsidies in the statement of cash flows in the financial statements to comply with the industry practice. They were previously presented as a deduction from net income in calculating the cash flow before financial income and taxes, they are now presented in the change in operating working capital (change in other current assets).

This change in presentation has no impact on the amount of net cash flows from operating activities.

b) Change in presentation of cost of net financial debt

The Company decided to present the gross amount of interest expense in the cash flow statements. The impact with the historical presentation is not significant.

c) Change in presentation of changes in working capital

The Company decided to break down the change in working capital in the financial statements to provide more detailed information for this position given its significant aspect.

d) Presentation of additional information

The Company decided to present the amount of interest paid as additional information to the cash flow statement.

The impact of these changes in presentation is not significant to the amount of different captions of cash flows (operating, investing and financing).

This treatment had not been applied for the interim financial statements as at June 30, 2014 previously submitted. The comparative information for the six months ended June 30, 2014 presented in these financial statements has been restated. The restatements are presented below:

<i>(amounts in euro)</i>	<i>June 30, 2014</i>	<i>(amounts in euro)</i>	<i>June 30, 2014</i>
	<i>Non-restated</i>		<i>Restated</i>
<i>Net loss</i>	<i>(3,184,056)</i>	<i>Net loss</i>	<i>(3,184,056)</i>
<hr/>			
<i>Expenses (income) with non-cash impact</i>		<i>Expenses (income) with non-cash impact</i>	
- <i>Amortization and depreciation</i>	<i>113,945</i>	<i>Amortization and depreciation</i>	<i>113,945</i>
- <i>Increase in long-term provisions</i>	<i>25,196</i>	<i>Increase in long-term provisions</i>	<i>25,196</i>
- <i>Expense related to share-based payments</i>	<i>79,488</i>	<i>Expense related to share-based payments</i>	<i>79,488</i>
- <i>part of subsidies transferred to income</i>	<i>-</i>		
- <i>Gain or losses on disposal of assets</i>	<i>-</i>		
<i>Subsidies</i>	<i>(707,266)</i>		
<i>Cost of net financial debt</i>	<i>(29,781)</i>	<i>Interest expense</i>	<i>25,750</i>
<i>Income tax (current and deferred)</i>	<i>4,173</i>	<i>Income tax (current and deferred)</i>	<i>4,173</i>
<i>Operating cash flow before financial income and tax</i>	<i>(3,638,739)</i>	<i>Operating cash flow before change in working capital</i>	<i>(2,935,504)</i>
<i>Tax paid</i>	<i>-</i>		
		<i>Change in inventory</i>	<i>(21,645)</i>
		<i>Change in trade receivables and related accounts</i>	<i>(19,622)</i>
		<i>Change in other current assets</i>	<i>(305,357)</i>
		<i>Change in suppliers and related accounts</i>	<i>18,958</i>
		<i>Change in other current liabilities</i>	<i>(654,062)</i>
<i>Change in working capital</i>	<i>336,252</i>	<i>Change in working capital</i>	<i>(371,014)</i>
<hr/>			
<i>Net cash flow used in operating activities</i>	<i>(3,302,486)</i>	<i>Net cash flow used in operating activities</i>	<i>(3,306,518)</i>
<hr/>			
<i>Cash flows from investing activities</i>		<i>Cash flows from investing activities</i>	
<i>Acquisition of assets</i>	<i>(163,117)</i>	<i>Acquisition of assets</i>	<i>(163,117)</i>
<i>Intangible assets</i>	<i>(8,777)</i>	<i>Intangible assets</i>	<i>(8,777)</i>
<i>Property, plant and equipment</i>	<i>(154,340)</i>	<i>Property, plant and equipment</i>	<i>(154,340)</i>
<i>Financial assets</i>	<i>-</i>	<i>Financial assets</i>	<i>-</i>
<hr/>			
<i>Disposal of assets</i>	<i>1,197</i>	<i>Disposal of assets</i>	<i>1,197</i>
<i>Intangible assets</i>	<i>-</i>	<i>Intangible assets</i>	<i>-</i>
<i>Property, plant and equipment</i>	<i>-</i>	<i>Property, plant and equipment</i>	<i>-</i>
<i>Financial assets</i>	<i>1,197</i>	<i>Financial assets</i>	<i>1,197</i>
<i>Net cash flow used in investing activities</i>	<i>(161,919)</i>	<i>Net cash flow used in investing activities</i>	<i>(161,919)</i>
<hr/>			
<i>Cash flows from financing activities</i>		<i>Cash flows from financing activities</i>	
<i>Capital increases</i>	<i>56,098</i>	<i>Capital increases</i>	<i>56,098</i>
<i>Transaction costs</i>	<i>-</i>	<i>Transaction costs</i>	<i>-</i>

<i>Proceeds from borrowings</i>	-	<i>Proceeds from borrowings</i>	-
<i>Repayment of borrowings</i>	(63,641)	<i>Repayment of borrowings</i>	(63,641)
<i>Treasury shares</i>	648,980	<i>Treasury shares</i>	648,980
<i>Cash paid for interests</i>	(4,031)		
<i>Net cash flow from financing activities</i>	637,407	<i>Net cash flow from financing activities</i>	641,437
<i>Changes in cash and cash equivalents</i>	(2,827,000)	<i>Changes in cash and cash equivalents</i>	(2,827,000)
<i>Cash and cash equivalents at the beginning of the period</i>	15,112,523	<i>Cash and cash equivalents at the beginning of the period</i>	15,112,523
<i>Cash and cash equivalents at the close of the period</i>	12,285,523	<i>Cash and cash equivalents at the close of the period</i>	12,285,523
<i>Changes in net cash and cash equivalents</i>	(2,827,000)	<i>Changes in net cash and cash equivalents</i>	(2,827,000)
		<i>Supplemental disclosure of cash flows information</i>	
		<i>Cash paid for interest</i>	7,738

V. STATUTORY AUDITORS' REPORT ON THE INTERIM FINANCIAL STATEMENTS

(Free translation of a French language original)

Erytech Pharma S.A.

Headquarters : 60, avenue Rockefeller – 69008 Lyon

Share capital : €690,164.10

Statutory auditors' report on the interim financial information as of June 30, 2015

Six month period ended June 30, 2015

In fulfillment of the assignment that was entrusted to us by your general meeting and in accordance with article L.451-1-2 III of French *Code monétaire et financier*, we hereby report to you on:

- the review on the accompanying interim condensed consolidated financial statements of the Company Erytech Pharma S.A., relating to the six month period ended June 30, 2015;
- the verifications of the information included in the half-year activity report.

These interim condensed consolidated financial statements are the responsibility of the Board of Directors. Our responsibility is to express a conclusion on these financial statements based on our review.

I- Conclusion on the financial statements

We conducted our review in accordance with professional standards applicable in France. A review consists primarily of making inquiries of persons responsible for financial and accounting matters and applying analytical procedures. A review is substantially less in scope than an audit conducted in accordance with professional standards applicable in France and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit.

Based on our review, nothing has come to our attention that causes us to believe that the accompanying consolidated financial statements are not prepared in conformity with IAS 34 - standard of the IFRSs as adopted by the European Union applicable to interim financial information.

II- Specific verifications

We also verified the information provided in the interim activity report commenting the interim condensed consolidated financial statements subject of our limited review. We have no observations to formulate regarding their fair presentation and consistency with the interim condensed consolidated financial statements.

(French original signed by)

Lyon, September 25, 2015

KPMG Audit Rhône Alpes Auvergne

Sara Righenzi de Villers
Commissaire aux comptes

Lyon, September 25, 2015

RSM CCI Conseils

Gaël Dhalluin
Associé

VI. CERTIFICATION BY THE PERSON RESPONSIBLE FOR THE HALF-YEAR FINANCIAL REPORT AS OF JUNE 30, 2015

"I hereby certify that, to my knowledge, the financial statements for the six-month period ended June 30, 2015 were prepared in accordance with applicable accounting principles and give a true and fair view of the assets and liabilities, and of the financial position and results of the Company, and that the half-year activity report attached includes a true and fair presentation of major events that occurred during the first six months of the financial year and their impact on the financial statements, the significant transactions with related parties and a description of the main risks and uncertainties mentioned in paragraph II.E for the remaining six months of the year."

Lyon, September 25, 2015

Gil BEYEN

Chairman and Chief Executive Officer

4 COMPANY'S PRESS RELEASES SINCE SEPTEMBER 28, 2015

4.1 Press Release, September 28, 2015



ERYTECH provides business update and financial results for the first half of 2015

*Conference call and webcast (in English) on Tuesday, September 29th
at 14:30 pm CET/08:30 am EST*

- ERY-ASP (GRASPA) enters European registration phase in acute lymphoblastic leukemia (ALL)
- Further EU and U.S. clinical development plans in ALL established
- Ongoing clinical and preclinical development programs on target
- Cash balance of €31.0 million

Lyon (France), September 28th, 2015 – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company developing ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, provides a business update and reports its financial results for the six-month period ending June 30, 2015.

Business Highlights

- Centralized Marketing Authorization Application (MAA) for GRASPA submitted to the European Medicines Agency (EMA) for the treatment of patients with ALL
- U.S. Phase 1 study with ERY-ASP in adult ALL escalated to next dose and protocol amended for faster enrollment
- Thirteen ‘double allergic’ patients treated in Expanded Access Program (EAP) in France
- Further development plans of ERY-ASP/GRASPA in ALL finalized with input of key opinion leaders
- Patient enrollment in the European Phase 2b study in acute myeloid leukemia (AML) on target
- No safety concerns identified in DSMB¹ safety reviews of Phase 2 pancreatic cancer study
- Preparing launch of clinical studies in non-Hodgkin lymphoma (NHL)
- Preclinical development programs progressing
- IP portfolio reinforced
- Executive management team strengthened
- New independent board member added

Financial Highlights

- Net loss of €6.5 million, reflecting increased activity level
- Net cash utilization of €5.9 million, in line with operating plan
- Cash position of €31.0 million on June 30, 2015
- Received EnterNext Tech 40 label
- Initiated Level 1 ADR program in U.S. and announced plans to conduct registered initial public offering in U.S.

¹ A DSMB (data safety monitoring board) is an independent external committee of clinical research experts who review data in ongoing clinical trials with particular attention to safety.

Upcoming Milestones

- Third DSMB review in Phase 2b AML study
- Launch of global pivotal Phase 2 study for the treatment of 'double allergic' ALL patients
- Further update on U.S. Phase 1 ALL study and U.S. development plan
- Launch clinical studies in NHL
- Launch pivotal Phase 3 study in first line ALL
- Launch Phase 1 study with new product candidate ERY-MET
- Results of U.S. Phase 1 study
- Primary results of Phase 2 pancreatic cancer study

"With our lead product candidate filed for marketing authorization in its first target indication in Europe, with our development strategy to extend GRASPA's proposed label and bring the product to the United States, and with the solid progress of our clinical and preclinical pipeline and platform technologies, ERYTECH is gearing up for its next phase of growth. With these key components of our strategy in place, our goal is to become the leading biopharmaceutical company focused on developing, manufacturing and commercializing innovative therapies based on our ERYCAPS platform to treat rare forms of cancer and other orphan diseases"
comments Gil Beyen, Chairman and CEO of ERYTECH.

Business Update

Centralized Marketing Authorization Application (MAA) for GRASPA submitted to the EMA for the treatment of patients with ALL

On September 11, 2015, ERYTECH submitted its MAA for GRASPA to the EMA for the treatment of ALL. The MAA for GRASPA, ERYTECH's lead product candidate, consisting of asparaginase encapsulated in red blood cells, is based on the positive findings of the GRASPALL 2009-06 study, a pivotal Phase 2/3 clinical trial comparing GRASPA to native L-asparaginase in children and adults suffering from relapsed or refractory ALL. If approved, we believe that GRASPA can become the asparaginase of choice for the treatment of pediatric and adult ALL patients that have either relapsed or failed first line treatment or who have an allergic reaction to free-form L-asparaginase.

U.S. Phase 1 study in adult ALL escalated to next dose and protocol amended for faster enrollment

The Phase 1 study with ERY-ASP is a dose escalation study evaluating the safety of ERY-ASP in adults with newly diagnosed ALL. Three centers are currently open for patient recruitment (The University of Chicago, Duke University Medical Center and Ohio State University). Professor Larson, Director of the Hematological Malignancies Clinical Research Program at the University of Chicago, is the principal investigator of the study. The study includes a safety review after each cohort of patients treated and requires FDA approval for moving to the next dose. In June of this year, the study steering committee reviewed the safety data of the first cohort of patients (at dose level of 50 IU/kg). There were no safety concerns and the steering committee recommended escalating ERY-ASP dose to the next dose level of 100 IU/kg. Further, the study has been amended to lower the age for patient inclusion from 40 to 18, and removing waiting time between each patient. The protocol amendment has been submitted to the respective Institutional Review Boards (IRB). ERYTECH expects the study to be completed in 2016.

Thirteen 'double allergic' patients treated in Expanded Access Program (EAP) with GRASPA in France

In 2014, ERYTECH launched an open label Expanded Access Program (EAP) in France to provide access to GRASPA to first line and relapsed ALL patients up to 55 years of age who could not be treated with available forms of asparaginase due to their risk of developing allergic reactions or other adverse events. To date, 13 patients have been treated in this EAP with multiple doses of GRASPA and ERYTECH has received a favorable DSMB safety review of the first seven patients treated. All of the patients treated, a mix of children and adults in first line and relapse, were 'double allergic', i.e. they had developed allergies to both the *E. coli*-derived and the *Erwinia*-derived asparaginase products in their prior treatments. Enrollment will continue in the EAP until ERYTECH starts a global pivotal clinical study in these double allergic patients.

Further development plan for ERYASP/GRASPA in ALL finalized with input from key opinion leaders

Building on the data generated in the clinical studies with ERY-ASP to date and the ongoing studies in double allergic patients in the United States, ERYTECH intends to commence two global pivotal studies in ALL patients aimed at label extension to first line treatment in Europe and at product approval in the United States, first in double allergic patients, later in first line treatment. The first of these global studies ERYTECH intends to start is a pivotal single arm Phase 2 study in double allergic patients. The next will be a pivotal Phase 3 study in first line pediatric ALL patients, also in Europe and the United States. Once the U.S. Phase 1 study is completed, ERYTECH intends to continue with a pivotal Phase 2 study in the United States in adults newly diagnosed with ALL. These development plans have been discussed with clinicians at different clinical advisory board meetings and will be the subject of further discussion with the regulatory authorities, EMA and FDA in the coming months.

Patient enrollment in the European Phase 2b study in acute myeloid leukemia (AML) on target

In 2013, ERYTECH initiated a multicenter, open, randomized, controlled Phase 2b trial evaluating the efficacy and tolerability of GRASPA in the treatment of newly diagnosed AML patients over 65 years of age and unfit for intensive chemotherapy. Today, more than 80% out of a total of 123 patients to be treated have been enrolled in the study in over 20 active centers in France, Spain, Finland, Germany and Italy. Two safety assessments were performed by an external DSMB when 30 patients and 60 patients had been treated in the study. No safety concerns were identified. A third DSMB safety review is scheduled for the fourth quarter of 2015. Primary results of the study at one year follow-up are expected in 2017.

Positive DSMB safety reviews in Phase 2 pancreatic cancer study

The ERY-ASP pancreatic cancer Phase 2 study is a multicenter, randomized trial in second-line treatment of patients with metastatic pancreatic cancer. In this study of approximately 90 patients, conducted in France, ERY-ASP in addition to the standard of care (Gemcitabine or FOLFOX regimen) is being compared to the standard of care alone in a 2-to-1 randomization. The primary endpoint is progression-free survival at 4 months. A pre-planned DSMB safety analysis of the first 24 patients treated was performed in July. The DSMB raised no safety concerns, and recommended the continuation of enrollment in the study. Two earlier DSMB reviews recommended proceeding with the combination of ERY-ASP with Gemcitabine and FOLFOX after safety evaluation of the first three patients in each treatment regimen. Primary results are expected in 2016.

Preparing launch of clinical studies in non-Hodgkin lymphomas

Based on ERYTECH's preclinical studies and available data on the use of asparaginases in non-Hodgkin lymphomas (NHL), ERYTECH believes that ERY-ASP could also be an effective agent against certain forms of NHL. Based on feedback from key opinion leaders, ERYTECH is in the process of preparing clinical trials in diffuse large B-cell lymphoma and Natural Killer T-Cell lymphoma.

Preclinical development programs progressing

Progress has been made in the preclinical development in the field of oncology

- The work done in the government co-funded TEDAC program to broaden the use of ERYTECH's encapsulation technology to other enzymes has led to the identification of two promising new 'tumor starvation' drug candidates, ERY-MET and ERY-ADI. ERY-MET consists of methionine-γ-lyase (MGL) encapsulated inside red blood cells. ERY-ADI is arginine deiminase (ADI) encapsulated in red blood cells. Based on promising preclinical results, ERYTECH intends to continue the development of ERY-MET and ERY-ADI, including initiating clinical trials. The industrial scale-up of the manufacturing is being initiated to enable a Phase 1 study with ERY-MET in 2016, with a Phase 1 study with ERY-ADI expected to follow about one year later.
- In addition to the use of ERYTECH's ERYCAPS platform to encapsulate enzymes to increase their circulating activity and reduce their toxicity, ERYTECH has explored the use of ERYTECH's ERYCAPS technology to develop cancer vaccines. By loading red blood cells with specific antigens and modifying the membrane of the cells subsequently to make them target specific antigen-presenting cells in the liver or the spleen, ERYTECH believes that ERYTECH has promising preclinical research in cancer vaccination applications. In preclinical studies with three different antigens loaded in red blood cells, ERYTECH has observed promising proof-of-concept data in three different tumor models. In these studies, ERYTECH

observed significantly increased antigen-specific T-cell responses and delays in tumor growth when the encapsulated antigens, modified to target the liver or spleen, were injected in mice with tumors, as compared to the injection of the unloaded antigens alone. ERYTECH plans to continue incubating this platform in order to confirm ERYTECH's earlier preclinical data and to determine ERYTECH's development strategy for these earlier-stage programs.

- ERYTECH's ERYCAPS platform also offers attractive development opportunities for enzyme replacement therapies, or ERT, outside of the oncology field. Over the past years, ERYTECH has performed preclinical research with enzymes like phenylalanine hydroxylase in phenylketonuria in collaboration with Genzyme, and ERYTECH is investigating other potential ERT applications as collaboration opportunities.

IP portfolio reinforced

During the first half of 2015, the patent entitled "*Medicament for the Treatment of Cancer of the Pancreas*" has been issued by the U.S. Patent and Trademark Office (USPTO) as U.S. Patent No. 8,974,802. It covers the use of ERY-ASP, ERYTECH's lead product candidate, for the treatment of pancreatic cancer. In accordance with the USPTO's mechanism of patent term adjustment (PTA), the USPTO has added almost a year of additional protection, extending the patent term to October 2029. The patent was filed in 2007 and its counterparts have since been granted in Europe, Australia, Israel and Singapore.

Separately, the USPTO has granted an additional one and a half year of patent term adjustment to ERYTECH's core process patent "*Lysis/Resealing Process for Preparing Erythrocytes*" (U.S. Patent No. 8,617,840), bringing the validity of the patent through at least 2030. In total, ERYTECH has been able to obtain five years of patent term adjustment for this core patent that covers the heart of its encapsulation technology and product candidates like GRASPA/ERY-ASP. The counterparts of this patent were already granted in Europe, Japan, China, Hong-Kong, Australia, India and South Korea.

Earlier this month, the patent entitled "*Erythrocytes Containing Arginine Deiminase*" was issued by the USPTO under U.S. Patent No. 9,125,876. This patent covers the use of ERY-ADI, a tumor starvation product candidate arising from ERYTECH's encapsulation platform. In accordance with the USPTO's mechanism of PTA, this patent received almost a year of additional protection, extending the patent term to April 2027. This patent has already been granted in Europe, China, Japan, Canada, Korea and Australia.

The term of these patents may also be eligible for limited patent term extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments.

ERYTECH's patent portfolio today consists of 12 patent families, covering the technology platform and applications in and outside oncology, and an exclusive license from the U.S. National Institutes of Health covering a diagnostic method to predict the efficacy of L-asparaginase.

Executive management team reinforced

In June, ERYTECH announced the appointment of Iman El-Hariry, M.D., Ph.D., as Chief Medical Officer. Dr. El-Hariry is a clinical oncologist with more than 15 years of global product development experience in the global biopharmaceutical industry, including as VP of Clinical Research with Synta Pharmaceuticals (Boston), Global Head of Oncology at Astellas Pharma, Inc. (Chicago) and Director of Clinical Development at GSK (London). She has successfully led the development and regulatory approvals of different products both in Europe and in the United States. Dr. El-Hariry holds an M.D. from Alexandria Medical School (Alexandria, Egypt) and a Ph.D. from the Imperial College of Science and Medicine (London). As Chief Medical Officer at ERYTECH Inc., based in Boston, Dr. El-Hariry is responsible for global clinical development, medical and regulatory affairs. She had already been advising ERYTECH on a consulting basis since the end of last year.

Earlier this month, ERYTECH also announced the appointment of Eric Soyer as Chief Financial and Chief Operating Officer (CFO/COO). Mr. Soyer brings more than 20 years of experience in executive leadership positions with responsibility for financial and operational functions with established and emerging public and private companies. Over the past eight years, Mr. Soyer served as the CFO of the Lyon based, NASDAQ listed therapeutic ultrasound company EDAP TMS, where he was responsible for finance, administration, investor relations, legal affairs, and human resources. During the past three years at EDAP TMS, Mr. Soyer was also Managing Director of the French affiliate of the group with responsibility for R&D and manufacturing operations and distribution for France, South America and EMEA. Previously, he was the CFO

and Chief Information Officer for Medica, a French leader in nursing homes and post-acute care clinics, and CFO and Legal Director for April Group, a leading French insurance company. He started his career as International Financial Controller at the Michelin Group. Mr. Soyer received his Executive M.B.A. from the HEC Paris School of Management (France), his M.B.A. from the University of Kansas (U.S.) and graduated from ESC Clermont School of Management (France).

New independent board member added

At the general shareholders' meeting in June 2015, Luc Dochez was appointed as an independent member of the Board of Directors of ERYTECH. Mr. Dochez has been the Chief Business Officer and Senior Vice President of Business Development of Dutch-based Prosensa Holding N.V. (NASDAQ: RNA) until its acquisition by Biomarin. In this role, he was the architect of a €500M+ licensing deal with GSK, was heavily involved in Prosensa's IPO on NASDAQ, and led the sale of the company to Biomarin for \$860M. Before Prosensa, Mr. Dochez was VP of Business Development at TiGenix (Euronext: TIG), Director Business Development at Methexis Genomics and a consultant at Arthur D. Little. Mr. Dochez is currently CEO of Tusk Therapeutics, a private immune-therapy company.

Pierre-Olivier Goineau resigned from the Board in January 2015. The Board now consists of two executive member and five independent members.

Financial Update

Net loss of €6.5 million reflecting increased activity level

The financial report for the six months ending June 30, 2015, approved by the board of directors on August 24, 2015, is available on ERYTECH's website (www.erytech.com). The report has been subject to a limited review procedure by ERYTECH's statutory auditors.

ERYTECH's key financial figures for the first half of 2015 compared with the same period of the previous year are summarized below:

Key figures (in thousands of euros):

	H1 2015	H1 2014
Revenues	0	0
Other income	1,474	722
Total operating income	1,474	722
Operating expenses:		
Research & development	(5,231)	(1,914)
General & administrative	(3,107)	(1,991)
Total operating expenses	(8,338)	(3,905)
Operating loss	(6,863)	(3,183)
Financial income	325	4
Income tax	5	(4)
Net result	(6,533)	(3,184)

Net loss for the first half of 2015 was €6.5 million, compared to €3.2 million for the first half of 2014. The €3.3 million increase was mostly due to the €4.4 million increase in operating expenses, both for R&D and G&A activities. The increase in operating expenses was partly compensated by the €0.8 million increase in operating income and the €0.3 million increase in financial income.

- R&D expenses increased by €3.3 million. The increase was primarily the result of a €0.6 million increase in third-party services, subcontracting and consulting fees paid to CROs and other service providers for ERYTECH's manufacturing and clinical trials conducted in the first half of 2015 and a €1.3 million increase in personnel expenses due to increasing headcount and share-based compensation issued to R&D personnel. ERYTECH also experienced a €0.2 million increase in consumables, which primarily related to purchases of clinical products such as enzyme and blood samples. Finally, ERYTECH also experienced a €1.1 million increase in direct research and development expenses related to ERY-ASP as a result of clinical trials performed in relation to pancreatic cancer and TEDAC, which is expected to continue in future periods given ERYTECH's intention to commence a Phase 1 clinical trial of ERY-MET in 2016.

- G&A expenses increased by €1.1 million. The increase was primarily due to a €0.6 million increase in services, subcontracting and fees associated with the development of ERYTECH's regulatory and commercialization strategy in the United States, as well as consulting fees and third-party fees in connection with the recruiting of ERYTECH's Chief Medical Officer and Chief Financial and Chief Operating Officer. ERYTECH also experienced an increase of €0.5 million in other expenses, primarily as a result of share-based warrants issued to board members.
- These increased expenses were mitigated by the €0.8 million increase in operating income, related to higher research tax credits (CIR) for €0.5 million, which reflected the increased effort in R&D activities, as well as a €0.2 million increase in non-refundable grants from BPI France for the TEDAC program and a €0.1 million increase in other income related to the re-invoicing to ERYTECH's partner Orphan Europe of AML study expenses.
- Financial income increased €0.3 million as a result of interest-bearing investments following ERYTECH's October 2014 follow-on offering on Euronext Paris.

Net cash utilization of €5.9 million in line with operating plan

Net cash utilization for the six-month period ended June 30, 2015 was €5.9 million, mainly due to negative cash flows from operating activities, as a result of ERYTECH's continued efforts in advancing ERYTECH's research and development programs as well as increased general and administrative expenses.

Cash position of €31.0 million on June 30, 2015

ERYTECH had a balance sheet with cash and cash equivalents of €31.0 million at end of June 2015, compared with €37.0 million on December 31, 2014.

EnterNext Tech 40 Label received

In an effort to highlight Euronext-listed technology companies, every year EnterNext grants its Tech 40 label to 40 out of over 320 small and midcap technology companies listed on the various Euronext markets. In April 2015, an independent group of European experts selected ERYTECH among the first forty grantees on the basis of its business, financial and stock market performance.

Level 1 ADR program in U.S. initiated and plans to conduct registered initial public offering in U.S. announced

Following the initial public offering of its ordinary shares on Euronext Paris in 2013 and an additional offering of ordinary shares in 2014, in January 2015, ERYTECH announced the launch of an American Depositary Receipt (ADR) Level 1 listing in the United States as part of its strategy to increase visibility with investors in the United States. ERYTECH's ADRs are traded in the U.S. on the over-the-counter (OTC) market under the ticker symbol "EYRY." Each ERYTECH ADR represents one ERYTECH ordinary share as traded on Euronext Paris. The Bank of New York Mellon acts as the depository for the Level 1 ADR program.

In July 2015, ERYTECH announced its plans to conduct a registered initial public offering in the United States. The timing and terms of this initial public offering have not yet been determined.

Next financial updates:

- Financial highlights for the 3rd quarter of 2015: November 3, 2015 (after market close)

Upcoming participations at investor conferences:

- BioEurope, November 2-4 in Munich
- BryanGarnier Healthcare Conference, November 12-13 in Paris
- Jefferies Global Healthcare Conference, November 18-19 in London
- Actionaria, November 20-21 in Paris
- German Equity Forum, November 24-25 in Frankfurt
- ODDO Midcap event, January 7-8 in Lyon
- LifeSci Capital Investor access meeting at JPM, January 11-14 in San Francisco

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Every year over 50,000 patients in Europe and the United States are diagnosed with ALL or AML. For about 80% of these patients, mainly adults and relapsing patients, current forms of L-asparaginase cannot be used due to their toxicity or as a result of allergic reactions. ERYTECH believes that the safety and efficacy profile of ERY-ASP/GRASPA®, as observed in its Phase 2/3 pivotal clinical trial, offers an attractive alternative option for the treatment of leukemia patients.

ERYTECH believes that ERY-ASP has the potential as a treatment approach in solid tumors and is conducting a Phase 2 clinical trial in Europe in patients with metastatic pancreatic cancer. In addition to its current product candidates that focus on using encapsulated enzymes to induce tumor starvation, ERYTECH is exploring the use of its platform for developing cancer vaccines and enzyme replacement therapies.

The EMA and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for ERY-ASP/GRASPA for the treatment of ALL, AML and pancreatic cancer. ERYTECH produces ERY-ASP at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). ERYTECH has entered into licensing and distribution partnership agreements for ERY-ASP for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, who will market the product under the GRASPA® brand name.

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Ticker : EYRY

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4.2 Press Release, October 20, 2015



ERYTECH announces publication of two articles describing clinical results with ERY-ASP/GRASPA

Lyon (France), October 20th 2015 – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, announces the publication of two peer-reviewed manuscripts describing clinical results obtained with ERY-ASP/GRASPA[®].

The first article, published in the September 2015 issue of the American Journal of Hematology, entitled “A Phase 2 study of L-asparaginase encapsulated in erythrocytes in elderly patients with Philadelphia chromosome negative acute lymphoblastic leukemia: the GRASPALL/GRAALL-SA2-2008 study” describes the results of a dose-escalating Phase 2 study, evaluating the safety and efficacy of GRASPA in thirty patients \geq 55 years of age with newly diagnosed Philadelphia negative acute lymphoblastic leukemia (ALL). The study concludes that the addition of GRASPA to standard induction chemotherapy regimen, especially at the 100 IU/kg dose level, is feasible in elderly patients without excessive toxicity and associated with durable asparagine depletion.

The article can be found on-line at: <http://www.ncbi.nlm.nih.gov/pubmed/26094614>

The second article, published in the October 2015 issue of Pancreas, entitled “Asparagine Synthetase Expression and Phase I Study With L-Asparaginase Encapsulated in Red Blood Cells in Patients With Pancreatic Adenocarcinoma” evaluates the expression of asparagine synthetase (ASNS) in over 500 pancreatic cancer tumor biopsies and presents the results of a Phase 1 study in 12 patients with metastatic pancreatic cancer. 79.4% of tumor biopsies analyzed had no or low ASNS expression with high concordance between primary tumor and metastases. In the Phase 1 study, ERY-ASP was well tolerated and no dose limiting toxicities were identified.

The article can be found on-line at: <http://www.ncbi.nlm.nih.gov/pubmed/26355551>

Iman El-Hariry, Chief Medical Officer of ERYTECH, comments: “Both studies provide additional support for the potential use of our lead product candidate ERY-ASP/GRASPA in very difficult to treat patient populations. The use of asparaginase in elderly ALL patients and metastatic pancreatic cancer patients has been limited by excessive toxicity so far. The favorable safety profile observed with ERY-ASP in these patients provided support for our ongoing Phase 1 study in adult ALL in the United States, our ongoing Phase 2 studies in acute myeloid leukemia patients over 65 years of age and our ongoing Phase 2 study in metastatic pancreatic carcinoma.”

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4.3 Press Release, November 3, 2015



ERYTECH reports financial highlights for Q3 2015

Lyon (France), November 3, 2015 – ERYTECH Pharma (Euronext Paris: ERYP), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other oncology indications with unmet medical needs, reports cash balance and revenues for the third quarter of 2015.

ERYTECH ended the third quarter of 2015 with a total net cash position, including short term treasury investments, of € 28.2 million, compared to total net cash position of € 31.0 million at the end of the second quarter of 2015. The total net use of cash amounted to € 2.8 million for the third quarter of 2015, compared to € 3.4 million in the second quarter of 2015.

These results are in line with the expectations and strategy of the company for 2015, which remains focused on the clinical development of its innovative treatments for acute leukemia and other oncology indications in Europe and in the United States.

ERYTECH has five ongoing clinical programs for its lead product candidate, ERY-ASP, which is known under the trade name GRASPA[®] in Europe and Israel. The company has reported positive results from its completed Phase 2/3 pivotal clinical trial in Europe of GRASPA[®] in children and adults with relapsed or refractory acute lymphoblastic leukemia (ALL) based on which it submitted a Marketing Authorization Application dossier to the European Medicines Agency in September of this year, and currently expects that it could receive European marketing approval by the end of 2016. The four other trials are: a Phase 2b clinical trial in Europe in patients with acute myeloid leukemia (AML), a Phase 2 clinical trial in France in patients with pancreatic cancer, an Expanded Access Program in France to provide GRASPA to ALL patients and a Phase 1 clinical trial of ERY-ASP in the United States in adults with newly diagnosed ALL.

Next financial update:

- Publication of preliminary financial highlights for the fourth quarter of 2015: January 11, 2016 (before market)

Upcoming participations at investor conferences:

- Bryan Garnier European Healthcare Conference, November 12-13, 2015 in Paris
- Jefferies 2015 Global Healthcare Conference, November 18-19, 2015 in London
- Salon Actionaria, November 20-21, 2015 in Paris
- German Equity Forum, November 24-25, 2015 in Frankfurt
- ODDO Midcap Forum, January 7-8, 2016 in Lyon
- J.P. Morgan Healthcare Conference, January 11-14, 2016 in San Francisco

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4.4 Press Release, November 5, 2015



ERYTECH announces data presentations at the American Society of Hematology 57th Annual Meeting

Lyon (France), November 5th 2015 – ERYTECH Pharma (Euronext Paris: ERYP & OTC US: EYRY), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other malignancies with unmet medical needs, announces the upcoming presentation of three abstracts at the American Society of Hematology (ASH) Annual Meeting taking place in Orlando, Florida, USA from December 5-8, 2015.

The poster presentations include:

- Updated Clinical Activity of GRASPA Versus Native L-Asparaginase in Combination with COOPRALL Regimen in a Phase 3 Randomized Trial in Patients with Relapsed Acute Lymphoblastic Leukemia
Abstract #3723 - Monday, December 7, 2015 from 6:00 PM to 8:00 PM – Location: section 612.
- Pharmacokinetic and Pharmacodynamic Characterization of GRASPA Versus Native L-Asparaginase in Combination with COOPRALL Chemotherapy in a Phase 3 Randomized Trial for the Treatment of Patients with Relapsed Acute Lymphoblastic Leukemia (NCT01518517)
Abstract #2492 - Sunday, December 6, 2015 from 6:00 PM to 8:00 PM - Location: section 612
- Evaluation of the Impact of the Presence of Neutralizing L-Asparaginase Antibodies on the Efficacy and Safety of GRASPA in a Phase 3 Randomized Trial Versus Native L-Asparaginase in Patients with Relapsed Acute Lymphoblastic Leukemia
Abstract #3734 - Monday, December 7, 2015 from 6:00 PM to 8:00 PM - Location: section 612

The meeting abstracts can be viewed online through the ASH website at: <http://www.hematology.org>

“The clinical data that will be presented at this year’s ASH meeting provide further insight into the results obtained in our pivotal Phase 2/3 study with GRASPA in Acute Lymphoblastic Leukemia and add to the body of data supporting the potential benefit of GRASPA in combination with chemotherapy in the treatment of ALL,” comments Iman El-Hariry, Chief Medical Officer of ERYTECH.

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ERY-ASP consists of an enzyme, L-asparaginase, encapsulated inside donor-derived red blood cells. L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells, from circulating blood plasma.

Every year over 50,000 patients in Europe and the United States are diagnosed with ALL or AML. For about 80% of these patients, mainly adults and relapsing patients, current forms of L-asparaginase cannot be used due to their toxicity or as a result of allergic reactions. ERYTECH believes that the safety and efficacy profile of ERY-ASP/GRASPA®, as observed in its Phase 2/3 pivotal clinical trial, offers an attractive alternative option for the treatment of leukemia patients.

ERYTECH believes that ERY-ASP has the potential as a treatment approach in solid tumors and is conducting a Phase 2 clinical trial in Europe in patients with metastatic pancreatic cancer. In addition to its current product candidates that focus on using encapsulated enzymes to induce tumor starvation, ERYTECH is exploring the use of its platform for developing cancer vaccines and enzyme replacement therapies.

The EMA and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for ERY-ASP/GRASPA for the treatment of ALL, AML and pancreatic cancer. ERYTECH produces ERY-ASP at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). ERYTECH has entered into licensing and distribution partnership agreements for ERY-ASP for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, which will market the product under the GRASPA® brand name.

ERYTECH is listed on Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: ERYP) and is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes. ERYTECH is also listed in the U.S. under an ADR level 1 program (OTC, ticker EYRY).

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Forward-looking information

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4.5 Press Release, November 18, 2015



ERYTECH wins Deloitte Technology Fast 50 “Promising Biotech Award” for France’s Grand Rhone-Alpes Region

Lyon (France), November 18th 2015 – ERYTECH Pharma (Euronext Paris: ERYP & OTC US: EYRY), the French biopharmaceutical company that develops innovative ‘tumor starvation’ treatments for acute leukemia and other malignancies with unmet medical needs, announced today that it received Deloitte Technology Fast 50 award in the “Promising Biotech” category for France’s Grand Rhone-Alpes region.

Created in 2001, the Deloitte Technology Fast 50 is a prominent award program for growing technology companies. ERYTECH Pharma received the ‘Promising Biotech’ award for achieving in 2014 the largest fund raise among biotech companies in the Grand Rhone-Alpes region. After ERYTECH’s IPO on Euronext Paris in 2013, the 30 million euros fund raise was completed in October 2014. It allowed the company to further and accelerate clinical developments, notably for the treatment of Acute Lymphoblastic Leukemia (ALL). ERYTECH submitted in September 2015 a European Market Authorization Application for the treatment of patients with ALL.

“We are very pleased to have won this ‘Promising Biotech’ award, which follows our EuropaBio award in 2014 for the most innovative European biotech company. It is a clear recognition for all the teams at ERYTECH of their efforts in the recent years. And certainly an additional encouragement to further develop our innovative therapies for the benefit of patients,” commented Gil Beyen, Chairman & Chief Executive Officer of ERYTECH.

About ERYTECH and ERY-ASP (GRASPA®): www.erytech.com

Founded in Lyon, France in 2004, ERYTECH is a clinical-stage biopharmaceutical company developing innovative therapies for rare forms of cancer and orphan diseases. Leveraging its proprietary ERYCAPS platform, which uses a novel technology to encapsulate therapeutic drug substances inside red blood cells, ERYTECH has developed a pipeline of product candidates targeting markets with high unmet medical needs. ERYTECH’s initial focus is on the treatment of blood cancers, including acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML), by depriving tumors of nutrients necessary for their survival. ERYTECH has recently announced positive efficacy and safety results from its completed Phase 2/3 pivotal clinical trial in Europe with its lead product candidate, ERY-ASP, also known under the trade name GRASPA®, in children and adults with relapsed or refractory ALL. ERYTECH also has an ongoing Phase 1 clinical trial of ERY-ASP in the United States in adults with newly diagnosed ALL, and a Phase 2 clinical trial in Europe evaluating GRASPA as a first-line therapy for the treatment of elderly patients with AML, each in combination with chemotherapy.

ERY-ASP consists of an enzyme, L-asparaginase, encapsulated inside donor-derived red blood cells. L-asparaginase depletes asparagine, a naturally occurring amino acid essential for the survival and proliferation of cancer cells, from circulating blood plasma.

Every year over 50,000 patients in Europe and the United States are diagnosed with ALL or AML. For about 80% of these patients, mainly adults and relapsing patients, current forms of L-asparaginase cannot be used due to their toxicity or as a result of allergic reactions. ERYTECH believes that the safety and efficacy profile of ERY-ASP/GRASPA®, as observed in its Phase 2/3 pivotal clinical trial, offers an attractive alternative option for the treatment of leukemia patients.

ERYTECH believes that ERY-ASP has the potential as a treatment approach in solid tumors and is conducting a Phase 2 clinical trial in Europe in patients with metastatic pancreatic cancer. In addition to its current product candidates that focus on using encapsulated enzymes to induce tumor starvation, ERYTECH is exploring the use of its platform for developing cancer vaccines and enzyme replacement therapies.

The EMA and the U.S. Food and Drug Administration (FDA) have granted orphan drug designations for ERY-ASP/GRASPA for the treatment of ALL, AML and pancreatic cancer. ERYTECH produces ERY-ASP at its own GMP-approved and operational manufacturing site in Lyon (France), and at a site for clinical production in Philadelphia (USA). ERYTECH has entered into licensing and distribution partnership agreements for ERY-ASP for ALL and AML in Europe with Orphan Europe (Recordati Group), and for ALL in Israel with TEVA, which will market the product under the GRASPA® brand name.

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5 RISK FACTORS

The Company has reviewed the risks that could have a material adverse effect on its business, its financial position, its results of operations or its ability to achieve its objectives, and considers that no material risks exist other than those indicated below and besides those appearing in Chapter 4 of the 2014 Reference Document and those described in the Half-Year Financial Report as of June 30, 2014 included in Chapter 3 of the Update.

Since registration of the 2014 Reference Document the risk factors listed below have changed and have been updated.

5.1 Operational risks

5.1.1 Risks related to product development

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

The marketing approval for ERY-ASP/GRASPA^{®1} could be delayed, be subject to "post-MA" studies (these two eventualities 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 development of its pipeline of products. 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 compel 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 subject of the study, and force the Company to delay or interrupt the trial. In light of the results of trials, the Company could also decide to abandon development projects that it initially believed to be promising.

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

- 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;
- 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 jeopardize 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;
- Patients included in the trial could, at any time and without justification, stop participating in the trial; 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, in particular, 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, where phase I results were positive, tolerance and safety problems or harmful side effects could occur and delay or interrupt the trials; and

¹ The GRASPA[®] brand has been licensed to Orphan Europe (Recordati Group) to market the product in ALL and AML in Europe and to Teva Group for Israel.

- In the event of serious tolerance or toxicity problems, the trials must be interrupted.

Furthermore, the formulations of the ERY-ASP/GRASPA[®] product used in Europe and in the United States differ, and the regulatory authorities of each jurisdiction may not accept the data from the clinical studies for an alternative formulation of ERY-ASP/GRASPA[®] used in another jurisdiction. This could lead to delays and additional costs in connection with the conduct of additional comparative studies or could require the Company to repeat clinical and non-clinical studies so as to obtain approval in each jurisdiction in which the Company wishes to market ERY-ASP/GRASPA[®].

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 MA for another indication, even if the latter may be related or linked by scientific rationale.

5.1.2 Risks relating to the particular nature of the products

ERY-ASP/GRASPA[®], ERYTECH's lead 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, among other things, those regarding donor compatibility (blood type). The red blood cells used during the manufacturing process of ERY-ASP/GRASPA[®] originate from blood donations prepared and tested by blood banks such as the *Établissement Français du Sang* (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, can occur despite having never been observed with ERY-ASP/GRASPA[®] as of the time of the Update:

- Risks from transmission of infectious agents:
 - viral;
 - bacterial;
 - parasitic; 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 will 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 of the patient. The level of knowledge of the risks inherent to encapsulated molecules will be greater for a molecule that has already been granted a marketing approval 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.

5.1.3 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 is found to be non-compliant, ERYTECH would be required to restart the manufacturing process, 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; and
- Rupture in cold chain.

These risks, should they occur, could have an adverse effect on the activities, financial position, results of operations, 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.

5.1.4 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 is forced to increase its 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.

5.1.5 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 MA. For the development and marketing of products based on its ERYCAPS platform, 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 authorizations to market these products, it is possible that:

- The marketing approvals (MA) for its products will not be obtained by the Company in a timely manner so as to gain a competitive advantage in the targeted markets;
- The health authorities will impose restrictions on use that limit the therapeutic value and potential of the product in these targeted markets;
- Health authorities will require that warnings on the use of the product be added to its instructions or packaging and impose more stringent conditions on advertising;
- The Company will not be able to successfully manufacture and market its future products at a price, reimbursement rate or scale allowing it to be profitable ([see also Section 5.3: Regulatory Risks, in the Update](#));
- The future products of the company will lose their competitive advantage and are rendered obsolete by third-party development of other equally or more innovative products ([see also Section 5.2, Strategic Risks, in the Update](#)); and
- The future products of the Company will not be marketable due to third-party intellectual property rights claims ([see also Section 5.2, Strategic Risks, in the Update](#)).

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 MA is obtained;
- The ease of integration of the product into the current care process;
- The efficient implementation of a scientific publication strategy; and
- The support of opinion leaders.

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

5.1.6 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 5.1.8 and Chapter 16 pertaining to Major Contracts in the Update](#)).

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 will not be able to enter into a partnership under economically reasonable conditions; or
- such a partnership will be challenged; or
- the partners will face difficulties or do not implement all means necessary to obtain the expected results pursuant to 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 on the risks related to competition*).

Such events may have a material adverse effect on the activity, prospects, results of operations, 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 laws and, more generally, optimize its marketing efforts.

5.1.7 Risks related to its ability to penetrate foreign markets

The future profitability of the Company will depend in part on its ability to market its candidate products on markets inside or outside of the United States and Europe. If the Company markets its candidate products on foreign markets it will be subject to additional uncertainties and risks such as:

- economic weaknesses, including inflation, or political instabilities in certain economies and markets;
- difficulties in complying with complex and changing foreign regulations on taxation, accounting and legal requirements that often vary from country to country;

- different medical practices and customs in foreign countries that may affect acceptance of the Company's products on the market;
- tariff and trade barriers;
- any other measure of trade protection, import or export licensing requirements or other restrictive measures imposed by the United States or other foreign governments;
- longer accounts receivable collection time;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for our employees living or travelling abroad;
- uncertainties concerning the workforce in countries where labor unrest is common;
- the language barrier for technical training;
- the reduced protection of intellectual property rights in certain foreign countries, and the resulting prevalence of generic alternatives to the products of the Company;
- fluctuating foreign exchange rates and currency controls;
- differing foreign reimbursement landscapes;
- the uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contractual dispute.

Sales of the Company's products abroad may also be adversely affected by the imposition of government controls, political and economic instabilities, trade restrictions and changes in tariffs.

5.1.8 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.

5.1.8.1 Teva Group

- The Company chose Teva Group (hereinafter “**Teva**”) as exclusive distributor for GRASPA® in the treatment of ALL in Israel ([see also Chapter 16 in the Update](#)).

A licensing and exclusive distribution agreement has been entered into between the parties as of March 28, 2011.

Although this agreement requires that, every year, Teva reach the minimum sales targets after the launch of GRASPA®, the only recourse that the Company has in the event that Teva fails to reach these targets is the termination of this agreement, which would cost it time and considerable resources either for the development of its own marketing capabilities in Israel or for the conclusion of an agreement with a new suitable distributor, if any exists. The Company cannot guarantee that Teva will succeed in obtaining regulatory authorization to market GRASPA. The marketing success of GRASPA® in Israel 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 Teva 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.

5.1.8.2 Orphan Europe (Recordati Group)

The Company has chosen Orphan Europe (Recordati Group) as the exclusive distributor of GRASPA® in the treatment of ALL and AML for 38 countries in Europe, including the European Union ([see also Chapter 16 in the Update](#)).

An exclusive licensing and marketing agreement was entered into by the parties on 23 November 2012.

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

- Orphan Europe (Recordati Group) 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 capacity to sell the treatments developed by the Company. Although this

agreement requires a periodic presentation by Orphan Europe on the marketing plans for estimating future sales of GRASPA[®], Orphan Europe is not subject to minimum sales requirements and the Company cannot guarantee the success of marketing GRASPA[®] in the event of MA. 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 such products developed.

- Milestones payments will be made to the Company: 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 according to the sales level achieved by Orphan Europe. Consequently, if the Company does not reach these milestones, this will have a material adverse effect on its business, financial position, results of operations or growth.
- The termination of the agreement by Orphan Europe in case of a wrongful breach by the Company could result in the payment of significant damages. However, the Company could also terminate the said agreement in the event of serious breach on the part of Orphan Europe, and claim significant damages.
- The non-compliance of guarantees given by the Company could reduce the milestone payments.

The Company expects that the revenues from its products would be adversely affected by a loss or change of current or future distributors of its products. If the Company decides to terminate any distribution agreement, it will either need to enter into a new agreement with, qualify, train and supply a replacement distributor or supply and service customer accounts in those territories itself. Current or future distributors could irreparably harm relations with current and potential local customers and the reputation of the Company with the biopharmaceutical community in general. In the event that the Company is unable to find alternative distributors or to mobilize its own sales force in the territories in which a distributor operates, the supplying of customers, its reputation and its operating results could be negatively affected.

5.1.9 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 likely to be launched on the market within the next five 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 lead product: ERY-ASP/GRASPA[®]. Indeed, if the Company does not successfully develop and, ultimately, market ERY-ASP/GRASPA[®], and if 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.

5.1.10 Risk of failure in the development of its ERYCAPS platform

The Company is only at an early stage in the development and its ERYCAPS platform has not yet, and may never lead to approved or marketable products. Even if the Company is successful in continuing to build its product pipeline, the potential candidate products that the Company has identified may not be suitable for clinical development for reasons such as their harmful side effects, their limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or be accepted by the market. For example, the FDA has required that the Company implement an additional red blood cell washing step in the manufacture of ERY-ASP to reduce the risk of hemolysis for patients. The use of red blood cells as the basis for its ERYCAPS platform could lead to similar risks affecting the ability of its products to be granted a marketing approval and to be accepted by the market. If the Company fails to develop and market its candidate products based on its ERYCAPS encapsulation technology approach, it may not be able to generate revenues from its products and from its collaborations in the future, which would adversely affect its business and prospects.

5.1.11 Risks related to dependence on key scientific partnerships

The loss of some scientific partnerships could hinder the growth of the Company.

The Company currently has and expects to continue to depend on partnerships with public and private research institutions, to conduct an important part of its discovery activities. If one of these partners 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 cancelled. 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.

5.1.12 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 [Chapters 14 and 16](#) of the 2014 Reference Document) are subject to a regulatory and legal framework, including for conflicts of interests. 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 material adverse effect on the activities, financial position, results of operations, reputation or growth of the Company.

Members of the scientific board ([see also Chapter 16 of the 2014 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 material adverse effect on the activities, financial position, results of operations, reputation or growth of the Company.

5.1.13 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, among other things, in:

- Red Blood Cell (RBC) Concentrates; and
- Asparaginase (see also [Chapter 16 of the Update](#)).

EFS (Établissement Français du Sang) is under contract with ERYTECH to supply the Company for its current clinical trials 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 and 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 no longer be able to procure RBC in a sufficient manner and to satisfy the demand of clinical trials and/or of the markets.

The asparaginase market is a closed market 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 for the supply of 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 2014 Reference Document](#));
- the management of its clinical trials to specialized Contract Research Organizations (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 terms 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 material adverse effect on the activities, financial position, results of operations or growth of the Company.

In addition, the contracts that the Company entered into with these companies usually contain limitation of liability clauses in their favor, meaning that the Company will not have recourse to full compensation for potential losses likely to be incurred by the Company in the event of failure.

To reduce its dependence on these companies, the Company's contracts provide for, where possible, an extended notice period before any termination or shutdown of activity in order to have sufficient time to find a new qualified contractor.

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

If products supplied and manufactured by third parties do not comply with regulatory standards, penalties may be imposed on the Company. These eventualities may include fines, injunctions, a refusal by regulatory authorities to allow the Company to pursue its clinical trials, delays, suspension or withdrawal of approvals, seizure or recall of its products and criminal prosecution; all such measures could have a considerable adverse impact on the Company's business.

In the event the Company is forced to 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. Such verification could be costly, time-consuming and could require the attention of the Company's most qualified personnel. In order to show absence of impact due to such 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 compelled to find another supplier/subcontractor which could delay the production, development or marketing of products and increase the manufacturing costs of these products.

5.1.14 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 expose it to chemical and biological risks and require 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 not only from donors but also from patients (see also [Section 5.1.2, Risk related to the particular nature of products from technology in the Update](#)), 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 has not identified any major environmental risks related to its activities, 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 insurance policies taken out by the Company or even not be covered by such policies.

Moreover, compliance with environmental, health and safety regulations imposes on the Company additional costs, and the Company may have to incur significant expenses to comply with future environmental legislation and regulations.

5.2 Strategic risks

5.2.1 Risk related to key personnel

The Company could lose key partners 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 keep 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 and 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 of operations, financial position and prospects.

Moreover, the loss or disability of one or more members of Management could lead to material adverse effects on the activities, financial position and overall growth of the Company. While the Company benefits from a "Key Persons" insurance policy (*described in Section 4.9 of the 2014 Reference Document*) for Gil Beyen and Yann Godfrin, this policy could prove insufficient to compensate for any damages suffered.

5.2.2 Risks related to key objectives not being reached

The Company might not reach its contractual objectives as set out under certain partnerships and partnership agreements.

The Company is bound to academic and commercial partners through financial agreements for research programs or by commercial development agreements. The payment of royalties or public fundings under these agreements are conditioned to the respect of certain commercial, industrial, proof of concept and others objectives.

Consequently, not reaching these objectives will have a material adverse effect on the Company's activities, financial position, results of operations or growth.

In particular, since the founding of the Company in October 2004 and until June 30, 2015, BPI France has awarded the Company €2,275,783 in non-repayable grants and €878,607 in conditional advances. If the Company fails to meet its contractual obligations under the applicable research program financing agreements, and especially if the Company loses its exclusive right for the commercial development of its candidate products, it may be required to repay early the conditional advances (of a total amount of €570,857 as of June 30, 2015). Such early repayment could have a negative impact on the Company's ability to finance its research and development projects, in which case it will have to find other sources of financing that may not be available under reasonable economic terms or may not be available at all.

5.2.3 Risks related to the management of internal growth

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

As part of its development 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:

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

If the Company fails to manage its development or if it encounters unexpected difficulties in its development, this could have a material adverse effect on its activities, financial situation, results of operations or growth.

5.2.4 Risks related to competition

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

The markets in which the Company operates in are well-defined, very competitive and progress rapidly. The Company competes with larger companies that have more industrial and marketing experience and which have access to clearly greater resources.

Consequently, the Company cannot guarantee that its drugs will:

- reach the target markets more rapidly than those 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 breakthroughs;
- be accepted by medical centers, physicians and patients in lieu of existing treatments; and
- be effectively competitive compared to other products treating the same indications.

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

Such events could have a material adverse effect on the activities, results of operations, 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. In addition to 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. Accordingly, 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. Moreover, rapid technological developments by these competitors could render the Company's candidate drugs or its potential products obsolete before the Company is able to make a profit on 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 6.6.4, The current L-asparaginase market, in the Update](#)).

Even if the Company's products are marketed successfully, market recognition could be delayed and the Company may 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 to significant marketing as well as investment efforts. To date, the Company has not undertaken significant marketing activities and has few financial and human resources available for such purposes.

5.2.5 Risks related to confidentiality of Company information and knowledge

The Company may not be able to protect the confidentiality of its information and/or know-how.

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

There is no guarantee that such confidentiality agreements will ensure the intended protection or will not be breached, and that the Company has appropriate solutions against such breaches, or that its trade secrets will not be disclosed to or be developed by its competitors.

More specifically, the Company has no control over the conditions under which third parties with which it contracts, use themselves other third parties, and protect its confidential information.

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

5.2.6 Risks related to the use of information systems

ERYTECH could be the target of cyber-attacks.

In order to maintain the security of its 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 an adverse effect on the activities, financial position, results of operations, reputation or growth of the Company.

5.2.7 Risk related to industrial espionage

ERYTECH could be a target 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 activities.

Such a situation, should it occur, is likely to have an adverse effect on the Company, its activities, financial position, results of operations or growth.

5.2.8 Specific risks related to the use of technologies owned by third parties

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

The Company has signed agreements with researchers working for public and/or private entities ([see Chapter 22 of the 2014 Reference Document](#)). The agreements signed with these entities contain clauses pertaining to intellectual property rights and confidentiality commitments.

It cannot be guaranteed that those agreements will ensure the intended protection or that they will be respected 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 contracted, 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 Chapter 22 of the 2014 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.

5.2.9 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 will not infringe on third-party intellectual property rights or patents and that the Company will not be forced to defend itself against such allegations made 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 do not 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 activities and, more particularly, could force the Company to:

- cease the sale or use of its products;
- acquire the right to use the intellectual property under costly terms; or
- 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, while the laws changed in 2012, 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 laws in the United States provide that the right henceforth belongs to the first inventor who files according to 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 sign licensing agreements with third parties (provided that such 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 respected, 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 material adverse effect on the activities, financial position, results of operations or development of the Company.

The Company will not seek to protect its intellectual property rights in all countries throughout the world and it may not be able to obtain good enforcement of those rights even in countries where it attempts to protect them.

The filing, processing and defense of patents associated with the candidate drugs of the Company in all countries and jurisdictions worldwide would be extremely expensive and its intellectual property rights in certain territories outside the European Union and the United States could be less extensive than within Europe and the United States if such rights are obtained in the United States or in Europe.

Furthermore, the laws of certain foreign countries do not protect intellectual property rights in the same way as European Union law and US federal and state laws do. Therefore, the Company may not be able to prevent third parties from using its inventions in territories other than the United States or the European Union or from selling or importing products manufactured on the basis of its inventions in Europe and in the United States or other jurisdictions.

The legal deadlines for patent protection applications in each foreign jurisdiction are based on the priority dates of each of the Company's patent applications. Competitors may use the Company's technologies in jurisdictions where it does not apply for and does not obtain patent protection in order to develop their own products and may even export illegal products to territories where it has patent protection but where enforcement is not as fundamental as in Europe or the United States. Such products could compete with the Company's products, and patents or any other intellectual property right may not be effective or sufficient to prevent such competition. Even if the Company applies for and obtains patents issued in certain particular jurisdictions, such patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from engaging in such competition.

The legislation of certain foreign countries does not protect intellectual property rights in the same way as the legislation of the European Union and the United States does. Many companies have encountered serious problems in the protection and defense of intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly developing countries, are not favorable to the enforcement of patents and other intellectual property protections, especially those involving biopharmaceutical products and biotechnologies. It may therefore be difficult for the Company to prevent infringement of its patents, even if it obtains them, or misappropriation of its other intellectual property rights.

For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Furthermore, many countries limit the enforceability of patents against third parties, particularly government agencies or government sponsors. In such countries, patents may be of limited benefit or no benefit at all. Patent protection should be considered country by country, which is a burdensome and time-consuming process, with uncertain results.

Therefore, it is possible that the Company will not apply for patent protection in certain countries and therefore would not be able to benefit from patent protection in those countries.

Litigation initiated for the enforcement of the Company's patent rights in foreign jurisdictions could result in substantial expenses and divert its efforts and attention from other aspects of its business, as well as result in the invalidity or a strict interpretation of its patents, prevent its patent applications from succeeding and enable third parties to make claims against it. It is possible that the Company may not prevail in any litigation that it undertakes and that the damages that it would be awarded, if any, would not be commercially significant. Moreover, changes in law and in the rulings of the courts in Europe, the United States and other countries may affect its ability to obtain adequate protection for its technology and for enforcement of its intellectual property. Therefore, the efforts made by the Company for worldwide enforcement of its intellectual property rights may prove unsuitable for obtaining significant commercial benefit deriving from the intellectual property that it develops or licenses.

5.3 Regulatory risks

5.3.1 Risks related to the regulatory environment

Obtaining prior marketing approvals is uncertain.

At this time, none of the Company products, 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 laws and regulations and to controls from regulatory authorities such as the Agence Nationale de Sécurité du Médicament et des Produits de Santé (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 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, restrictions of use and criminal prosecutions.

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. The Company's inability to follow its development schedule or to conduct clinical trials for its products within expected time limits could have a material adverse effect on its activities, financial position, results of operations or growth.

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 being able to successfully conduct clinical trials within stated time limits and with the resources and under the conditions originally set out;
- the Company's trials showing the safety and efficacy of its products as well as a positive risk/benefit for the patient;
- the Company obtaining clinical results that are more promising than those of its competitors;
- the results of clinical trials, although positive, not meeting the applicable regulatory criteria;
- the Company's inability to submit to the competent regulatory authority in its respective jurisdiction the results of clinical trials conducted in another jurisdiction or for other candidate drugs;

- the Company being required to conduct additional clinical trials requested by regulatory authorities;
- the Company's competitors announcing 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 set out in the development plan; and
- the ability of the Company to respond (among other things, 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 marketing.

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.

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

Marketing conditions may become less favorable to the Company.

While it is becoming increasingly difficult to obtain marketing approvals for the reasons mentioned above, government authorities are seeking to facilitate the entry of generic drugs into the market of products already being sold by the implementation of new regulations aimed at modifying patent law and the rules on the exclusivity of data in the main markets.

To the extent that these new regulations may lead to an increase in the costs of obtaining and maintaining product marketing approvals or may limit the economic value of a new product for its inventor, the growth prospects for the pharmaceutical industry and for the Company may diminish.

5.3.2 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. Those regulations require, in some cases, patient consent, confidentiality of the patient's 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 such regulations or if the relevant regulations were to be amended unfavorably, research projects and activities and growth at ERYTECH as well as its related schedule could be penalized.

5.3.3 Risks related to changes in health care reimbursement policies

The conditions for determining the price and reimbursement 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 agencies, 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 to the sufficiency of such reimbursement.

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

Moreover, the legislative and regulatory measures implemented 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.

5.3.4 Risks related to the regulatory status of the Company

The upholding of the status required to manufacture and market Company products is uncertain.

To date, the Company has the regulated status of "Etablissement Pharmaceutique de Fabrication" and of "Etablissement Pharmaceutique d'Exploitation". There is no guarantee that the Company or its partners will retain those designations to manufacture and market any of its products. The Company as well as its products are subject to extensive and very stringent laws and regulations and to controls from regulatory authorities such as the ANSM, the FDA and the EMA. The applicable regulatory requirements are known, but subject to change. The Company must show that it meets the quality and safety criteria defined by relevant authorities.

Any failure to comply with such 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 criminal prosecution.

If the Company or its partners fail to maintain such status, it or they will not be able to manufacture and/or sell the relevant product in the jurisdiction concerned; this would have a material adverse effect on the Company's activities, financial position, results of operations or growth.

5.4 Financial risks

5.4.1 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 tax losses since the beginning of its activities in 2004. As of December 31, 2014 and as of June 30, 2015, the cumulative losses amounted, respectively, to €37.3 million under IFRS and €42.5 million under IAS 34, "Interim Financial Reporting". These operating losses are principally due 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 Update, neither ERY-ASP/GRASPA[®] nor any other of its products had generated 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 be generated, 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 is 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 Chapter 20 of the 2014 Reference Document and to Chapter 3 of the Update.

5.4.2 Risks related to uncertain additional funding

The Group may need to strengthen its equity base or use 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 the development of existing and new products. However, the Group believes that its self-financing capacities will be sufficient to cover its financing needs for the next 24 months. These financing needs, other than committed fixed costs, concern clinical trials that the Group has planned to conduct (refer to Chapter 6 of the Update) as well as expenses involved in research programs assisted by Oséo (refer to Section 9.3 of the 2014 Reference Document). 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 projected time frame.

At the date of this Update, the Group conducted a specific review of its liquidity risk and considers that it is not exposed to a liquidity risk for the next 12 months given the cash and cash equivalents available as at October 31, 2015, or €25.2 million.

It is possible that the Company may fail to obtain additional capital when it is needed, or that such capital may not be available on financial terms acceptable to the Company. If the necessary funds are not available, the Company may need to:

- delay, reduce or eliminate the number or scope of its preclinical and clinical trials program;
- grant licenses on its technologies to partners or third parties; or
- sign new cooperation agreements under conditions that are less favorable to the Company than those it could have obtained under different circumstances.

Moreover, if the Company raises capital by issuing new shares, its shareholders' stakes could be diluted. Debt financing, to the extent that it may be available, could also generate restrictive conditions on the Company and its shareholders.

If one or more of these risks materializes it could have a material adverse effect on the Company, its business, its financial position, its results of operations, its development and its prospects.

5.4.3 Risk of major financial crisis

The Group could be linked to major events related to the economic environment and external to its activities 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 material adverse effect on its financial position, results of operations, and growth.

5.4.4 Risk of dilution

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

6 OVERVIEW OF BUSINESS ACTIVITIES

6.1 General overview

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.

ERYTECH lead product ERY-ASP, named GRASPA^{®2} in Europe and Israel, is positioned in the treatment of acute leukemia, a cancer of the blood and bone marrow, the proliferation of which is rapid and requires urgent treatment. The two most frequent 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[®] has convincing clinical results obtained in several clinical trials and is in the final phase of clinical development in Europe to obtain a marketing approval (MA) in Europe in ALL.

ERY-ASP, developed on the basis of ERYTECH's proprietary technology, consists of an enzyme, the L-asparaginase encapsulated in red blood cells. L-asparaginase is an essential weapon in the treatment of acute leukemia. The enzyme has the property of being able to stop the supply of asparagine to leukemic cells, a naturally occurring substance in the blood that is essential for their growth. The existing treatments, based on free form L-asparaginase, causing the death of cancer cells, have demonstrated their effectiveness in children with ALL; approximately 90% of those having received treatment enter remission and have a high probability of recovery. However, their use is considerably limited by their serious side effects (for example, allergic and immune reactions, coagulation problems, pancreatitis). Clinicians cannot administer them to most adult and older patients, who often cannot tolerate free form asparaginase.

Worldwide sales of the three forms of existing treatments based on L-asparaginase are estimated at approximately \$300 million³. Other leukemia patients, i.e., adults and older adults with ALL as well as children allergic to free form asparaginase, and nearly all patients with AML (more than 80% of patients with acute leukemia) have little or no access to these drugs because they are often too weak to tolerate them.

Through the encapsulation of asparaginase in red blood cells using ERYTECH's proprietary technology, ERY-ASP is uniquely positioned to provide a solution to the significant unmet 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, and thus from 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 has the potential to become a reference drug in the treatment of acute leukemias: ERY-ASP allows fragile patients who currently do not have the possibility, due to their state of general health and induced side effects, to be treated with free form L-asparaginase, and who have therefore smaller chances of survival. For patients who are unable to receive the current treatments based on L-asparaginase, ERY-ASP aims to provide an effective alternative with a considerably improved tolerance profile.

ERYTECH is in the final stages of clinical studies in Europe 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 relapse ALL, (b) the results of a Phase II study performed on patients over 55 years of age with ALL, and (c) the positive results of a Phase

² GRASPA is the brand name approved in Europe for ERY-ASP. It has been licensed to Orphan Europe (Recordati Group) for marketing of the product in ALL and AML in Europe and to TEVA for marketing the product in ALL in Israel.

³ Source: Jazz Pharmaceuticals and ERYTECH.

II/III study (in adults and children in relapse). These studies support the application for Marketing Approval (MA) at the European level, which was filed by the Company with the EMA in September 2015.

In November 2012, ERYTECH signed a marketing and exclusive licensing agreement with Orphan Europe, a subsidiary of Recordati Group specialized in orphan drugs, a leading European pharmaceutical group, to distribute ERY-ASP under the brand name GRASPA[®], in 38 European countries. With the establishment of this partnership, GRASPA[®] may be commercialized efficiently as soon as the necessary approvals are obtained in all European countries; pursuant to this agreement ERYTECH will receive a substantial part of the profits. ERYTECH has also signed a marketing and exclusive licensing agreement with Abic Marketing Limited, a subsidiary of Teva Group (hereinafter “Teva”), to distribute GRASPA[®] in Israel.

The Company has a production unit based in Lyon qualified as a “*Etablissement Pharmaceutique*” and “*Etablissement Exploitant*”, which makes it possible to serve the European and Israeli markets.

ERYTECH is developing possible new indications for ERY-ASP outside the field of leukemias. Initial pre-clinical and clinical results suggest that ERY-ASP could also be effective against certain solid tumors for which therapeutic options are currently limited. ERYTECH launched a Phase II study on pancreatic cancer in 2014, the primary results of which should be presented in the second half of 2016. In addition to the existing candidate-products which are intended to starve tumors through the use of enzymes encapsulated in red blood cells, ERYTECH is exploring other uses of its ERYCAPS platform technology in order to develop cancer vaccines and enzyme replacement therapies.

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 be used to 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 patient survival and quality of life.

6.2 Strategy of the Group

The Company’s objective is to become the leading biopharmaceutical company in the development, production and marketing of innovative therapies based on its ERYCAPS platform in order to treat rare forms of cancer and other orphan diseases. The key elements of our strategy to achieve this objective are as follows:

- **Completing the development and obtaining the marketing approvals in Europe for GRASPA in the treatment of ALL**

In September 2015, the Company submitted an application for a MA to the EMA for GRASPA[®] as a treatment, in combination with chemotherapy, for adult and pediatric ALL patients in relapse, and for the treatment of adult and pediatric ALL patients with hypersensitivity to asparagine.

The Company plans to obtain the marketing approval in Europe by the end of 2016, after which Orphan Europe (Recordati Group) will be responsible for the marketing launch of GRASPA[®] in Europe. The Company will also seek to expand the potential indications of GRASPA[®] for the treatment of ALL in Europe by transforming its current Expanded Access Program (EAP) into a global pivotal trial for double-allergic patients and by conducting a global, randomized pivotal trial of GRASPA[®] as a first-line ALL treatment.

- **Progressing rapidly in the clinical development of ERY-ASP for other indications**

The Company is planning to finalize its ongoing phase II clinical trials of ERY-ASP for the treatment of pancreatic cancer and AML in 2016 and 2017, respectively, and to launch and finalize other clinical studies for other types of cancer. In addition, the Company is also preparing to launch clinical trials of ERY-ASP for the treatment of certain forms of non-Hodgkin’s lymphoma (NHL), such as diffuse large B-cell lymphoma (DLBCL) and Natural Killer T-cell lymphoma (NKTCL).

- **Obtaining approvals to market and sell ERY-ASP in the United States**

The objective of the Company is to rapidly obtain MA for ERY-ASP in the United States first for the treatment of double-allergic ALL patients and, subsequently, for a larger population of ALL patients, based on the results of its current global pivotal clinical trials. The Company has begun clinical trials of ERY-ASP in the United States for the treatment of adults with ALL, and has also planned to seek regulatory approval to market ERY-ASP in the United States for other indications, including AML and solid tumors. The Company has retained all rights to commercialize its candidate products in the United States. Although it believes it is in a position to market its candidates itself, if approved in the United States, thanks to a targeted sales force, the Company may consider collaborations with third parties for the distribution and marketing of the approved products.

- **Leveraging the ERYCAPS platform to develop new, innovative drugs targeting rare forms of cancer and other orphan diseases**

In addition to L-asparaginase, the active ingredient in ERY-ASP, the Company intends to leverage the broad scope of application of its ERYCAPS platform in order to develop new candidate drugs that use other therapeutic drug substances. On the basis of its preclinical research, the Company has identified two other enzymes, methionine- γ -lyase (MGL) and arginine deiminase (ADI), which can be encapsulated in red blood cells in order to induce tumor starvation. The Company plans to launch a Phase I clinical trial in Europe in the first half of 2016 to evaluate the safety of administering encapsulated MGL to cancer patients. The Company is also planning to expand its product pipeline and include other therapeutic approaches, such as cancer vaccination and enzyme replacement therapies. In order to support this strategy, the Company intends to continue to seek robust worldwide intellectual property protection for its platform technology and the resulting drug candidates.

- **Exploring opportunities for collaboration and licensing agreements**

The Company will seek to maximize the value of its proprietary technology platform through the combination of in-house development and carefully selected partnership opportunities. In certain cases, the Company may decide to continue the development and market activities by strengthening its in-house capacities and, in the cases where it will be more appropriate, it will evaluate and pursue collaboration agreements with third parties for the development and marketing of its drug candidates for specific indications and territories. The Company believes that it will benefit in this regard from the experience acquired during the negotiations of the exclusive distribution contracts with Orphan Europe (Recordati Group) and TEVA for ALL and AML respectively in Europe and Israel. The Company may also explore other opportunities for co-development or licensing its platform technology to third parties or via the creation of spin-off companies.

6.3 Advantages and strengths of the Group

ERYTECH has all necessary strengths to establish itself as a mature biotechnology company with revenues from partnership agreements for the distribution of a drug to the doorstep of the market and a pipeline of promising products and indications:

- **ERYCAPS, a proprietary platform that offers a unique positioning to respond to an unmet medical need**

In order to respond to the unmet medical need of fragile patients suffering from acute leukemia, the Company has developed an innovative technology platform known as ERYCAPS designed to use red blood cells in order to boost the efficacy of the administration of active ingredients with a lower risk of side effects, by trapping these active ingredients within red blood cells using the principles of reversible hypotonic and hypertonic osmotic stress. This platform technology uses red blood cells from different donors with specific blood groups which are compatible with the blood group of the patients that will be receiving the treatment. The Company is supplied by blood banks with transfusion-grade, standard packed red blood cells. The red blood cells are submitted to osmotic stress in order to open and close the pores at the surface of the cells and thus allow the therapeutic compounds to be added and trapped within the cell. This encapsulation process (as described in Section 6.4.1) offers many advantages over therapeutic compounds in free form. By protecting the therapeutic compound against detection by the organism's immune system, the encapsulation is designed to reduce potential allergic reactions and allow the therapeutic compound to remain in the body longer.

The cellular membrane also protects the body against the direct toxicity of the active ingredient, which should have the effect of reducing the incidence of side effects. In the case of L-asparaginase, it has been demonstrated that encapsulation extends the half-life of L-asparaginase in free form by a period ranging from one to approximately thirty days, which should reduce the number of injections necessary during treatment as well as the overall dose. The Company believes that these properties make ERY-ASP a promising treatment for patients who cannot tolerate the administration of current treatments based on free form L-asparaginase.

The Company believes that its ERYCAPS platform technology is an innovative approach offering a number of key advantages:

- A longer period of activity.
 - A reduced risk of side effects.
 - High reproducibility with a rapid turnaround on commercial scale.
 - Stability and ease of administration.
 - Broad scope of application.
- **An initial target market with high potential: Acute leukemia**

ERYTECH is positioned as a treatment for acute leukemias, which are most common forms of leukemia, and account 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, who account for approximately 12% of new cases of acute leukemia, have a 5-year survival rate of over 90% due to L-asparaginase-based treatment. All other patients, adults and older adults, and relapsed patients typically cannot tolerate this treatment, despite efforts over decades to adapt it. Adult and older adult patients with ALL have a 5-year survival rate of 15% to 30%, one of the lowest rates of all cancers. Existing asparaginase-based treatments generate sales estimated at approximately \$300 million, largely in children. However, the existing forms of treatment based on L-asparaginase actually target only a limited number of patients with acute leukemia, and the Company believes that a large number of other patients could benefit from a perfected L-asparaginase-based treatment.

- **Convincing clinical results ERY-ASP (GRASPA®): Efficacy and tolerance**

ERYTECH has completed three clinical studies in Europe, in which 100 patients with ALL were treated with GRASPA®. ERYTECH filed application for regulatory market approval with the European Medicines Agency (EMA) to market GRASPA® on the market for ALL in September 2015, based on those three studies (including one Phase I/II and one Phase II/III study) in adult and pediatric patients with ALL in relapse and one Phase II study carried out in patients aged over 55 years. The first study, in children and adults with ALL in relapse, demonstrated good tolerance of the product and identified the appropriate dose. It also demonstrated that an injection of GRASPA® can result in the same depletion of asparagine as up to 8 injections of the free form L-asparaginase. It was followed by a Phase II/III study in the same type of patients. The analysis of the data from the clinical trial, named GRASPIVOTALL or GRASPALL2009-06, after one year of follow-up shows that the trial is convincingly achieving its primary objectives and its secondary objectives confirm a favorable 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 ALL patients aged over 55 years as the first line of treatment. The study showed that, in this category of fragile patients who often cannot be treated with L-asparaginase in induction, GRASPA® was well-tolerated and resulted in complete remission for 70% of patients completing their induction.

In 2013, ERYTECH began a Phase IIb clinical study in 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 I study, again on ALL, in the United States.

- **Strong marketing partnerships: Orphan Europe (Recordati Group) and Teva Group**

ERYTECH has entered into two major partnerships for the marketing of GRASPA[®] in 38 European countries with Orphan Europe (Recordati Group) and in Israel with Teva. Due to the innovative nature of GRASPA[®], its ability to respond to unmet medical needs, and its progress in clinical development, ERYTECH was able to obtain favorable terms, particularly with regard to the sharing of future revenues (representing up to 45% of the net sale price). Both partners have recognized sales 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) provides, among other things, for the payment of €5 million on signing, sharing in the development costs for GRASPA[®] in AML, and future payments of up to €37.5 million, subject to regulatory and sales milestones. ERYTECH will receive a payment for product delivered, and royalties on the sales made 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 subscribed to convertible bonds issued by the Company and that were converted into an equity stake in the Company's share capital worth €5 million at the time of the initial public offering.

- **Favorable conditions for market access: the orphan drug designation, current medical practices and expected medical needs**

ERY-ASP/GRASPA[®] has obtained orphan drug designation in ALL, AML, and pancreatic cancer in Europe from the EMA, and in the United States from the FDA. ERYTECH will therefore be able to take advantage of research subsidies, tax credits, and a marketing procedure with shorter lead times and reduced costs, and will benefit from exclusive marketing after obtaining the marketing approval for the product for 7 and 10 years, in the United States and Europe, respectively. L-asparaginase-based treatment has been included in almost all European and American chemotherapy protocols since the 1970s for pediatric ALL patients. ERY-ASP/GRASPA[®] will be incorporated in or added to current medical regimens. As a result, ERYTECH anticipates a rapid adoption of ERY-ASP/GRASPA[®]. Moreover, these same clinicians treat AML patients and, for this indication, ERY-ASP/GRASPA[®] will capitalize on the clinical experience of these prescribers. The marketing of ERY-ASP/GRASPA[®] will require reasonable promotional and sales resources, given the specialized positioning of the drug (clearly identified and relatively few prescribers, hospital treatment or special care center).

- **Proprietary and industrialized technology:** regulated status of "Etablissement Pharmaceutique" and "Etablissement Exploitant"

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 500 bags of ERY-ASP 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 regulated status of "Etablissement Pharmaceutique" and "Etablissement Exploitant" from ANSM to produce ERY-ASP/GRASPA[®] for the European and Israeli markets. The current production capacity is sufficient to meet the needs of the various clinical trials scheduled and at least for the first two years of commercialization in Europe.

- **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 I clinical trial in adult patients with ALL is in progress, after having obtained authorization for this study from the US Food and Drug Administration (FDA). The Company is relying on studies already conducted in Europe and will also rely on the other studies that will be launched in the United States in order to obtain regulatory approvals for ALL treatment and for other indications like AML and solid tumors. The Company retains all rights to commercialize its candidate products in the United States. Even though the Company believes that it is able to market its product candidates itself, once the marketing approval in the United States has been issued, through a small and, targeted sales force, it may consider agreements with third parties for the distribution and sale of its approval products. Moreover, ERYTECH has established a close partnership with the

American Red Cross of Pennsylvania (Philadelphia, USA) to produce, under the Company's supervision, the batches needed for clinical studies.

- **A promising pipeline: Solid tumors and other orphan diseases**

Asparagine has been shown to also be an essential nutrient for several other types of cancer. In partnership with the MD Anderson Cancer Center (Houston, USA), one of the most renowned hospitals in the world for the treatment of cancer, ERYTECH analyzed various types of solid tumors and determined that asparaginase could effectively combat solid tumors and lymphomas. The first milestone for developing ERY-ASP for solid tumors was achieved with a positive Phase I study in patients with pancreatic cancer, 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. The Company hopes to be able to present the first results of this study in 2016. ERYTECH is also preparing to launch Phase II clinical studies in non-Hodgkin's lymphomas.

The efficacy of the technology to induce tumor starvation has been demonstrated mainly with L-asparaginase, but it is possible to encapsulate other enzymes that starve tumors in red blood cells, such as methionine- γ -lyase (MGL) and arginine-deiminase (ADI). In the TEDAC program, we are developing them as new drug candidates ERY-MET and ERY-ADI.

In addition, the ERYTECH technology platform is versatile and can encapsulate other enzymes and molecules, and opens possibilities to develop cancer vaccines and enzyme replacement therapies, for example.

We have used our ERYCAPS platform to develop a pipeline of drug candidates to treat rare forms of cancer and other orphan drugs. The following table shows our pipeline of products:

Mode of action	Product candidate/ Program	Drug substance	Indication	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3/ Pivotal	Status/Milestones	Commercial rights	
Tumor starvation	ERY-ASP (GRASPA in Europe and Israel)	Asparaginase	ALL	EU					Submitted MAA in September 2015; regulatory approval expected by end of 2016	Europe: Recordati Israel: Teva US and ROW: ERYTECH	
				US					Expect to complete Phase 1/2 clinical trial in 2016 and initiate global pivotal trials		
			AML	EU, then EU/US					Ongoing Phase 2b clinical trial; DSMB review in fourth quarter of 2015; results expected 2017		
			Pancreatic Cancer	EU, then EU/US					Ongoing Phase 2 clinical trial; primary results expected 2016		ERYTECH
			NHL	Global					Expect to initiate clinical trials in 2016 (expected to be Phase 2 based on safety data from other trials)		ERYTECH
	ERY-MET	Methionine-γ-lyase	TBD					Expect to initiate Phase 1 clinical trial in 2016	ERYTECH		
	ERY-ADI	Arginine deiminase	TBD					Continue preclinical development	ERYTECH		
Enzyme replacement	ERY-ERT	Therapeutic enzymes	TBD					Continue preclinical development	ERYTECH		
Tumor vaccination	ERY-VAX	Specific tumor antigens	TBD					Continue preclinical development	ERYTECH		

• 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 special care centers.

• An experienced and highly complementary team

ERYTECH is led by Gil Beyen, Chief Executive Officer of the Company, who brings strong expertise in international development and pharmaceutical partnerships, and by one of its co-founders, Yann Godfrin, Deputy Chief Executive Officer, Chief Scientific Officer, biologist and scientific expert in the development of healthcare products and the industrialization of processes. The management team is also composed of Iman El-Hariry, Chief Medical Officer and oncologist with more than 15 years of experience in product development in the pharmaceutical industry, Jérôme Bailly, Deputy Chief Executive Officer, Chief Pharmacist and Director of Pharmaceutical Operations, who is a Doctor of Pharmacy and holds a degree in chemical engineering with a concentration in pharmaceutical engineering, and Eric Soyer, Chief Financial Officer and Chief Operating Officer, who has more than 20 years of experience in management positions in the financial and operational departments of public and private, new and established companies. The Company relies on a talented team of 45 professionals with diverse, complementary backgrounds and skill sets that are fully in line with 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 have been 4 transactions finalized or in progress in the L-asparaginase market: Shire's project for a hostile takeover of Baxalta for \$30 billion, the acquisition of OPI (France) by EUSA (UK) for €110 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's objective is to create significant strategic value with ERY-ASP/GRASPA[®] and its platform technology.

6.4 ERYTECH's encapsulation technology

6.4.1 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 approximately 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; and
- The body is protected against attack from its contents, and as a result, there are fewer side effects.

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 targeted.

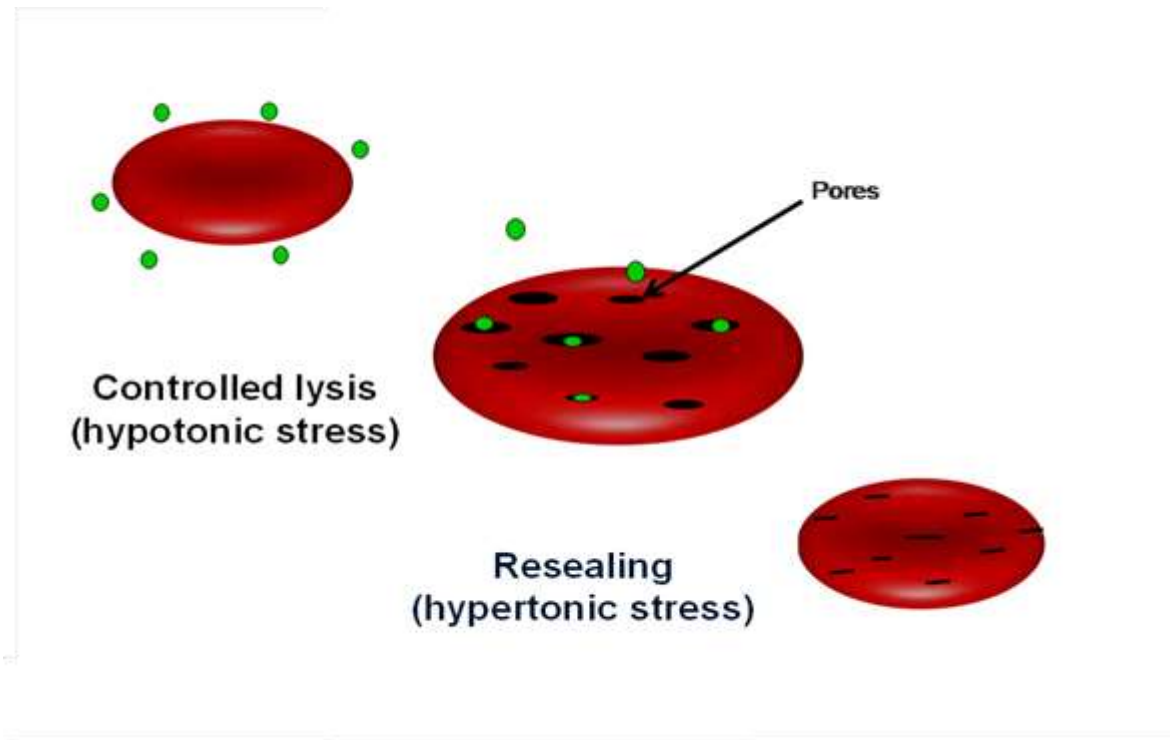
In addition, on the basis of the Company's preclinical studies and the first clinical experience in the field of hemato-oncology, the Company believes that a variety of other therapeutic molecules can be encapsulated in red blood cells in order to induce cancer cells starvation, both in blood cancers or in solid tumors, and develop cancer vaccines and enzyme replacement therapies (*see Section 1.11 Other ERYCAPS development projects*).

6.4.2 Automated and strong industrialized encapsulation process

The ERYCAPS platform uses the Company's proprietary technology to trap active ingredients within red blood cells using the principles of reversible hypotonic and hypertonic osmotic stress. To allow therapeutic compounds to enter the red blood cells, the cells are subjected to a hypotonic solution that causes them to swell and the pores of the cellular membrane to dilate 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. As soon as the desired concentration level of molecules is reached within the red blood cells, the cells are plunged into a hypertonic solution to restore their isotonicity. This procedure draws water outside the cell, thus closing the pores, and makes the membrane impermeable to the macromolecules. Only permeability to very small elements (less than 200 Daltons) is retained. The molecule is thus permanently encapsulated.

The capacity of a red blood cell to dilate, known by the term osmotic fragility, is not uniform and varies depending on the batch of red blood cells. When the Company receives a package of red blood cells from a blood bank, it identifies the key hematological parameters, including the osmotic fragility of the blood sample. Depending on the osmotic fragility measures, the Company is able to calculate the specific amount of osmotic pressure to apply in order to obtain the desired concentration of active substances to be encapsulated, which ensures that quantifiable levels of active substances can be captured in each production batch. This procedure thus reduces the variations in the amount of active substances in each production batch.

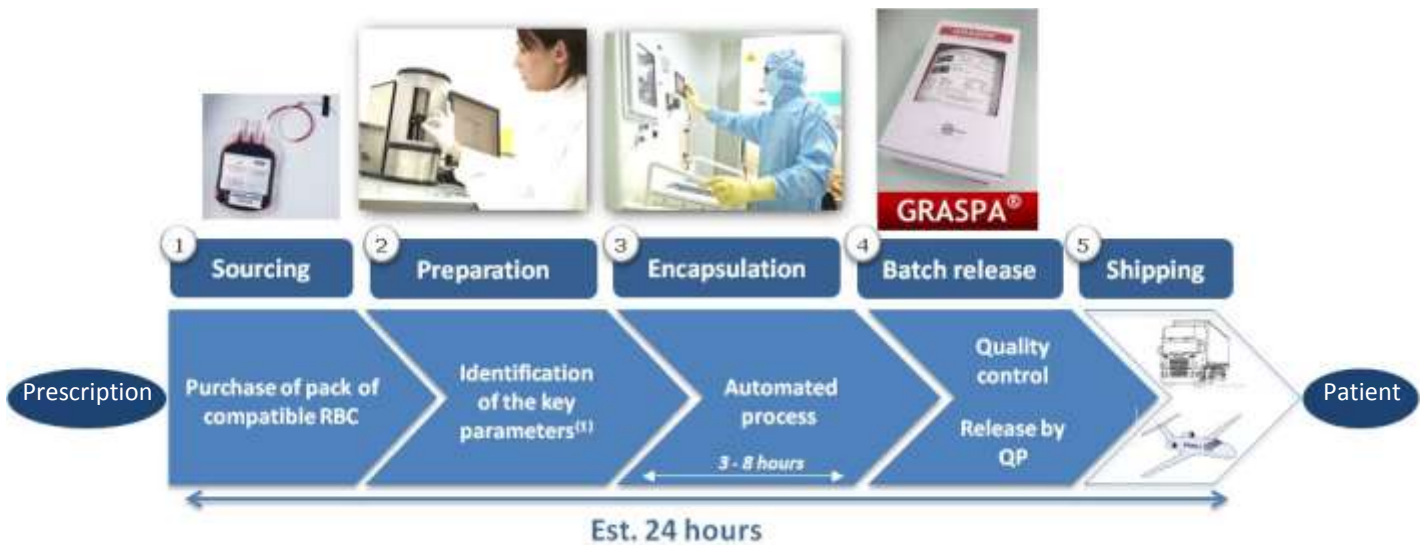
Principle of the encapsulation process



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 core of the ERYTECH patented process (*see Chapter 9 "Research and development, patents and licences" of this Update*)

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. The delivery of ERY-ASP, the first product developed by ERY-TECH on the basis of the ERYCAPS technology, to patients which includes the phase to encapsulate L-asparaginase in the red blood cells, generally takes approximately 24 hours from the end of production until shipping of the product to the hospital. More than 500 bags of ERY-ASP/GRASPA[®] have already been produced and transfused during the five clinical trials conducted by ERYTECH.

An automated and industrialized encapsulation process



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

- its speed: fully automated, the preparation of the products takes only 3 hours;
- its stability: 72 hours (at a temperature of 2-8°C) and 6 hours (at ambient temperature). This allows hospital personnel to perform the necessary blood transfusions at an optimal time and to retain control of the treatment administration procedure. On the basis of the stability studies the Company has performed, it believes that it is able to extend the shelf life of ERY-ASP to at least 5 days.
- its reproducibility: loaded erythrocytes are produced at constant quality, regardless of the initial properties and origin of the red blood cells used. Various control steps ensure the quality of the product before release by the head pharmacist,
- its safety: red blood cells of transfusion quality are obtained from blood banks operating in accordance with the highest quality standards and following a quality control process that is strengthened at each production step.

The ERYTECH production unit is based in Lyon and there are 12 employees dedicated to the production. 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 the regulated status of “*Etablissement Pharmaceutique*” and “*Etablissement Exploitant*” status, which allows it to operate on the European market.

6.4.3 Organized production in the United States for future clinical trials

In anticipation of clinical trials in the United States, ERYTECH has 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.

6.5 Acute leukemias: a significant unmet medical need

6.5.1 Bone marrow cancer

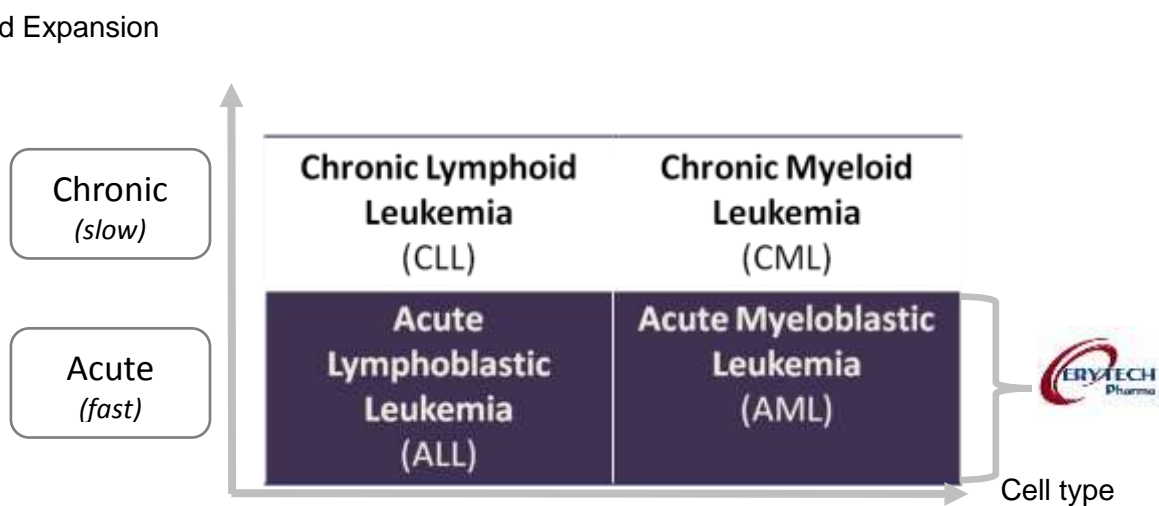
Leukemia is a cancer of the bone marrow cells, sometimes referred to as blood cancer. Leukemia is characterized by an abnormal and excessive proliferation of white blood cell precursors which, left untreated, invade the bone marrow and then the blood.

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

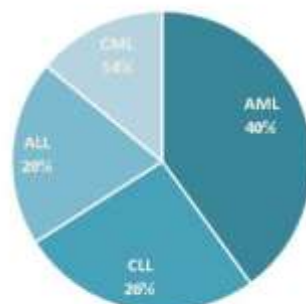
- Acute leukemia (AL) is characterized by the rapid proliferation of abnormal cells in the bone marrow and requires urgent treatment. Chronic leukemia (CL) has a slow proliferation with a clinical tolerance of cancer cells and a development that may take place over months or years.
- The cancer cell 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. ERYTECH is focused exclusively on acute lymphoblastic leukemia (ALL) and acute myeloblastic leukemia (AML), which are quickly life-threatening for patients.

The 4 categories of leukemia



Leukemias breakdown by cellular types



Source: PETRI Study

6.5.2 An increasing number of patients worldwide

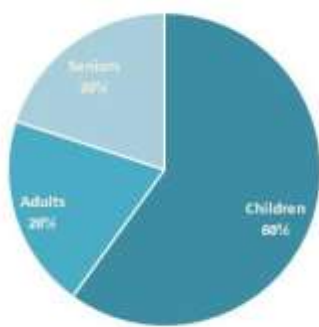
Each year, approximately 50,000 patients are diagnosed with acute leukemia in Europe and the United States. Around 6,000 new cases of ALL are diagnosed in the United States⁴ and at least as many in Europe, which equals, with an age-adjusted incidence estimated at about 2 new cases per 100,000 people each year⁵.

AML has an age-adjusted incidence approximately twice as high, which is around 4 new cases for 100,000 people each year, representing approximately 17,000 new cases in Europe⁶ and 20,000 in the United States⁷.

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 older adults (>55 years old).

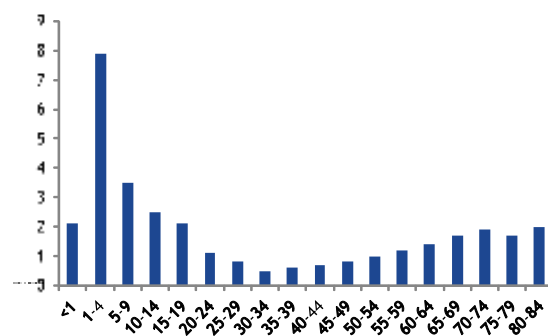
Breakdown of ALL patients by age and disease incidence according to age

Breakdown by patient type



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

Incidence according to age



Source SEER Cancer Statistics 1975-2007

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

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

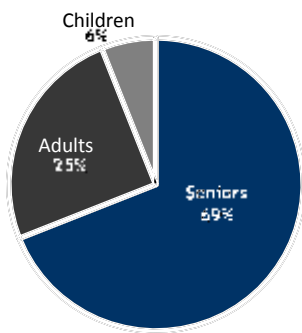
⁴ Siegel et al., CA Cancer J Clin, 2013.

⁵ Dore et al., Blood 2010; SEER Cancer Statistics.

⁶ Rodrigues-Abreu et al., Annals of Oncology, 2007.

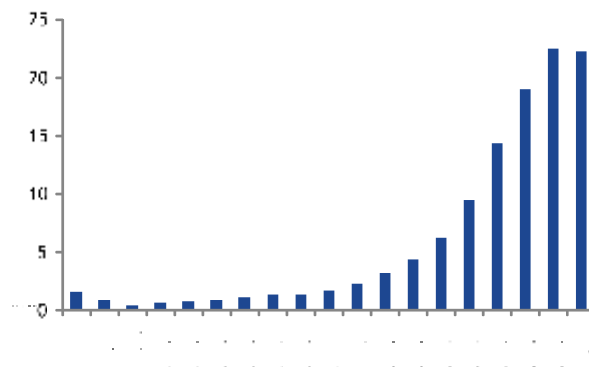
⁷ Siegel et al., CA Cancer J Clin, 2013 RARE Cancer, American Cancer Society.

Breakdown by patient type



Source : SEER-17, 2001 to 2007

Incidence according to age



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

The exact causes of leukemia are not completely known, but different studies⁸ have shown that the following conditions increase the risks:

- Radiation
- Benzene, formaldehyde and dioxins
- Tobacco
- Anticancer chemotherapy
- Some genetic disorders

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

6.5.3 A lower 5-year survival rate for adults and older adults

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

The 5-year survival rates for ALL vary significantly between young patients (children and young adults) which today achieve a 5-year survival rate of around 90%⁹, and older patients (adults and older adults), who have a low 5-year survival rate (15 to 30%).

The development 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 L-asparaginase, are often not transposable in older subjects due to their low tolerance for intensive chemotherapy because of their general health.

Especially for these patients as a priority, clinicians have a great need for new treatments with a better safety profile. ERYTECH is developing a new product ERY-ASP/GRASPA[®] to respond to this need.

⁸ Rodriguez-Abreu et al., Annals of Oncology, 2007.

⁹ Source: Cancer Statistics Review 1975–2005.

In AML, because of the damaging effects of induction treatments, the mortality rate from high intensity chemotherapies varies from 5% to 15% in young patients with AML and from 20% to 50% in aging patients. Because of the aggressive nature of the treatment, a significant percentage of patients over 65 opt for palliative care only, which highlights the unmet medical need for effective and safe treatments for AML.

6.6 L-asparaginase: a decisive drug in the treatment of acute leukemias

6.6.1 Current treatment of patients with acute leukemias

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 the diagnostic and preparation step, the chemotherapy protocols consist of several phases: induction of complete remission, consolidation of remission, deferred intensification to prevent reappearance of the 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, taken primarily by mouth for about two to three years.

6.6.2 The crucial role of L-asparaginase in patient remission

Asparagine is an amino acid naturally produced by cells for their own use in protein synthesis. This amino acid produced in excess 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 treatment principle is to eliminate the circulating asparagine using a specific enzyme: L-asparaginase. This enzyme is able to destroy the asparagine and deprive the cancer cells of an important nutrient, resulting in death of the cells.

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

L-asparaginase was introduced into standard ALL treatment in the 1970s. Its use has revolutionized pediatric protocols by improving complete remission rates and duration of remission. It benefits from a significant therapeutic hindsight both with regard to its efficacy and its tolerance¹⁰.

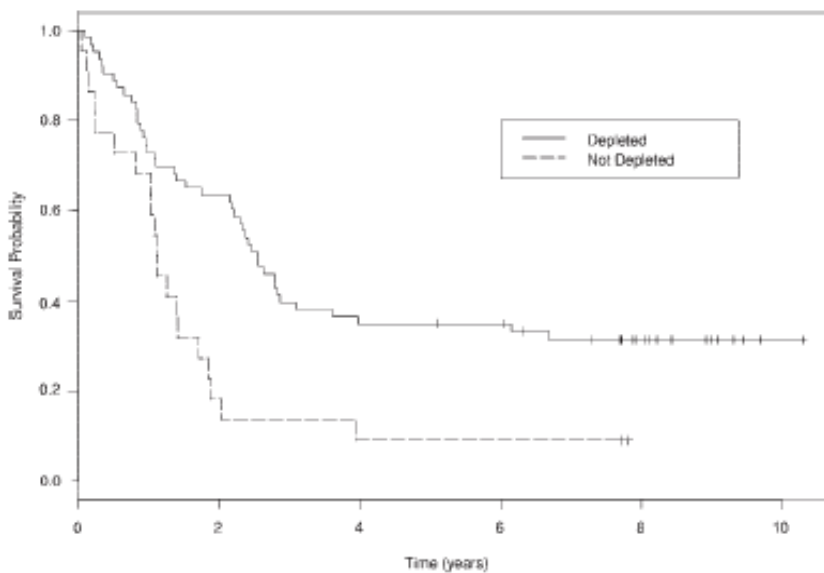
¹⁰ Stock et al., *Leukemia & Lymphoma*, 2011

Asparaginase gradually established itself as a pillar of antileukemia 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. Current clinical practices are based on systems of intensive use of L-asparaginase (as many doses as early as possible and for as long as possible). Indeed, it has been shown that the longer the tumor cells are deprived of asparagine, the higher the chances of complete and maintained remission are, and the longer the remission is sustained¹¹.

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 asparagine depletion level



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

In AML, L-asparaginase has been only very partially used to date. It has a Marketing Approval for AML in certain 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 conducted on 195 AML patients demonstrated the efficacy of L-asparaginase¹² in addition to the cytarabine-based reference treatment.

The significant risks of side effects for this patient population with often elderly patients and in fragile health are a major obstacle to the use of L-asparaginase.

In addition, in vitro experiments have demonstrated the efficacy of L-asparaginase on over 60% of several biological samples from different AML subtypes (M0, M1, M4 and M5), comparable to the results obtained on biological

¹¹ Silverman et al., *Blood* 2001.

¹² Capizzi & White, *The Yale Journal of Biology and Medicine*, 1988

samples of ALL. It is estimated that approximately 50%-70% of the patients could respond to an L-asparaginase treatment¹³.

In addition, the Company has a license with the U.S. National Institutes of Health (NIH) on the rights to a diagnostic test to measure the presence of asparagine synthetase (ASNS), an enzyme that produces asparagine, in order to determine tumor sensitivity to asparaginase in relation to treatment with ERY-ASP. We are currently using this diagnostic test on biopsy samples collected in Phase IIb of the clinical trial on AML patients.

6.6.2.1 *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 around 5% of ALL in children and around 20% to 25% of ALL in adults. Its frequency increases with age.

ALL patients with the Philadelphia chromosome (known as Ph+, “Phi positive”) are treated primarily with monoclonal antibodies, particularly tyrosine kinase (BCR-ABL) inhibitors like imatinib, which is sold by Novartis under the Gleevec[®]/Glivec[®] name, and dasitinib, sold by BMS under the name Sprycel[®]. However, clinical trials have demonstrated the lack of efficacy of imatinib and dasitinib in 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”). The lymphoblasts of these patients 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.

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

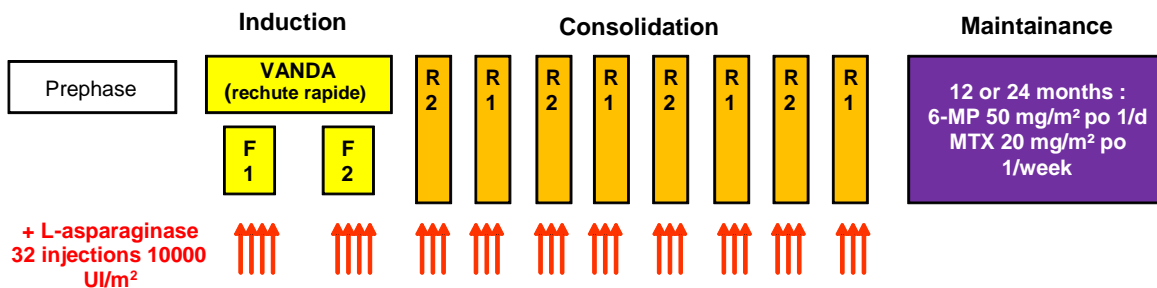
¹³ Okada et al., Br J Haematology, 2003, L-Asparaginase Sensitivity and Asparagine Synthetase Expression In Primary Tumor Cells From AML Patients Willy Berlier

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 Dexamethasone Asparaginase	Cytarabine VCR Cyclophosphamide 6-Mercaptopurine(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

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)



6.6.2.2 AML treatment

Acute myeloid leukemia (AML) is a form of cancer that affects bone marrow cells that produce the blood components (red cells, white cells and platelets). Left untreated, it is rapidly fatal because of the risk of infection and bleeding. It is potentially curable with intensive chemotherapy regimens, and the risks of relapse are lower if a bone marrow transplant can be performed, but at the expense of mortality risks related to the transplant, which increase with age. The chances of remission and the risks of relapse vary by 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.

Left untreated, 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 state is referred to as "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 *all-trans retinoic acid molecule* 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.

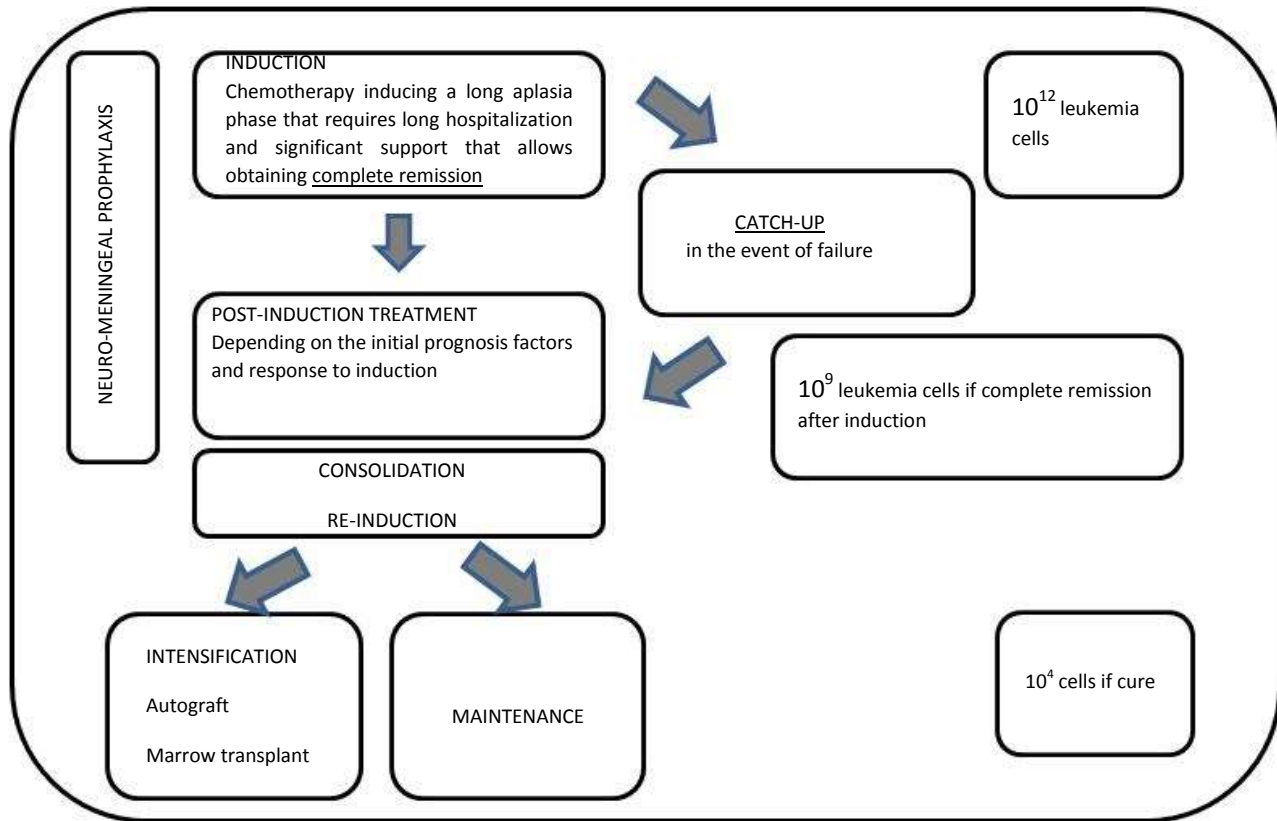
For AML in children, the therapeutic strategy after obtaining complete remission is a bone marrow allograft from an intra-family donor (75% disease-free 5-year survival rate) or treatment intensification with high-dose cytarabine and maintenance treatment with subcutaneous cytarabine and 6-thioguanine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

In AML patients aged 18-65, intensive chemotherapy can be proposed with several phases: an induction phase, a consolidation phase and, finally, a maintenance treatment consisting of a bone marrow allograft, an autograft or other chemotherapy treatments.

- *Induction.* Its objective is to achieve remission. The standard used is based on an infusion of cytarabine for 7 days associated with an 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 additional hospitalizations for varying lengths of time. 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.

Approach to the treatment of AML



In patients over the age of 65, 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. Similar to the case for young subjects, it is associated with anthracycline that is different from that used in induction, novantrone or the use of another interposing treatment such as amsacrine. Hematopoietic growth factors could reduce the toxicity of the treatment. Maintenance treatment follows 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	MAINTENANCE (RESERVE FOR AML3)
SUBJECT < 18	ARACYTINE MITOXANTRONE	HIGH DOSE ARACYTINE AMSACRINE VP16 DAUNORUBICINE ASPARAGINASE MARROW TRANSPLANT	OR HIGH DOSE CYTARABINE (HIDAC)	
SUBJECT 18-60	STANDARD 7+3 CYTARABINE + IDARBUICINE OR DAUNORUBICINE	HIGH DOSE CYTARABINE (HIDAC) STEM CELL GRAFTS	-	
SUBJECT > 60	LOW DOSE 7+3	HIGH DOSE CYTARABINE (HIDAC) NOVANTRONE AMSACRINE	-	
TREATMENT DURATION	~ 1 MONTH	6-9 MONTHS	~1-2 MONTHS	4-12 MONTHS

Like the lymphoblasts in the case of ALL, most of the myeloblasts need circulating asparagine to grow and proliferate, even though it is believed that the myeloblasts in AML do not respond as well to L-asparaginase as the lymphoblasts in ALL. The medical rationale for the use of L-asparaginase for the AML is therefore identical.

L-asparaginase is used in certain pediatric treatment protocols: for example, in France in the EAML 02 protocol, in the United States in the COG or St Jude protocols, or in Canada where it has a Marketing Approval. However, its toxicity profile prevents its widespread use in fragile children and especially in adult patients, where it is rarely used.

6.6.3 Limitations of direct administration of L-asparaginase

In clinical practice, ERYTECH estimates that one third of ALL patients – mostly older adults 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.

6.6.4 The current market for L-asparaginase

ERYTECH believes that the current market for the different forms of asparaginase is around \$300 million worldwide¹⁴ even though these different forms of treatment actually target only a small number of patients with acute leukemia. ERYTECH believes that a large number of other patients could benefit from an improved treatment based on L-asparaginase. 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.

The current market for L-asparaginase consists mainly of 3 products: native L-asparaginase (Kidrolase[®], Leunase[®], asparaginase medac[®]), Oncaspar[®], and Erwinase[®], which represent different formulations and/or different production processes. As a result, these products have distinct profiles, particularly in terms of duration of activity, frequency of injections, and side effects.

The native form (Kidrolase[®], Leunase[®] or asparaginase medac[®]) is the first L-asparaginase. It was first commercialized in France in 1971. Erwinase[®] and Oncaspar[®] were commercialized 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.

The main L-asparaginase-based drugs are described briefly below:

¹⁴ Source: Jazz Pharmaceuticals and Erytech

- **Native L-asparaginase**

The introduction of native L-asparaginase to the standard treatment of ALL in children and later in adults dates back to the 1970s. This L-asparaginase is 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.

The 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 name Kidrolase[®], and by the German company Medac under the L-asparaginase medac name. In the United States, the native form (Elspar[®]) was recently withdrawn from the market because of production problems and because of competition with 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 extend 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, the incorporation of PEG-asparaginase in chemotherapy for adults is still uncommon because of the side effects feared by clinicians.

The only form of PEG-asparaginase authorized on the market is Oncaspar[®]. 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[®] was previously distributed in Europe by Medac; Sigma Tau assumed direct marketing in August 2012. Baxalta purchased the Oncaspar[®] product from Sigma-Tau in 2015.

ERYTECH estimates that approximatively one third of current sales of L-asparaginase are related to the use of PEG-asparaginase. Worldwide sales of Oncaspar[®] totaled approximately \$100 million¹⁵ in 2014.

- **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 available in some European countries since 1985 and in the United States where it was approved again in November 2011.

Worldwide revenues from Erwinase[®] reported by Jazz Pharmaceuticals for 2014 totaled \$199.7 million.

The 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) experienced by patients to the form produced with *E. coli* are specific to that form in particular, and do not target L-asparaginase derived from *Erwinia chrysanthemi*. However, the treatment based on Erwinase[®] can generate an immune response with development of anti-Erwinase antibodies itself.

The differences in half-life among the different preparations have the effect of a more frequent administration of Erwinase[®] over the form derived from *E. coli*.

¹⁵ Baxalta Corp Pres.

In the United States, for ALL patients who have just been diagnosed and for ALL patients in relapse or resistant, physicians generally prescribe Oncaspar as first-line treatment, or Erwinaze if Oncaspar cannot be tolerated by the patient. In Europe, depending on the country, either the native L-asparaginase or Oncaspar are generally used for the initial treatment of ALL patients who have just been diagnosed, or for patients in relapse or resistant, with Erwinaze also used when one of these forms of L-asparaginase cannot be tolerated by the patient.

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-asparaginase¹⁶.
- Medac is also developing a pegylated form currently in Phase I.
- Jazz Pharmaceuticals is developing a pegylated recombinant form of its Erwinia L-asparaginase currently in Phase I.

The L-asparaginase market has seen four major transactions finalized or in progress which are part of a more general trend in interest from pharmaceutical groups in rare and orphan diseases. ERYTECH believes that these transactions were performed based on particularly attractive valuations:

- In August 2015, the pharmaceutical company Shire, listed on the London Stock Exchange, launched a hostile takeover for \$30 billion (£19 billion) on Baxalta, a company that specializes in the treatment of rare diseases.
- In June 2012, Jazz Pharmaceuticals acquired EUSA for \$650 million in cash plus a \$50 million earn-out based on certain deferred sales objectives. The transaction values EUSA at about 3x sales expected by the company for 2013 (\$210 million to \$230 million). Erwinaze[®] is the principal product of EUSA and represents approximately two thirds of sales (revenues of \$125 million expected at the time of the acquisition; \$131.9 million realized in 2012, the year after the marketing approval in the United States; \$200 million realized 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 four marketed drugs, Oncaspar[®], Adagen[®], DepoCyt[®], and Abelcet[®], as well as a site in the United States. These four products recorded total sales of \$116.5 million 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 held a portfolio of specialty products including Kidrolase[®] (L-asparaginase derived from *Escherichia coli*) and Erwinase[®] (crisantaspase, L-asparaginase derived from *Erwinia chrysanthemi*) as well as monoclonal antibodies at 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, which is developing blinatumomab, product in development purchased with Micromet in January 2012, in an ALL sub-category known as line B. This drug candidate is in Phase 2 with ALL line-B adults in relapse or resistant to existing treatments, in Phase 2 with adults within a minimal residual rate of – B precursors in ALL, in Phase 1/2 for pediatric ALL line-B patients in relapse or resistant and in Phase 1/2 for adults in relapse or resistant suffering from large cell B diffuse Lymphoma. Blinatumab has received drug designation in various indications, including ALL in Europe and the United States.
- Pfizer, which is developing inotuzumab ozogamicin in line-B ALL. The drug candidate is currently in Phase 3 with line-B ALL patients in relapse or resistant to existing treatments, and in phase 1/2 in older adult line-B ALL patients. Inotuzumab ozogamicin has received the status of ALL orphan drug in the United States from the FDA.
- Marquibo[®], a new formulation of Vincristine, developed by the American company Talon Therapeutics was approved in the US in 2012. 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.

¹⁶ Borghorst et al., *Pediatric Hematology and Oncology*, 2012

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

6.7 ERY-ASP/GRASPA®: An innovative treatment entering the market in ALL

Noting a real need for an L-asparaginase-based drug, ERYTECH developed the product ERY-ASP/GRASPA®. ERY-ASP/GRASPA® consists of a red blood cell encapsulated L-asparaginase. 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 prolonged therapeutic efficacy in comparison with other forms and a considerably improved tolerance profile allowing the treatment of fragile patients.

ERYTECH has conducted five clinical trials since 2006, four of which in ALL, in order to establish the efficacy and safety of use of ERY-ASP/GRASPA®.

Based on completed clinical studies, ERYTECH filed application for marketing approval through the centralized procedure for Europe in 2015 for ALL, and hopes to obtain a marketing approval by the end of 2016.

In the meantime, ERYTECH in 2014 launched an open trial in order to obtain expanded access (Expanded Access Program or EAP) to give access to GRASPA® to patients who are allergic to all current forms of asparaginase. In the context of this EAP, on the date of this update, 13 patients have been treated with several doses of GRASPA® and the Company has received a positive opinion from the DSMB at the end of the tolerance analysis on the first seven patients treated. Recruitment will continue in the context of the EAP while waiting for the Company to launch a global pivotal clinical study on these doubly allergic patients.

The European Drug Agency (EMA) and the American Food and Drug Administration (FDA) have granted the status of orphan drug to ERY-ASP/GRASPA® in ALL, which gives it marketing exclusivity after it obtains marketing approval on the product for 7 and 10 years in the United States and Europe respectively.

6.7.1 L-asparaginase encapsulated for greater efficacy and improved safety

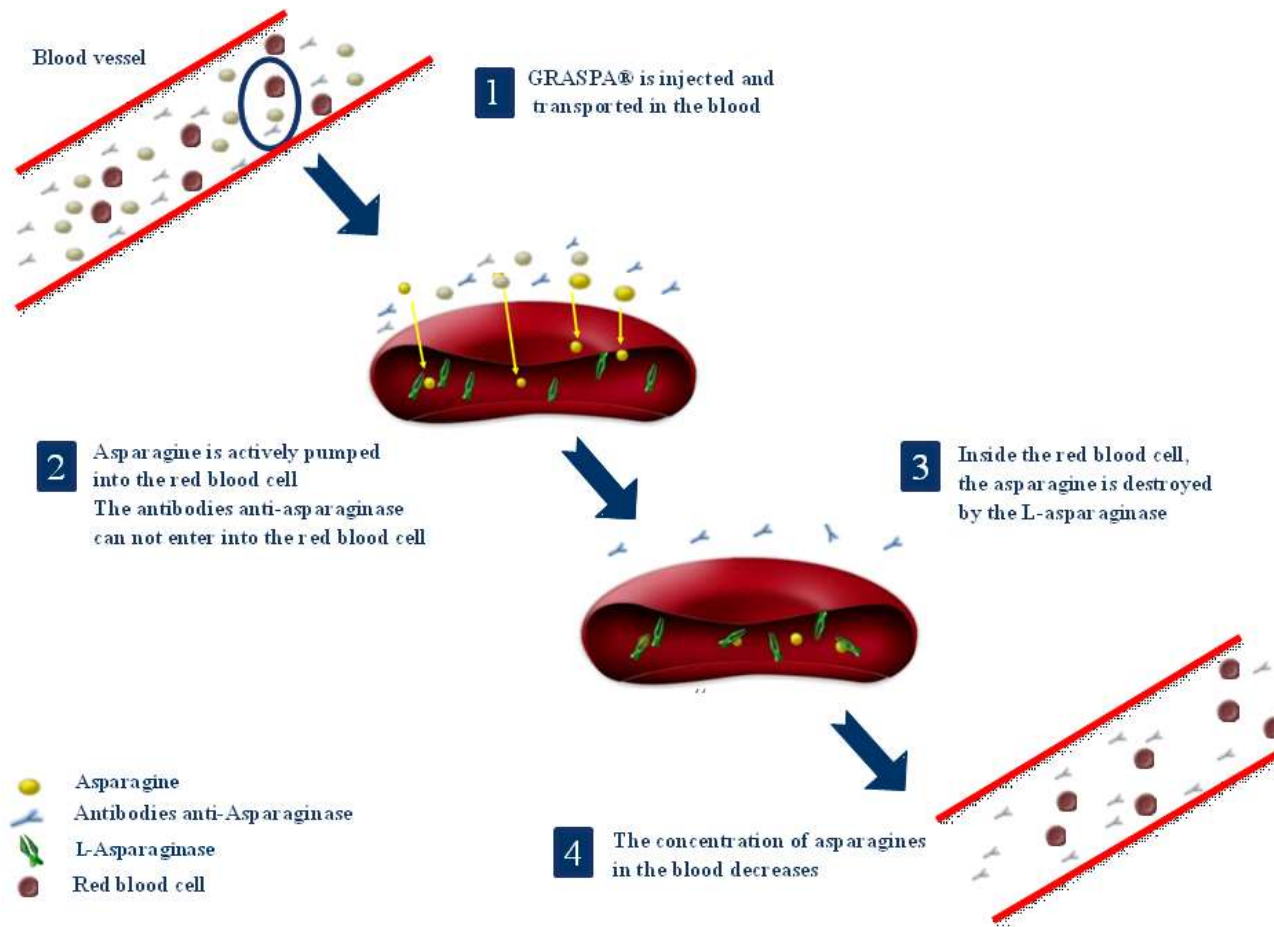
ERY-ASP/GRASPA® consists of the encapsulation of the enzyme L-asparaginase. The red cell membrane protects the L-asparaginase from the antibodies that are present in patients' blood and would likely substantially lessen or completely neutralize the enzyme activity or cause a hypersensitivity reaction. Thus, L-asparaginase remains active within the red blood cell without causing immune or allergic reactions in the patient. The red blood cells are biocompatible vehicles with a half-life of around one month in the body. This half-life, coupled with the protection of the cellular membrane, allows the therapeutic active substances that have been encapsulated in the cell to remain longer in the body, thus increasing the duration of their therapeutic effect and their potential efficacy with lower doses and fewer injections.

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® will be able to be administered to fragile patients who cannot receive the 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.¹⁷ The enzyme encapsulated in the cell, L-asparaginase, can then degrade 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.

¹⁷ Ataulakhanov 1985

Mode of action



6.7.2 Clinical results and ongoing clinical programs for acute leukemia

Clinical development program for acute leukemias

As of June 30, 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	12-18

Phase IIb study in patients over the age of 65 with AML (Europe)	Ongoing	123
<i>Expanded Access Program</i> for ALL in children and adults not eligible for other forms of asparaginase (France)	Ongoing	N/A
Total		269 - 275

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 conducted a Phase I/II randomized, multi-center (France and Belgium) clinical trial of GRASPA[®] in comparison with the reference treatment (free L-asparaginase – Kidrolase[®]) on 24 patients - children and adults with ALL in relapse. The study has demonstrated the safety use 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 up to 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 principal objective of this comparative study was to determine the relation 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 assess the efficacy profile of GRASPA[®] in comparison with the standard treatment through the duration of activity of the asparaginase, as well as the tolerance of the product through the study of side effects related to the encapsulated L-asparaginase GRASPA[®].

The protocol for the clinical trial consists of treating a portion of the adult patients or children in ALL relapse, using the standard treatment, i.e. chemotherapy combined with free asparaginase Kidrolase[®], then the rest of the patients with chemotherapy associated with GRASPA[®]. Patients were randomly distributed into 4 groups of 6 people: three groups received three gradual doses of GRASPA[®] (50, 100 and 150 IU/kg) 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 dosed at 150 IU/kg, 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 product dosage 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 (17%)
including clinical thrombosis	1 (17%)	0 (0%)

Source: Domenech e.a, BJH 2010

The injections of GRASPA[®] in dosages of 50IU/kg were too weak to result in depletion of the L-asparaginase, even though injections with higher dosages resulted in sufficient depletion in 85% and 71% of the patients who received dosages of 100 and 150 UI/kg respectively. The patients in the groups that received the two highest doses presented rates of complete remission of 77% and 64% respectively.

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 older adult 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 six 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 IU/kg) 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 three-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 three to four weeks and then every two to three months to collect data pertaining to patient survival.

Study results:

The following table shows 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 elevations	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 resistant acute lymphoblastic leukemia (ALL). The study is a three-arm trial. 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 (GRASPA-s).

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 primary evaluation criterion of this study consisted of two objectives, in line with the opinion of the CHMP¹⁸: a) a higher tolerance, resulting in a significant reduction in the incidence of allergic reactions to GRASPA[®] compared with the control group, and b) a duration that was not lower of the asparaginase activity, above the threshold of 100 UI/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 were as follows:

- Statistically significant reduction in allergic reactions: none of the 26 (0%) patients treated with GRASPA[®] had an allergic reactions versus 13 out of 28 patients (46%) treated with native L-asparaginase in the control group (p<0.001).
- Statistically significant increase in the duration of activity of circulating asparaginase: in the GRASPA[®] group, the levels of asparaginase were maintained above 100 UI/l for an average of 20.5 days, also with 2 injections during the first month of treatment (induction phase) compared with 9.6 days in the control group (p<0.001).

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

¹⁸ Based on the scientific opinion obtained by the Scientific Advice Working Party (SAWP)/Commission for Human Medicinal Products (CHMP) in the European Drug 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 prior observations made with GRASPA[®] in the randomized, progressive dosage Phase I/II in 24 patients with a relapse of their ALL, and the Phase II study in ALL patients over the age of 55 who received first-line treatment.

Summary table of the results of Phase III of the GRASPIVOTALL clinical trial with ERY-ASP/ GRASPA[®]:

	Randomized groups			HypSen group
	GRASPA [®] N=26	L-ASP N=28		GRASPA [®] N=26
Primary objectives				
Duration with asparaginase activity >100UI/l (days)*	20.5 ± 5.2	9.4 ± 7.4	p < 0.001	18.6 ± 6.3
Hypersensitivity to asparaginase				
All grades	0 (0%)	13 (46%)	p < 0.001	3 (12%)
Grade ≥ 3	0 (0%)	7 (25%)		0 (0%)
Main secondary objectives				
Complete remission	17 (65%)	11 (39%)	p < 0.05	14 (54%)
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%

*measured in total blood** at the end of induction

On May 30, 2015, the Company presented the complete results of its Phase III pivotal study on GRASPA[®] in acute lymphoblastic leukemia (ALL) at the 51st Annual Congress of the American Society of Clinical Oncology (ASCO).

The presentation was titled:

“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)”

The main conclusions of the study presented were as follows:

- GRASPA[®], combined with chemotherapy, demonstrated the maintenance of activity for the asparaginase longer than with L-ASP for the treatment of patients with ALL. The duration of activity of asparaginase greater than 100 IU/l was 20.5 days in the GRASPA[®] group versus 9.4 days in the control group L-ASP (p < 0.001).
- GRASPA[®] demonstrated a significant reduction in the risk of hypersensitivity reactions when compared with the L-ASP. No hypersensitivity reactions of any kind were observed in the GRASPA treatment group, compared with 46% in the L-ASP control arm (p < 0.001).
- The prolonged activity of the asparaginase resulted in an improvement in the full remission rate. 65% of the patients in the GRASPA[®] group were thus in full remission after the induction phase, compared with 39% of the patients in the control group (p=0.026).

- The treatment was generally well tolerated, with a low risk of major incidents such as coagulation disorders (35% of the patients in the GRASPA[®] group compared with 82% of the patients in the control group, and 35% of the patients in the hypersensitive group¹⁹), pancreatic toxicities (27% of the patients in the GRASPA[®] group compared with 50% of the patients in the control group, and 27% of the patients of the hypersensitive group) and hepatic toxicities (19% of the patients in the GRASPA[®] group versus 43% of the patients in the control group and 27% of the patients in the hypersensitive group).
- The favorable profile of harmless effects and efficacy of GRASPA[®] offers effective alternative options for patients previously treated with asparaginase, particularly those who have already developed a hypersensitivity to asparaginase derived from *E.coli*.
- The plenary session was pleasantly closed by the commentator, who concluded by considering GRASPA[®] as an “advance”. The main role of the commentator is to give to the oncology medical community a constructive criticism on the research, the questions discussed, the results presented, and the ability of the publications to open new perspectives in this medical area.

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

A Phase IIb multi-center clinical trial is currently in progress for patients over the age of 65 with AML who have just been diagnosed and are 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 main goal of this study is to assess the efficacy of GRASPA[®] when it is added to the standard product (cytarabine in low doses). To do this, survival without progression will be analyzed between patients who have received GRASPA[®] in combination with low doses of cytarabine, and patients who have received only low doses of 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 when sixty patients have experienced a progression of their disease.

The GRASPA-AML trial was launched in mid-2013. On the date of this update, 101 of the 123 patients who must be recruited for the study have been treated. Two reviews have been conducted by the DSMB (a committee of independent experts) on 30 and 60 patients respectively. 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. A third DSMB analysis is imminent. The first results of the study are expected in 2017. Depending on the results of this study, ERYTECH will determine the next steps in the development of this research program.

On May 31, 2015, the Company presented a poster on the design of the current Phase IIb trial, titled: “GRASPA-AML 2012-01 study: A multi-center, open, randomized Phase 2b trial evaluating ERY001 (L-asparaginase encapsulated in red blood cells) plus low-dose cytarabine vs low-dose cytarabine alone, in treatment with newly diagnosed acute myeloid leukemia (AML) elderly patients, unfit for intensive chemotherapy”.

6.7.3 Obtaining orphan drug designation and its benefits

The regulatory authorities in Europe (EMA) and in the United States (FDA) have established specific procedures for marketing approval and reimbursement for drugs that treat orphan diseases in order to encourage the development and innovation efforts for these diseases with a very small number of 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.

¹⁹ Percentage of patients with at least one adverse effect related to the medication during the induction phase.

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

6.7.4 Marketing GRASPA®

On the basis of the results from the Phase II/III clinical trial in adults and children with ALL in relapse, and based on previous studies, ERYTECH filed a request for MA through the European centralized procedure in September 2015, and hopes to obtain marketing approval by the end of 2016.

The Company will seek the broadest indication possible for its MA from the health authorities. It will then be up to the health authorities to accept it or not, and to specify whether additional trials are necessary to obtain the MA (*cf. Section 4.4.1 and Chapter 6.1*).

Tentative timetable

ALL: Submission of the MA application to the EMA	H2 2015
ALL: European MA through the centralized procedure	2016
AML: Results at one year from the Phase IIb trial	2017

6.7.5 Positioning of GRASPA® on the market

GRASPA® will be marketed by Orphan Europe (Recordati Group) in 38 European countries and by 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, such as older adult and elderly patients who cannot receive the current forms of L-asparaginase, and with relapsed or resistant adult and pediatric patients who also cannot be treated with L-asparaginase. The use of GRASPA® can be naturally extended to other patients with the clinical experience acquired by the onco-hematologists and by capitalizing on the proven safety of use of GRASPA®.

Worldwide sales for the three existing forms of treatments based on L-asparaginase are estimated at \$300 million²⁰. However, these forms of treatment actually target only a limited number of patients with acute leukemia, and the Company believes that a large number of other patients could benefit from a perfected L-asparaginase treatment.

The lack of an L-asparaginase-based treatment that is approved and/or used in AML will allow GRASPA® to be positioned for first-line treatment for these patients. Clinicians have expressed strong interest in being able to use L-asparaginase in the treatment of AML and ERYTECH intends to meet this demand with GRASPA®.

6.8 Commercialization of GRASPA® in Europe and Israel

ERYTECH has signed two major partnership agreements to commercialize GRASPA® in 38 European countries with Orphan Europe (Recordati Group) and in Israel with Teva Group. Thanks to the innovative nature of GRASPA®, its ability to satisfy unmet medical needs and its advance 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 hemato-oncologists, who are clearly identified. Therefore, awareness of specialized products such as

²⁰ Source: Jazz Pharmaceuticals and ERYTECH

GRASPA[®] and adoption of the drug can occur very quickly. In addition, GRASPA[®] does not require the modification of existing ALL treatment protocols 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 commercialization in Europe:

On November 23, 2012, ERYTECH signed an exclusive licensing and marketing agreement with Orphan Europe (Recordati Group), 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 (Recordati Group) holds a portfolio of orphan drugs already commercialized in different fields, including neonatal, pediatrics and metabolic disorders. Orphan Europe (Recordati Group) is a leading player in the field of orphan diseases and has the medical, clinical, regulatory and commercial expertise to market and effectively commercialize GRASPA[®] 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 (Recordati Group) will market GRASPA[®] for the treatment of ALL and AML in 38 European countries, including all the countries in the European Union. The parties have the opportunity to discuss the extension of this agreement to other areas around Europe and other indications.

ERYTECH is retaining production of GRASPA[®] at its Lyon site and will supply Orphan Europe in the various European countries where the drug will be sold. Orphan Europe (Recordati Group) has agreed not to participate in the development or marketing of competing products containing L-asparaginase for the treatment of ALL or AML.

Pursuant to this agreement, Orphan Europe (Recordati Group) paid €5 million on signing. Orphan Europe (Recordati Group) will have to pay ERYTECH up to €37.5 million in future payments based on various clinical, regulatory and commercial events, and Orphan Europe (Recordati Group) will share the clinical development costs of GRASPA[®] in AML. ERYTECH will receive a price for product delivered and royalties on the sales made by Orphan Europe (Recordati Group) with GRASPA[®], for a total of up to 45% of the net sale price.

Separately, another Recordati Group company subscribed convertible bonds that were converted into an equity stake in ERYTECH's share capital worth €5 million in the initial public offering on Euronext Paris in April 2013.

Partnership with Teva Group for marketing in Israel:

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

In accordance with the terms of the agreement, Teva Group will submit the application for approval of the drug for ALL in Israel and ensure marketing and distribution in the long term in that country. Teva Group will make milestone payments and share net earnings of product sales in Israel.

Marketing strategy 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 Teva Group for ALL. In particular, ERYTECH retains all rights to commercialize ERY-ASP outside Europe and Israel, particularly in the United States, for the treatment of ALL and AML, and in all other indications, such as solid tumors for example, outside Israel. ERYTECH also retains all rights to develop and market its other candidate products.

Subject to obtaining the MAs, ERYTECH hopes to begin marketing activities through the creation of a targeted sale and marketing unit to commercialize its products in the United States and abroad. ERYTECH believes that this unit

will allow it to target the community of physicians specializing in the treatment of patients for whom its candidate products have been developed. ERYTECH will be able to sign other marketing and distribution agreements with third parties in specific geographic areas, such as Russia, Turkey, other countries in the Middle East, and all African countries, for all its candidate products that have received a marketing approval. In some of these countries, Orphan Europe (Recordati Group) has a right of first negotiation.

ERYTECH is also planning to develop a sales and marketing management unit in order to create and implement its marketing strategies for any products it will market directly and to oversee and support its sales teams force. The responsibilities of this unit will include developing educational initiatives on the Company's products on the market, and the establishment of a network with opinion leaders in the relevant fields of medicine.

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 at least the first two years after initial marketing. This unit meets the highest requirements of ANSM and has "Etablissement Pharmaceutique Exploitant" regulated 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[®], in the therapeutic indications defined by ERYTECH. Medac is a German pharmaceutical company based near Hamburg that commercializes L-asparaginase (*see also Chapter 22 of the 2014 Reference Document*).

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

6.9 Development of ERY-ASP for leukemia in the United States

ERYTECH's objective 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 Investigational New Drug (IND) approval from the FDA to begin a Phase Ib clinical trial in ALL, and began recruiting its first patients in the third quarter of 2014. ERYTECH believes that this clinical trial will be finalized in 2016. 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 clinical trials for ALL and AML and could make it possible to submit an application for a market authorization by 2018/2019.

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 seconded to Philadelphia.

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

Phase I clinical trial in adult patients as first-line treatment for ALL

In 2013, ERYTECH launched a Phase Ib clinical trial in the United States for patients over 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 multi-center, non-randomized clinical trial strictly in the United States aims mainly to validate the toxicity, safety and efficacy profile of ERY-ASP, in combination with standard chemotherapy. This Phase Ib trial is the first

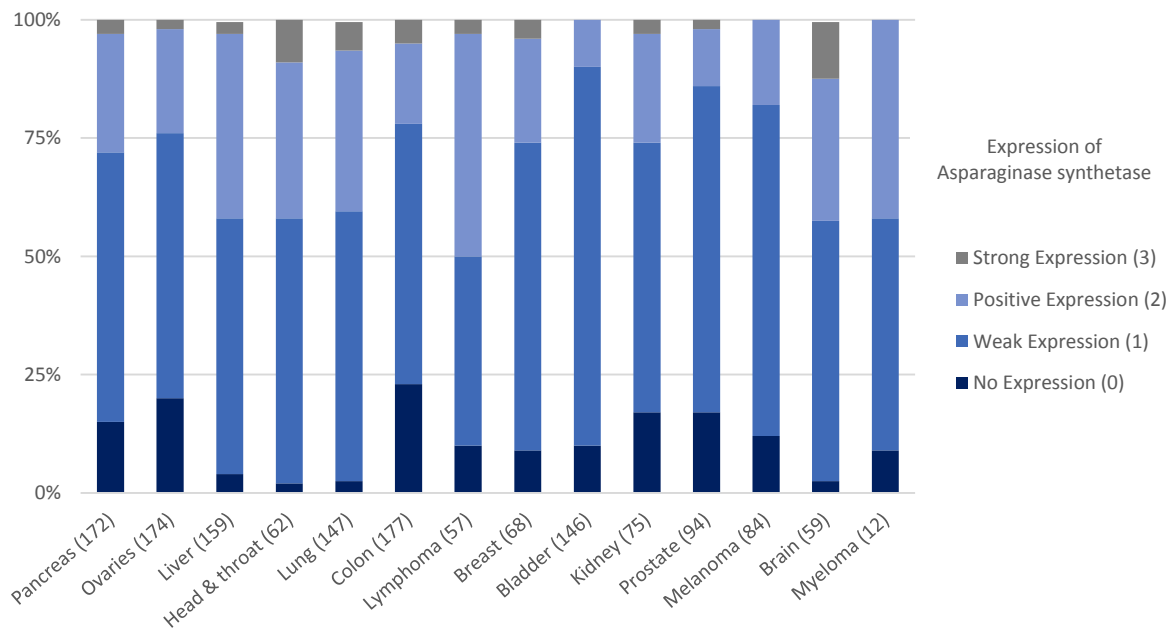
clinical trial conducted by ERYTECH in the United States. As a toxicity study, the results will also be used in the Phase I AML trial.

The safety data for the first cohort of three patients dosed at 50 UI/Kg were reviewed in June 2015 by a steering committee consisting of members of the DSMB and investigators in the study. No safety concerns were identified and this steering committee recommended escalating the dose to 100 UI/Kg. In addition, the study was amended to lower the age for patients' inclusion from 40 to 18, and remove the waiting periods between each patient. The request to modify the protocol has been submitted to the relevant Institutional Review Committees (IRC) for approval. The Company expects this study to be completed in 2016.

6.10 Potential new indications for ERY-ASP: Solid tumors

As with leukemia, the rationale of treating tumor cells deprived of asparagine synthetase is also applicable to solid tumors, as long as they do not express asparagine synthetase and need to consume the asparagine contained in the 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.

Sensitivity of some solid tumors to asparagine deprivation



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. The test is currently used in clinical trials and could be developed commercially with an industrial partner.

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

ERYTECH is preparing for the launch of a Phase II study on non-Hodgkin's lymphoma. The Company believes that it will be able to use the safety data collected during its other clinical trials conducted to date as a basis for beginning this clinical study directly in Phase II.

Phase I and Phase II clinical trials on pancreatic cancer

In 2011, ERYTECH finalized a Phase I open clinical trial on 12 patients with pancreatic cancer at four sites in France. The patients participating in the study were divided into four groups of three patients. ERY-ASP was administered by injection of four different doses: 25 IU/kg, 50 IU/kg, 100 IU/kg or 150 IU/kg. The main objective of this study was to determine the maximum tolerance dosage of the product. The second objective of the study was to assess the safety and preliminary efficacy indicators of the product. No toxicity limiting the dose was reported, even for the strongest dose administered in the study. The treatment led to a depletion of the asparagine with a trend toward extension of the duration of depletion with a higher dose. The results of this study were used as a basis for more advanced clinical research with a dose of 150 IU/kg. In 2014, based on the initial clinical results in solid tumors, ERYTECH continued the development of ERY-ASP in pancreatic cancer in a Phase II study with patients as the second line of treatment.

The Phase II study involves a total of 90 patients randomized at a 2:1 ratio 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

In the context of this clinical trial, ERYTECH is using a diagnostic test developed by the NIH which the Company holds under a license to assist it in the identification of cancer cells that might respond to the GRASPA[®] L-asparaginase treatment and, based on the results of these tests, ERYTECH stratifies the patient population. The main evaluation criterion for this clinical trial is progression-free survival at 4 months after the start of treatment in patients whose tumors are deficient in ASNS.

The DSMB conducted safety analyses of the product in the first three patients treated with the two combinations (Gemcitabine or FOLFOX), and a third broader analysis of the product in the first 24 patients was performed by this DSMB. In each of these analyses, no safety problem was identified by the DSMB. ERYTECH is planning to publish the first results for this study in 2016. Based on the results of the trials, ERYTECH will determine the next steps in the clinical study.

6.11 Other ERYCAPS development projects

ERYTECH's platform technology is versatile and opens up many possibilities for developing new drugs. The demonstration of the efficacy of the technology was mainly achieved with asparaginase, but it is possible to encapsulate into red blood cells other enzymes, molecules or proteins for which long-duration therapeutic activity or rapid or precise targeting is desired.

TEDAC/ERY-MET/ERY-ADI

In addition to its pipeline of products centered on the treatment based on L-asparaginase, ERYTECH is using its ERYCAPS technology to identify other enzymes able to induce tumor starvation. ERYTECH has received grants

from BPI France to finance its research program TEDAC, which is intended to identify other agents able to induce tumor starvation as well as the companion diagnostic tests. In pre-clinical studies conducted within the TEDAC program, ERYTECH has identified two other amino acids and their respective enzymes, methionine- γ -lyase (MGL) and arginine deiminase (ADI) which, according to the Company could be promising treatments once encapsulated into red blood cells. ERYTECH is planning to launch a Phase I clinical trial in 2016 for its ERY-MET candidate product, which is composed of MGL encapsulated in red blood cells, and a subsequent clinical study in 2017 for its ERY-ADI candidate product, which is composed of ADI encapsulated in red blood cells.

Enzyme Replacement Therapies (ERT)

ERYTECH believes that its platform offers other attractive development opportunities, outside oncology, in enzyme replacement therapies (ERT). ERYTECH has completed pre-clinical studies on enzymes like phenylalanine hydroxylase (PAH) in the treatment of phenylketonuria (PKU) in collaboration with Genzyme, and is studying other opportunities for collaboration for other possible applications of EST.

Vaccin'ERY System[®]

In addition to the use of the ERYCAPS platform for enzyme encapsulation in order to increase their effect and reduce their toxicity, ERYTECH believes that it is able to expand the use of its ERYCAPS platform to develop cancer vaccines. This consist in the development of a new anti-tumor vaccine using the Vaccin'ERY System[®] technology or ERY-VAX by intra-erythrocyte encapsulation of tumor antigens and adjuvant(s) to activate immune cells in situ and generate an immune response.

By loading red blood cells with specific antigens, then modifying the membrane of the cells subsequently to make them target specific antigen-presenting cells in the liver or spleen, ERYTECH believes it holds promising clinical research into cancer vaccination applications. 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, absorb them, and thus incorporate 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.

In pre-clinical studies on three different antigens loaded into red blood cells, ERYTECH has observed promising proof-of concept in three different tumor models. In these studies, ERYTECH has observed a significant increase in the responses of the T Lymphocytes specific to the antigens and delays in tumor growth when the encapsulated antigens, modified to target the liver or spleen, were injected into mouse tumors, as compared to the injections of free form antigens.

The Company is planning to continue to develop this platform in order to validate the initial preclinical data and to define a development strategy for its programs in the preliminary phase. Among the possibilities, the Company may consider the creation of a spin-off company for this technology if it believes it can optimize shareholder value.

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 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.

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

ENHOXY

ENHOXY[®] could be a product capable of improving tissue oxygenation rapidly and effectively in order to prevent or significantly reduce sickle cell deformation and thus cure and prevent the crisis. The process consists in the encapsulation of a molecule that allows greater salting out of oxygen in the presence of hypoxic tissues or cells when compared with a normal red blood cell. The preclinical results of this study have been presented at various international congresses and generated keen interest.

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

6.12 Environmental, social and corporate responsibility policy

See Appendix 2 to the 2014 Reference Document.

6.13 Regulations applicable to the Group

Government Regulation

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

U.S. Biological Product Development

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

Our product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed product candidate for its proposed indication;
- submission to the FDA of a BLA;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the pre-clinical and clinical trial sites that generated the data in support of the BLA;
- and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

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

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

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

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials generally involve large numbers of patients at multiple sites, in multiple countries, from several hundred to several thousand subjects, and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use and its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase

3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In some instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA and FDA Review Process

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

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual product fee for human drugs and an annual establishment fee on facilities used to manufacture prescription drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Once a BLA has been accepted for filing, which occurs, if at all, sixty days after the BLA's submission, the FDA's goal is to review BLAs within 10 months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening disease or condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The review process is often significantly extended by FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific or educational programs must comply with state and federal fraud and abuse laws, data

privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow an entity to enter into supply contracts, including government contracts. In addition, even if an entity complies with FDA and other regulatory requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, and/or our commercial operations; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping and/or documentation requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, which was part of the Affordable Care Act. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological product is biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biological product is granted 12 years of exclusivity from the time of first licensure of the reference product. The first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitting applications under the abbreviated approval pathway for the lesser of one year after the first commercial marketing, 18 months after approval if there is no legal challenge, 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

European Union Drug Development

In the European Union, our product candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, a new Regulation (EU) No 536/2014 on clinical trials on medicinal product candidates for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The new Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. The new Clinical Trials Regulation entered into force on June 16, 2014, but will apply no earlier than May 28, 2016. Until then the Clinical Trials Directive 2001/20/EC will still apply. In addition, the transitional provisions of the new Clinical Trials Regulation offer sponsors the possibility to choose between the requirements of the Directive and the Regulation for one year from the entry into application of the Regulation.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions, or SUSARs, to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

European Union Drug Review and Approval

In the European Economic Area, or EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Marketing authorizations may be granted either centrally or nationally:

The Community MA is issued centrally by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs are issued nationally by the competent authorities of the Member States of the EEA and only cover their respective territory. National MAs are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SmPC, and a draft of the labeling and package leaflet, which are sent to the other Member States, referred to as the Concerned Member States, or CMSs, for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SmPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e. in the RMS and the CMSs).

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

Orphan Drugs

In the European Union, Regulation (EC) No 141/2000, as amended, states that a drug will be designated as an orphan drug if its sponsor can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a drug as an orphan drug. An application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug before filing of a MA application.

If a Community MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, regulatory authorities will not, for a period of 10 years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. Notwithstanding the foregoing, a MA may be granted, for the same therapeutic indication, to a similar drug if:

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

Regulation (EC) No 847/2000 lays down definitions of the concepts 'similar drug' and 'clinical superiority'. Other incentives available to orphan drugs in the European Union include financial incentives such as a reduction of fees or fee waivers and protocol assistance. Orphan drug designation does not shorten the duration of the regulatory review and approval process.

Other European Regulatory Matters

French Regulatory Framework

In the European Union, the regulation governing clinical trials is currently based on Directive 2001/20/EC of April 4, 2001 relative to the implementation of good clinical practices in the conduct of clinical trials on medicinal products for human use. Each Member State of the European Union had to transpose this Directive into national law, which resulted in Member States adapting it to their own regulatory framework.

In France, for example, Directive No. 2001/20/EC has been implemented by Act Law 2004-806 of August 9, 2004 regarding the public health policy and Decree 2006-477 of April 26, 2006, modifying the section of the Public Health Code, or PHC, on biomedical research. Law 2004-806 abolishes the prior notification procedure introduced by the Law Huriet-Sérusclat of December 20, 1988. Indeed, Article L. 1121-4 PHC, as amended by Law 2004-806, establishes a system of prior authorization. This authorization is granted by the French Medicines Agency, or ANSM, provided that the competent Ethics Committee issued a favorable opinion. Under Article L. 1123-7 PHC, the Ethics Committee shall assess whether the conditions in which the trial will be conducted are valid. This assessment should be based on whether: adequate protection is offered to individuals, in particular to participants; adequate information is provided to the participants and appropriate procedure is in place to obtain their informed consent; the project is relevant; the benefits/risks assessment is satisfactory; the objectives of the trial are adequate to the means implemented; the qualification of the investigator(s) is satisfactory; the conditions and amount of patients' remuneration is compliant; and the method for recruiting participants is adequate. The ANSM, after submission of the complete file containing not only information on the clinical protocol, but also specific product data and its quality control, as well as results of pre-clinical studies, may inform the sponsor that it objects to the implementation of the research. The sponsor can then modify the contents of its research project and submit this amended or supplemented request to the ANSM; this procedure may not, however, be applied more than once. If the sponsor does not alter the content of its request, the request is considered rejected. Under R. 1123-32 PHC, the time limit for the examination of a request for authorization cannot exceed 60 days from the receipt of the complete file. Finally, under Article L. 1123-11, in the event of risk to public health or if the ANSM considers that the conditions in which the research is implemented no longer correspond to the conditions indicated in the request for authorization or does not comply with the provisions of the Public Health Code, it may at any time request changes to procedures for the realization of research, and suspend or ban this research. The decision of November 24, 2006 sets the rules for Good Clinical Practice for clinical trials on medicines for human use as referred to in Article L. 1121-3 of the Public Health Code. Good Clinical Practice rules, or GCPs, aim to ensure both the reliability of data arising from clinical trials and the protection of the persons participating in these clinical trials. GCPs shall apply to all clinical trials, including pharmacokinetics, bioavailability and bioequivalence studies in healthy volunteers as well as Phase 2 to Phase 4 clinical trials.

Personal data collected during clinical trials should be declared in simplified form to the French Data Protection Agency (Commission Nationale de l'Informatique et des Libertés, or CNIL). Patients then have a right to access and rectify this data pursuant to Law 78-17 of January 6, 1978, as amended, on data protection.

The main French regulatory texts concerning the conduct of clinical trials are as follows:

- Law 2004-806 of August 9, 2004 related to the public health policy;
- Decision of November 24, 2006 establishing the rules for Good Clinical Practice;
- Decision of January 13, 2011 establishing the rules of Good Manufacturing Practice;
- Law 78-17 of January 6, 1978, as amended, on data protection and its implementing decrees;
- Law 2002-3003 of March 4, 2002 and its implementing decrees regarding patient's rights and the quality of the healthcare system;
- Decision of January 5, 2006 concerning the approval of a standard methodology for the processing of personal data carried out within the context of clinical trials (standard methodology MR-001);
- Law 2011-2012 of December 29, 2011 strengthening the safety of medicines and health products; and
- Law 2000-230 of March 13, 2000, Decree 2001-272 of March 30, 2001 as amended, and Decree 2002-535 of April 18, 2002, relative on electronic signature.

French Pharmaceutical Company Status

We have the regulated status of pharmaceutical establishment and operating company, which allows us to manufacture and market our product candidates. Obtaining a pharmaceutical establishment license, either as a distributor or as a manufacturer requires the submission of an application dossier to the ANSM. The application package will vary depending on the type of application (distribution license or manufacturing license). The ANSM grants such license after verifying that the company has adequate premises, the necessary personnel and adequate procedures to carry out the proposed pharmaceutical activities.

Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the case of GRASPA, we have entered into distribution arrangements with Orphan Europe and Teva for marketing in Europe and Israel, respectively, and those third parties will be responsible for obtaining coverage and reimbursement for GRASPA in those territories if it is approved. Sales of our products will depend, in part, on the extent to which our products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursement levels for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

To secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, utilization management and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidates and could have a material adverse effect on our sales, results of operations and financial condition.

For example, the Patient Protection and Affordable Care Act, or ACA, enacted in the United States in March 2010, has already had, and is expected to continue to have, a significant impact on the health care industry. The ACA has expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program. We cannot predict the full impact of the ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. Specifically, the Joint Select Committee on Deficit Reduction was created to

recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2012 through 2021, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013, which will stay in effect through 2024 unless additional Congressional action is taken. Additionally, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third party payors and patients may expose us to broadly applicable federal and state fraud and abuse and other healthcare laws. These laws may impact, among other things, our research, proposed sales, marketing and education programs of our product candidates that obtain marketing approval. The laws that may affect our ability to operate include, among others:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil False Claims Act, which impose penalties and provide for civil whistleblower or qui tam actions against individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willingly falsifying, concealing or covering up a material fact or making materially false statements, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements on covered entities and their business associates relating to the privacy, security and transmission of individually identifiable health information; and
- State and/or foreign equivalents of each of the above federal laws and regulations, such as: state antikickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state and/or foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

The ACA broadened the reach of the federal fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and certain federal criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or the civil monetary penalties statute.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to, for example, significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to administrative, civil, and/or criminal sanctions, including exclusions from government funded healthcare programs.

7 ORGANIZATION CHART

As of the date of this document, the Company wholly owns the subsidiary “ERYTECH Pharma, Inc.”, founded in Delaware, United States on April 9, 2014. The purpose of the subsidiary is:

- the research, manufacture, import, distribution, and marketing of experimental and other 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 fulfilment.

Its directors are Gil Beyen (Chairman) and Eric Soyer (Treasurer and Secretary).

Its share capital is one dollar.

The Company does not have any branches or secondary facilities.

The Group’s scope of consolidation is presented in the IFRS consolidated financial statements in Chapter 20.1, Section 5.5 of the 2014 Reference Document.

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 assets.

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 France	Commercial (Laboratories and Offices)	7/1/2015	6/30/2024 with an early termination option for the Company in June 2019 or June 2021	€396,292 (excluding VAT) in annual rent and rental charges Re-invoicing share of property tax

The Group plans to lease other facilities in the United States to expand its clinical trials and prepare for its commercial growth.

9 RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

9.1.1 Patents

9.1.1.1 In its own name

As of October 31, 2015, ERYTECH Pharma's patent portfolio consisted of 12 patent families held in its own name.

Technology/products	Family	Title	Filing date	First year of expiration for each patent family*	Status
Production process	2	Lysis/resealing process and device for incorporating an active ingredient in erythrocytes	8/5/2004	2024/2030	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
		Process for stabilizing suspensions of erythrocytes encapsulating the active ingredient, suspensions obtained	5/7/2013	2033/2034	Issued in France National/regional phases in the process of being initiated
ERY-ASP/GRASPA®	3	Medication for the treatment of pancreatic cancer	12/24/2007	2027/2029	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	11/7/2008	2032/2033	Issued in Europe Issued in the United States Issued in Australia Issued in Singapore National/regional phases for other territories
		Medication for the treatment of acute myeloid leukemia	3/21/2012	2028/2029	National/regional phases initiated

Technology/products	Family	Title	Filing date	First year of expiration for each patent family*	Status
TEDAC	2	Erythrocytes containing Arginine deiminase	4/25/2005	2026	Issued in Europe, Japan, China, Canada, Korea, Australia and the United States
		Pharmaceutical composition comprising erythrocytes encapsulating an enzyme	2/12/2014	2034/2035	PCT application filed National applications filed
Immune modulation platform	2	Composition to induce specific Immune Tolerance	10/27/2009	2030	Issued in Australia Issued in Singapore Issued in Canada National/regional phases for other territories
		Composition and therapeutic anti-tumor vaccine	8/8/2007	2027/2028	Issued in France Issued in China Issued in Australia Issued in Singapore Issued in Israel National/regional phases for other territories
Other earnings	3	Formulation and method for the prevention and treatment of skeletal manifestation of Gaucher's disease	2/13/2008	2028	Issued in Europe Issued in Israel Other national/regional phases
		Formulation and method for the prevention and treatment of bone metastases and other bone diseases	3/10/2008	2028/2029	Issued in France Issued in China Issued in Australia Issued in Hong Kong National/regional phases for other territories
		Composition of	2/10/2013	2033/2034	PCT application filed

Technology/products	Family	Title	Filing date	First year of expiration for each patent family*	Status
		erythrocytes encapsulating phenylalanine hydroxylase and therapeutic use thereof			

* Does not take into account the additional protection certificates that may be obtained for the Company's patent in the United States, Europe or other countries. The expiration dates for the US patents that have not yet been issued may be adjusted.

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 US 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 16 of the Update to 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 was the subject 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 5.2.9 of the Update to the Reference Document*). ERYTECH was informed of the decision 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, was the subject of a priority filing in France on February 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, as well as 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 16 of the Update to the Reference Document*) for the development and distribution of GRASPA[®] in the EU-27. The contract covers the indications 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, the US, 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) which makes it possible to validly file for more than 100 countries: PCT filing is done one year after the priority filing. The 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 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, eight 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 the invention, made in the context of the employee’s work, is the property of ERYTECH, which holds all rights. A supplemental remuneration policy for each additional invention has been implemented and a confidentiality clause is included 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 may 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.


9.1.1.2 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 2014 Reference Document*). This intellectual property based on developments of the National Cancer Institute includes two issued US patents (US 7,985,548 and US 9,181,552).

9.1.2 Trademarks

The Company has filed the following trademarks:

	TRADEMARK	DESIGNATED COUNTRIES	NO.	DATE	
1	ERYtech Pharma	France	03 3 264 900	December 26, 2003 (Renewed)	
		European Community	00 3 921 319	July 5, 2004	
		Albania	947 762	November 26, 2007	
		Bosnia and Herzegovina			
		China			
		Croatia			
		Former Yugoslav Republic of Macedonia			
		Liechtenstein			
		Monaco			
		Serbia			
		Switzerland			
		Australia			
		United States			
		Iceland			
		Japan			
		Turkey			
		Singapore			May 14, 2008
		Belarus			December 18, 2013
		Algeria			
		Egypt			
		Georgia			
		Russia			
		Ukraine			
Montenegro					
Norway					
Iran					

	TRADEMARK	DESIGNATED COUNTRIES	NO.	DATE	
		Republic of Korea			
		Morocco			
		Israel	226 992 226 993 226 994	February 3, 2010	
		Canada	1 387 023	March 12, 2008	
		Kosovo	KS/M/2013/ 1211	December 17, 2013	
2		France	1239 11 751	April 10, 2012	
		European Union	1127934	June 20, 2012	
		Australia			
		South Korea			
		United States			
		Israel			
		Iceland			
		Monaco			
		Russia			
		Singapore			
		Switzerland			
		Turkey			
		Montenegro			October 26, 2012
		Norway			
3	GRASPA	France	06 3 421 435	April 6, 2006	
		Algeria			
		Albania	947 759	November 26, 2007	
		Bosnia and Herzegovina			
		China			
		Croatia			
		Former Yugoslav Republic of Macedonia			
		Liechtenstein			
		Monaco			

	TRADEMARK	DESIGNATED COUNTRIES	NO.	DATE
		Serbia		
		Switzerland		
		Australia		
		European Community		
		Iceland		
		Japan		
		Republic of Korea		
		Turkey		
		United States		No. 77 751 705 June 4 2009
		Singapore		May 14, 2008
		Russia		June 20, 2012
		Montenegro		October 26, 2012
		Norway		
		Belarus		
		Egypt		
		Georgia		December 18, 2013
		Morocco		
		Ukraine		
		Israel	226985	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
5	Cleav'ERY System	France	06 3 402 981	January 12, 2006
		European Community		
		Switzerland	947760	November 26, 2007
		United States		
6	Oxygen'ERY System	France	06 3 402 941	January 12, 2006
		European Community	947760	November 26, 2007
		Switzerland		

	TRADEMARK	DESIGNATED COUNTRIES	NO.	DATE
		United States		
7	Vaccin'ERY System	France	07 3 533 090	October 22, 2007
		European Community	967450	May 14, 2008
		Switzerland		
		US		
8	ERYCAPS	France	07 3 546 157	December 21, 2007
		European Community	972 047	July 8, 2008
		Switzerland		
9	Deliv'ERY System	France	06 3 402 968	January 12, 2006
10	EryDexone	France	06 3 459 689	October 26, 2006
11	ERYTECH Pharma Deliv'ERY System	France	07 3 543 340	December 10, 2007
12	ENHOXY	France	11 3 819 125	March 23, 2011
		European Union	1 110 463	February 10, 2012
		United States		
		China		
		Switzerland		
		Australia		
		Iceland		
		Japan		
		Republic of Korea		
		Turkey		
		Israel		
		Singapore		
		Russia		
		Monaco		
13	KYTASPAR	France	14 4 103 802	July 8, 2014
14	ASPACELL	France	14 4 103 800	July 8, 2014
		European Union	013 466 123	November 17, 2014
		International: - Albania	1 235 383	December 3, 2014

	TRADEMARK	DESIGNATED COUNTRIES	NO.	DATE
		<ul style="list-style-type: none"> - Armenia - Azerbaijan - Belarus - Bosnia and Herzegovina - Iceland - Kazakhstan - Kyrgyzstan - Liechtenstein - Macedonia - Moldova - Montenegro - Norway - Uzbekistan - Russia - Serbia - Switzerland - Tajikistan - Turkmenistan - Turkey - Ukraine 		
		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 Teva Group and Orphan Europe, for the trademark GRASPA® (see also Chapter 16 "Major Contracts" of the *Update to the Reference Document*).

The Company has established global monitoring of its main trademarks, namely ERYTECH Pharma® and GRASPA®.

The Company is particularly vigilant about defending the rights of trademarks and thus regularly opposes trademark applications likely to infringe upon its trademarks and, to the extent possible, a trademark coexistence agreement is signed with third parties and/or there is a limitation of the goods and services designated.

9.1.3 Domain Names

The Company filed the following domain names:

Domain Name	Expiration Date
erytech.com	July 20, 2017
erytech.fr	May 5, 2017
erytech.eu	September 30, 2017
graspa.fr	September 23, 2016
graspa.bio	September 23, 2016
graspa.biz	September 23, 2016

graspa.eu	September 23, 2016
graspa.de	September 23, 2016
graspa.uk	September 23, 2016
graspa.info	September 23, 2016

10 ADMINISTRATIVE AND MANAGEMENT BODIES

10.1 Executive Officers and Directors

10.1.1 Composition of the Board of Directors

The Company has the following directors:

Last name, first name, age	Term of office	Position
Gil Beyen, 53	Date of first appointment: the General Meeting of April 2, 2013 (he had been Chairman of the Supervisory Board since 2012). Term expires: the 2016 Ordinary General Meeting voting on the financial statements for the fiscal year ending December 31, 2015.	Chairman of the Board of Directors and Chief Executive Officer
Yann Godfrin, 43	Date of first appointment: 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 2016 Ordinary General Meeting voting on the financial statements for the fiscal year ending December 31, 2015.	Director and Chief Operating Officer
Galenos SPRL , represented by Sven Andreasson, 62 25 rue Jean-Baptiste Meunier, B 1050 Ixelles, Belgium Independent director ⁽¹⁾	Date of first appointment: co-optation at the Board of Directors' meeting of April 2, 2013, ratified by the General Meeting of June 17, 2014 (Chairman of the Supervisory Board from 2009 to 2011, Deputy Chairman of the Supervisory Board since 2011). Term expires: the 2016 General Meeting voting on the financial statements for the fiscal year ending December 31, 2015.	Director
Philippe Archinard, 54 47 rue Professeur Deperet, 69160 Tassin-la-Demi-Lune. Independent director ⁽¹⁾	Date of first appointment: The Board of Directors' meeting of April 2, 2013 (Member of the Supervisory Board since 2005). Term expires: The 2016 General Meeting voting on the financial statements for the fiscal year ending December 31, 2015.	Director
Martine Ortin George, 66 9 Southern Hills Drive 08558 Skillman NJ United States of America Independent director(1)	Date of first appointment: The General Meeting of June 17, 2014. Term expires: the 2017 General Meeting voting on the financial statements for the fiscal year ending December 31, 2016.	Director
Hilde Windels,	Date of first appointment: the General Meeting of	Director

Last name, first name, age	Term of office	Position
49 Rollebaan 85 9860 Moortsele Belgium Independent director ⁽¹⁾	June 17, 2014. Term expires: the 2017 General Meeting voting on the financial statements for the fiscal year ending December 31, 2016.	
Luc Dochez, 40 8 Klein Vilvoordestraat 3078 Meerbeek Belgium Independent director ⁽¹⁾	Date of first appointment: co-optation at the Board of Directors' meeting of March 26, 2015, ratified by the General Meeting of June 23, 2015. Term expires: the 2016 General Meeting voting on the financial statements for the year ending December 31, 2015.	Director

(1) Independent member as understood by the Middelnext Corporate Governance Code for small and mid-caps of December 2009.

The Chief Executive Officer, Gil Beyen, and the Deputy Chief Executive Officer, Yann Godfrin, have as their business address the Company's registered office, 60 avenue Rockefeller, 69008 Lyon.

The business 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 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;
- has been banned from managing; and
- has not been the subject of indictment or official public sanction by statutory or regulatory authorities, including by designated professional bodies.

In the fiscal year ended December 31, 2014, the following changes took place in the Board of Directors:

- Sven Andreasson resigned from his position as director on January 22, 2014;
- 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 at the Combined General Shareholders' Meeting of June 17, 2014, for a three-year term. Her term of office will end at the close of the 2017 Ordinary General Shareholders' Meeting voting on the financial statements for the year ending December 31, 2016;
- Hilde Windels was appointed to a director position by the shareholders at the Combined General Shareholders' Meeting of June 17, 2014, for a three-year term. Her term of office will end at the close of the 2017 Ordinary General Shareholders' Meeting voting on the financial statements for the year ending December 31, 2016;
- KURMA Life Science Partners, for which Vanessa Malier was the permanent representative, replacing Alain Munoz as from 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 fiscal year ended December 31, 2014, the following changes have taken place in the Board of Directors:

- Pierre-Olivier Goineau resigned from his positions as Deputy Chairman, Deputy Chief Executive Officer, and Director of the Company;

- Luc Dochez was co-opted in the Board of Directors' meeting as Company director replacing Pierre-Olivier Goineau, who resigned. This appointment was ratified by the General Meeting of June 23, 2015. The term of office of Luc Dochez will end at the close of the 2016 Ordinary General Shareholders' Meeting voting on the financial statements for the fiscal year ending December 31, 2015.

10.1.2 Experience with administrative and managerial bodies

The experience of each of the Company's executive officers and directors is described below.

- **Gil Beyen, Chairman and Chief Executive Officer, Chairman of the Board of Directors, Chief Executive Officer:**

Gil Beyen has held the position of Chief Executive Officer of the Company since May 2013 and Chairman of the Board of Directors of the Company since August 2013. Prior to his appointment as Chief Executive Officer, he had worked with the Company since 2012 as a consultant and also served as Chairman of our Supervisory Board from August 2012 to May 2013. 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 the international management consulting company Arthur D. Little in Brussels. He holds a master's degree in bioengineering from Université de Louvain, Belgium and an MBA from University of Chicago, US.

- **Yann Godfrin, Deputy Chief Executive Officer and Director:**

Since co-founding the Company, Yann Godfrin has held the position of Scientific Director and member of the Board of Directors of the Company. He also held the position of Chief Executive Officer of the Company from 2004 to 2010. Prior to the co-founding of the company, Yann Godfrin was the R&D director of Hemoxymed Europe. He was also an industrial development consultant for BioAlliance Pharma and Hemosystem. Yann holds a doctorate in Life and Health Sciences from Université de Nantes, a degree in Biomedical Engineering from Université de Technologie de Compiègne, and a master's degree in Clinical Development of Health Products from Université de 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, Deputy Chief Executive Officer, Chief Operating Officer:**

Jérôme Bailly has held the position of Chief Pharmacist in the Company since 2011 and of Director of Pharmaceutical Operations since 2007. Before joining the company in 2007, Jérôme Bailly was QA/Production Manager at Skyepharm and Laboratoire Aguetant. Jérôme Bailly has a doctorate of Pharmacy and holds a Chemical Engineering degree with a concentration in Biopharmaceutical Engineering and Cell Production from École Polytechnique de Montréal.

- **Galenos, represented by Sven Andreasson, director:**

Sven Andreasson is the Director of Business Affairs at Novavax, United States and former Chairman and Chief Executive Officer of Isconova AB, Uppsala, Sweden, Beta-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 Andréasson holds a Bachelor of Science and Business Administration and Finance from the Stockholm School of Economics and Business Administration.

- **Philippe Archinard, director:**

Philippe Archinard was appointed General Manager of Transgene on December 7, 2004, after spending 15 years with bioMérieux in various positions, including management positions in the US subsidiary. Philippe Archinard has been CEO of Innogenetics since March 2000. He is a chemical engineer and holds a Ph.D in biochemistry from Université de Lyon in addition to the Harvard Business School's Program for Management Development (PMD).

- **Martine Ortin George, director:**

A doctor of medicine, Martine George has 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 Institut Gustave Roussy in France, and was a visiting professor at Memorial Sloan Kettering Cancer Center in New York.

- **Hilde Windels, director:**

Hilde Windels has more than 20 years of experience in corporate financing, capital markets, and strategic initiatives. She is the Chief Executive Officer and Director at Biocartis, a molecular diagnosis and immunodiagnostic solutions company based in Belgium and in Switzerland. Hilde Windels was previously the Chief Financial Officer 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. From early 2009 to mid-2011, she worked as an independent Chief Financial Officer 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 has a degree in economics from Université de Louvain, Belgium.

- **Luc Dochez, director:**

Luc Dochez was Chief Business Officer and Senior Vice-President of Business Development at the Dutch 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 million; he was likewise actively involved in the successful introduction of the company on NASDAQ and managed the acquisition of the company by Biomarin for an amount of \$860 million. Before Prosensa, Luc was Vice President of Business Development at TiGenix (Euronext: TIG), Director Business Development at Methexis Genomics, and consultant at Arthur D. Little.

11 REMUNERATION AND BENEFITS

11.1 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

In the fiscal year ended December 31, 2014, the executive officers and persons referred to in Article L.621-18-2 of the French Monetary and Financial Code carried out the following transactions on Company securities:

- on March 24, 2014 Françoise Horand Phothirath, an executive equivalent person, exercised 2000 founder subscription warrants (BSPCE2012) at a unit price of €7.362;
- on March 27, 2014, Françoise Horand Phothirath, an executive equivalent person, sold 149 ERYTECH Pharma shares at a unit price of €13.7;
- on March 28, 2014, Françoise Horand Phothirath, an executive equivalent person, sold:
 - 150 ERYTECH Pharma shares at a unit price of €13.40;
 - 100 ERYTECH Pharma shares at a unit price of €13.45;
- on April 2, 2014, Françoise Horand Phothirath, an executive equivalent person, sold 350 ERYTECH Pharma shares at a unit price of €15.67;
- on May 14, 2014, Françoise Horand Phothirath, an executive equivalent person, sold 250 ERYTECH Pharma shares at a unit price of €15.04;
- On September 5, 2014 Françoise Horand Phothirath, an executive equivalent person, sold 300 ERYTECH Pharma shares at a unit price of €15.04;
- on September 17, 2014, Françoise Horand Phothirath, an executive equivalent person, sold 125 ERYTECH Pharma shares at a unit price of €16.88;
- on September 26, 2014, Françoise Horand Phothirath, an executive equivalent person, sold 250 ERYTECH Pharma shares at a unit price of €23.02;
- on September 30, 2014, Jérôme Bailly, Deputy Chief Executive Officer, exercised 500 founder subscription warrants (BSPCE2012) at a unit price of €73.62;
- on October 1, 2014, Françoise Horand Phothirath, an executive equivalent person, sold 300 ERYTECH Pharma shares at a unit price of €34.78;
- on October 2, 2014, Philippe Archinard, Director, exercised 1,337 share subscription warrants (BSA2012) at a unit price of €73.62;
- on October 13, 2014, GALENOS SPRL, Director, exercised 500 share subscription warrants (BSA2012) at a unit price of €73.62;
- 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;
- on October 17, 2014, Jérôme Bailly, Deputy Chief Executive Officer, sold 940 ERYTECH Pharma shares at a unit price of €25.30;
- on December 2, 2014,
 - Philippe Archinard, Director, sold 1,370 ERYTECH Pharma shares at a unit price of €28;
 - Jérôme Bailly, Deputy Chief Executive Officer, sold 550 ERYTECH Pharma shares at a unit price of €28.

Since December 31, 2014, the executive officers and persons referred to in Article L.621-18-2 of the French Monetary and Financial Code have carried out the following transactions 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;
- on January 14, Yann Godfrin, Deputy Chief Executive Officer, sold 550 ERYTECH Pharma shares at a unit price of €29.7951;
- on January 15, 2015,
 - Gil Beyen, Chief Executive Officer, sold:
 - 8,684 ERYTECH Pharma shares at a unit price of €29.0293; and

- 25,316 ERYTECH Pharma shares at a unit price of €29.7951;
- Yann Godfrin, Deputy Chief Executive Officer, sold:
 - 38,313 ERYTECH Pharma shares at a unit price of €29.0293;
- on February 20, 2015, Jérôme Bailly, Deputy Chief Executive Officer, sold 300 ERYTECH Pharma shares at a unit price of €27.60;
- On February 27, 2015 Françoise Horand Phothirath, an executive equivalent person, exercised 160 founder subscription warrants (BSPCE2012) at a unit price of €73.62;
- on April 9, 2015, Jérôme Bailly, Deputy Chief Executive Officer, sold:
 - 300 ERYTECH Pharma shares at a unit price of €26.08; and
 - 200 ERYTECH Pharma shares at a unit price of €27.50;
- on May 4, 2015, Jérôme Bailly, Deputy Chief Executive Officer, sold 1,000 ERYTECH Pharma shares at a unit price of €32.50;
- on May 22, 2015, Françoise Horand Phothirath, an executive equivalent person, sold 596 ERYTECH Pharma shares at a unit price of €34.11;
- on May 25, 2015, Françoise Horand Phothirath, an executive equivalent person, sold 404 ERYTECH Pharma shares at a unit price of €34.5;
- on May 27, 2015, Françoise Horand Phothirath, an executive equivalent person, sold 1,000 ERYTECH Pharma shares at a unit price of €35;
- on July 16, 2015, Françoise Horand Phothirath, an executive equivalent person, sold 200 ERYTECH Pharma shares at a unit price of €35.00;
- on July 21, 2015, Jérôme Bailly, Deputy Chief Executive Officer, sold 500 ERYTECH Pharma shares at a unit price of €35.00;
- on July 24, 2015, Jérôme Bailly, Deputy Chief Executive Officer, sold 500 ERYTECH Pharma shares at a unit price of €35.50; and
- on August 7, 2015, Françoise Horand Phothirath, an executive equivalent person, exercised 90 founder subscription warrants (BSPCE₂₀₁₂) at a unit price of €73.62.

12 OPERATION OF THE ADMINISTRATIVE AND MANAGEMENT BODIES

12.1 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 Middledex Code of corporate governance, at its meetings of May 24, 2013 and August 31, 2015, the Board of Directors established the terms for severance package and change of control package awarded to the company’s executive corporate officers (i.e., Gil Beyen, Jérôme Bailly and Yann Godfrin).

These agreements provided:

- that should Gil Beyen and/or Yann Godfrin leave the Company, that is to say in the event of:
 - a term of office ending (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 labour chamber of the French *Cour de cassation*),the interested party may claim severance equal to 12 times the mean monthly compensation (bonuses included) effectively received over the course of the 12 months preceding the removal decision or the expiration of the term of office.
- in the event of the dismissal of Jérôme Bailly for any reason whatsoever, except serious misconduct or gross negligence, the interested party shall be entitled to severance pay equal to six months’ fixed compensation, plus an additional three months’ fixed compensation per year of employment with the company, up to 12 months’ fixed compensation, subject to more favorable contractual provisions.

In addition, these agreements provide that if within 12 months following a change in control of the Company (by the acquisition of more than 50% of voting rights):

- Gil Beyen and/or Yann Godfrin:
 - is removed, (except for removal due to serious misconduct or gross negligence as this term is understood with respect to the case law of the labour chamber of the French *Cour de cassation*),
 - resigns, provided that such resignation is the result of a refusal on his part of a proposal by the Company, its acquirer or by one of its subsidiaries of a position with less responsibility and/or lower compensation compared to the position held before the change in control; or
- Jérôme Bailly:
 - is dismissed, except for serious misconduct or gross negligence,
 - is approved for termination under his employment contract, whether at the initiative of the company or the employee;
 - resigns, provided that such resignation is the result of a demotion by the Company, its acquirer or by one of its subsidiaries of a position with less responsibility and/or lower compensation compared to the position held before the change in control;

the interested party may claim severance equal to 12 times the mean monthly compensation (variable compensation included) effectively received over the course of the 12 months preceding such party’s departure.

The decision by the Board of Directors of August 31, 2015, made with respect to the procedure for regulated commitments and agreements provided under the “TEPA” law, was published in its entirety on the Company’s website. The commitments will be approved by the General Shareholders’ Meeting as a specific resolution pertaining to each of the executive corporate officers.

The Board of Directors decided that payment of severance package and change of control package 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 interested party assessed with regard to those of the Company, defined on this day as being:

- respect of the Company's budget and expenditures; and
- at least one of the two following conditions:
 - at least one collaboration or licensing agreement underway;
 - at least one product in active phase of clinical development by the Company.

13 EMPLOYEES

13.1 Personnel

13.1.1 Experience and positions of the principal managers

- **Eric Soyer, Chief Financial Officer and Chief Operating Officer:**

Eric Soyer has over 20 years of experience in management positions in financial and operational departments of public and private companies, both new and established. Over the past eight years, he was the Chief Financial Officer of EDAP-TMS, a Nasdaq listed company based in Lyon specializing in therapeutic ultrasound, where he was in charge of administration and finance, investor relations, legal affairs and human resources. During his last three years at EDAP-TMS, he was also Chief Executive Officer of the French subsidiary of the group, responsible for R&D, production and distribution for France, South America and EMEA. He previously served as Chief Financial Officer and Director of Information Systems for a French leader in nursing homes and care facilities, and Chief Financial Officer and Chief Legal Officer for a large French insurance company. He began his career as a financial controller within the Michelin Group. Mr. Soyer holds an Executive M.B.A. from HEC Paris, an M.B.A. from University of Kansas in the United States and graduated from the ESC Clermont in France.

- **Iman El Hariry, Chief Medical Officer:**

Iman El-Hariry, M.D., Ph.D., is an oncologist and has over 15 years of product development experience in the biopharmaceutical industry. She served as VP Clinical Research at Syntha Pharmaceuticals in Boston, Global Head Oncology at Astellas APGD in Chicago and Group Director at GSK Clinical Oncology in London. She successfully led the development and regulatory approval of various products in Europe and the United States.

The experience and the positions of the other principal executive officers are described in Section 10.1.2 above.

13.1.2 Personnel distribution

As of June 30, 2015, the Company's workforce included 45 full-time employees.

- Changes in personnel

The average workforce has varied in the following proportions:

Year	Average number of employees	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 filings, table 2058-C, "miscellaneous information"

– Distribution by business segment

As of June 30, 2015, the Company's personnel (including its executive officers) was distributed based on the following areas:

Departments	Number of employees
Business & Competitive Intelligence	3
Clinical affairs	4
Finance	2
Legal	3
Administration	2
Public Relations/Investors	1
Production	12
Quality Assurance	3
Preclinical	13
Regulatory	2
Grand total	45

– Distribution by status

As of June 30, 2015, the workforce of the company (including its executive officers) was divided into the following groups:

Status	Number
Management	24
Non-management	21
Grand total	45

13.2 Investment stakes held by corporate officers

Based on the share capital structure and the existing diluting elements as of the date of this document, stakes held by the Company's executive corporate officers may be summarized as follows:

	Number of shares	% capital **	% voting right	Type of warrants	Issue date and number of warrants	Number of warrants awarded	Number of warrants exercised	Number of warrants remaining to be exercised	Exercise price in € per new share subscribed**	Last date for exercise	Max number of shares tied to the number of warrants remaining to be exercised	Stock options
Gil Beyen*	-	-	-	Founder's share warrants ₂₀₁₂	5/21/12 issue of 11,263 warrants	11,263	3,400	7,863	7.362	5/20/20	78,630	N/A
				Founder's share warrants (BSPCE) ₂₀₁₄	1/22/14 issue of 6,000 warrants	6,000	0	6,000	12.25	1/22/24	60,000	N/A
Yann Godfrin *	142,990	2.07%	3.29%	Founder's share warrants ₂₀₁₂	5/21/12 issue of 7,508 warrants	7,508	0	7,508	7.362	5/20/20	75,080	N/A
				Founder's share warrants (BSPCE) ₂₀₁₄	1/22/14 issue of 3,000 warrants	3,000	0	3,000	12.25	1/22/24	30,000	N/A
Philippe Archinard *	8,000	0.12%	0.09%	Share warrants (BSA) ₂₀₁₂	5/21/12 issue of 11,263 warrants	2,554	1,837	717	7.362	5/20/20	7,170	N/A
GALENOS *	4,500	0.07%	0.05%			1,288 ⁽¹⁾	1,288 ⁽¹⁾	0 ⁽¹⁾			12,170	
						1,717	500	1,217				
						3,005 total						
						1,217	0	1,217				
Martine Ortin George*	-	-	-								12,170	
Hilde Windels*	-	-	-				12,170					
Luc Dochez	-	-	-			867	0	867		8,670		

Jérôme Bailly*	1,000	0.01%	0.01%	Founder's share warrants ²⁰¹ ₂	5/21/12	1458	600	858	7.362	5/20/20	8,580	N/A
				Founder's share warrants (BSPCE) ²⁰ ₁₄	1/22/14	800	0	800	12.25	1/22/24	8,000	N/A

* See details for positions currently held in Chapter 10 - Administrative and management bodies

** Registered shares

**** As delegated by the General Meeting

***** One warrant gives rights to 10 new shares

⁽¹⁾ Granted to Sven Andreasson, GALENOS representative on the Company's Board of Directors

14 MAJOR SHAREHOLDERS

14.1 Distribution of share capital and voting rights

In accordance with the provisions of Article L.233-13 of the French Commercial Code, we have listed below 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.

The Company's shareholder structure as of December 31, 2014 was as follows, based on information available:

Last name, first name/Company name	% share capital	% voting rights	Number of shares	
FCPR AURIGA VENTURES III	14.79%	21.46%	1,018,212	
RECORDATI ORPHAN DRUGS	6.26%	5.20%	431,034	
YANN GODFRIN	4.26%	7.07%	292,990	
PIERRE-OLIVIER GOINEAU	3.83%	6.36%	263,490	
HOLDING ENTREPRISE ET PATRIMOINE ¹	0.75%	1.24%	51,530	
Other nominal shareholders who hold capital less than or equal to 0.5%	1.66%	1.85%	114,513	
BEARER SECURITIES	Held by the Company within the scope of the buyback program ²	0.07%	0,00%	4 500
	OTHER BEARER SHARES	68.38%	56,77%	4 706 492
TOTAL	100.00%	100.00%	6,882,761	

¹Funds managed by IDINVEST PARTNERS

² See Section 3.8.9 of the Annual Financial Report

The Company's shareholder structure as of October 31, 2015 was as follows, based on information available:

Last name, first name/Company name	% share capital	% voting rights	Number of shares	
FCPR AURIGA VENTURES III	16.62% ¹	24.94%	1,147,522	
RECORDATI ORPHAN DRUGS	6.24%	9.93%	431,034	
YANN GODFRIN	2.07%	3.29%	142,990	
PIERRE-OLIVIER GOINEAU	1.45%	2.30%	100,000	
IDINVEST Partners	4.82% ²	4.42%	332,366	
Registered shareholders who own no more than 0.5% share capital	1.21%	1.38%	82,543	
BEARER SECURITIES	Held by the Company within the scope of the buyback program	0.03%	0.00%	2,500
	Other bearer shares ³	67.56%	53.71%	4,664,086
TOTAL	100.00%	100.00%	6,903,041	

¹ Including, based on the latest information received from the disclosure threshold statements, 1.87% bearer shares.

² Including, based on the latest information received from the disclosure threshold statements, 4.07% bearer shares.

³ Including Baker Bros., which, based on the latest information received from the disclosure threshold statements, owns 674,027 bearer shares representing a percentage of capital and voting rights of 9.76% and 7.76%, respectively.

During the fiscal year ended December 31, 2014, the Company received the following disclosure threshold statements:

- on February 13, 2014, following a sale of shares:
 - the capital and voting rights held by Ardian France (FCPR Axa Venture Funds IV) fell below the 5% disclosure threshold. At that date, Ardian France no longer held any Company shares;
 - the capital and voting rights held by Idinvest Partners fell below the 20% disclosure threshold. 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 voting rights held by Auriga Partners (FCPR Auriga Ventures III) exceeded the 25% disclosure threshold. At that date, Auriga Partners held 1,147,522 shares representing 20.64% of the capital and 27.12% of the voting rights;
 - the capital and voting rights held by Idinvest Partners fell below the 15% disclosure threshold. 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 capital held by Idinvest Partners fell below the 15% disclosure threshold. At that date, Idinvest Partners held 813,400 shares representing 14.61% of the capital and 12.30% of the voting rights;
- following the Company's capital increase (Prospectus with AMF approval no. 14-566 of October 23, 2014):
 - on 23 October 2014:
 - the threshold of 10% of the 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 voting rights held by Auriga Partners (FCPR Auriga Ventures III) fell below the 25% disclosure threshold and the capital held fell below the 20% disclosure threshold. 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 capital held by Idinvest Partners fell below the 10% disclosure threshold. 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 the following disclosure threshold statements:

- On January 14, 2015, the voting rights held by Yann Godfrin fell below the 5% disclosure threshold as a result of the sale of ERYTECH Pharma shares on the market. At that date, Yann Godfrin held 142,990 shares representing 2.08% of capital and 3.45% of voting rights;
- The voting rights held by Pierre-Olivier Goineau fell below the 5% disclosure threshold 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 capital and 4.28% of voting rights;
- On May 19, 2015, the voting rights held by Idinvest Partners fell below the 5% disclosure threshold following an increase in the total number of the Company's voting rights. At that date, Idinvest Partners held 377,582 shares representing 5.48% of shares and 4.91% of voting rights.
- On May 28, 2015, the voting rights held by Idinvest Partners fell below the 5% disclosure threshold following a sale of shares of the total number of voting rights. At that date, Idinvest Partners held 334,473 shares representing 4.86% of shares and 4.2% of voting rights.

14.2 Major shareholders not represented on the Board of Directors

As of the date of this Update, three major shareholders, i.e., Auriga Ventures III, Recordati Orphan Drugs, Baker Bros. and Pierre-Olivier Goineau were not represented on the Board of Directors.

14.3 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 to a double vote.

A double voting right is nevertheless granted, in accordance with legal conditions, to all shares fully paid up for which evidence is provided 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 the shareholder's 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, profit, or issue premiums, the double voting right is granted, upon issue, to registered bonus shares awarded to replace existing shares already carrying double voting rights.

The double voting right will be automatically withdrawn from any share converted to a bearer share or subjected to a transfer of ownership, except where such transfer results from a succession, a sharing of the community of property between spouses, or an inter vivos gift granted by a shareholder to such shareholder's 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.

15 ADDITIONAL INFORMATION

15.1 Share capital

15.1.1 Amount of subscribed capital

As of the date of this Update, the share capital, fully paid up, totaled €690,953.10, divided into 6,909,531 common shares with a nominal value of €0.10 each, all of the same class.

15.1.2 Acquisition of shareholder equity by the Company

The Company's Combined General Shareholders' Meeting of June 23, 2015, modified as follows the authorization given to the Board of Directors by the Combined General Shareholders' Meeting of June 17, 2014 to implement a buyback program of Company shares, according to the provisions of Article L.225-209 of the French Commercial Code and the French *Autorité des Marchés Financiers* General Regulations.

Maximum number of shares that can be repurchased: 5% of the number of shares constituting the Company's share capital at the date of these buybacks, as calculated according to applicable legal 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 repurchase:

- 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 profit sharing in the results of the company's expansion, employee shareholder plans, or company savings plans, the stock options plan, or by way of the award of bonus shares;
- Retaining 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 French *Autorité des Marchés Financiers* and within the limits provided by Article L.225-209 of the French Commercial Code;
- Assuring liquidity of 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 French *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 Eighth Resolution of this General Meeting of Shareholders if adopted;
- 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 French *Autorité des Marchés Financiers*.

Maximum purchase price: ninety (90) euros (excluding purchase costs), it being specified that, in the event of a transaction affecting the share capital, such particularly through incorporation of reserves and award of bonus shares, or share splits or reverse splits, or even changes of the nominal value of shares, this price will be consequently adjusted.

During the fiscal year ended December 31, 2014, this buyback program was used exclusively within the scope of a liquidity agreement with an objective of stimulating trading or liquidation of the Company shares, stipulated with the company Bryan Garnier as investment service provider.

	January 1, 2014 to December 31, 2014	January 1, 2015 to October 31, 2015
Securities purchased	167,345	52,181
Nominal share value	€0.10	
Average share price	€19.487	€28.239
Total amount paid for acquisition of securities	€3,261,099.75	€1,473,538.94
Shares sold	215,780	54,181
Nominal share value	€0.10	
Average share price	€18.129	€28.378
Total amount received for the sale of shares	€3,911,775.10	€1,537,537.31

Trading costs totaled €7,223.09 for the 2014 fiscal year and €3,011.23 since January 1, 2015.

As of December 31, 2014, the Company held 4,500 ERYTECH shares, valued at €125,100 (0.07% of the share capital), reduced to 2,500 shares at October 31, 2015 (0.03% of the share capital).

15.1.3 Other securities giving access to the capital

All the securities giving access to the Company's share capital and in circulation as of October 31, 2015 are described in the table below.

	Founder's share warrants (BSPCE) ₂₀₁₂	Share warrants (BSA) ₂₀₁₂	Founder's share warrants (BSPCE) ₂₀₁₄	Share warrants (BSA) ₂₀₁₄
Date of General Meeting	May 21, 2012		April 2, 2013	April 2, 2013
Number of shares that the Company is authorized to issue	45,050		19,500	3,000
Total number of subscription warrants issued	44,547		14,500	3,000
Number of warrants exercised	13,720		140	0
Number of warrants not yet exercised	30,828		14,360	3,000
Maximum number of shares remaining to be issued	308,280		143,600	30,000
Of which the maximum number of shares that can be subscribed by:	<i>Y. GODFRIN</i>	75,080	30,000	0
	<i>P.O GOINEAU</i>	75,080	10,000	0
	<i>G. BEYEN</i>	78,630	60,000	0
Number of shares issued	137,200		1,400	0
Starting point for exercise of subscription warrants	May 21, 2012		April 1, 2015	April 1, 2015
Expiry date of subscription warrants	May 20, 2020		January 22, 2024	January 22, 2024
Warrant subscription price	€0.00		€0.00	€0.00

Founder subscription warrants (“BSPCE”) and share subscription warrants (“BSA”)

Types of securities	Founder’s share warrants (BSPCE) ₂₀₁₂	Share warrants (BSA) ₂₀₁₂	Founder’s share warrants (BSPCE) ₂₀₁₄	Share warrants (BSA) ₂₀₁₄
Number of warrants that the company is authorized to issue	45,050		19,500	3,000
Maximum number of warrants not yet exercised	30,827		14,360	3,000
Number of warrants awarded	33,787	10,760	14,500	3,000
Date of General Meeting	May 21, 2012		April 2, 2013	
Exercise price per new share subscribed	€7.362		€12.25	
Final date for exercising warrants	May 20, 2020		January 22, 2024	
Exchange ratio	1 warrant for 10 shares			
General conditions of exercise	Warrant holders can only exercise their subscribed warrants upon the occurrence of a firm, definitive transaction involving the initial listing of Company shares for trading		BSPCE ₂₀₁₄ BSA ₂₀₁₄ warrants can be exercised: - on one single occasion, or	

	<p>on a regulated or unregulated stock market, in France or the European Union, or a foreign securities exchange:</p> <p>(i) on one single occasion, or</p> <p>(ii) on multiple occasions, within a limit of twice a year and at least 100 warrants.</p> <p>Upon the occurrence of one of the following transactions:</p> <p>(i) acceptance, by shareholders representing at least sixty-six point sixty 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 French Commercial Code);</p> <p>(ii) the signing of a merger agreement providing for absorption of the Company;</p> <p>warrant holders can exercise all the warrants they hold.</p> <p>The securities to which the warrants give rights are common shares.</p> <p>Each warrant will give the right to ten (10) shares in the Company's share capital.</p> <p>Periodic requests for admission for trading on the regulated NYSE Euronext market will be made for the new shares resulting from the exercise of founder's share warrants (BSPCEs).</p>	<p>- 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) warrants</p> <p>By way of exception, the possibility of early exercise has been established in the event of (i) a change in control as pursuant to Article L.233-3(1) of the French Commercial Code, or (ii) a merger of the Company, without conditions on minimum threshold or frequency.</p> <p>The securities to which the warrants give rights are common shares.</p> <p>Each warrant shall give the right to ten (10) shares in the Company's share capital.</p> <p>Periodic requests for admission for trading on the regulated NYSE Euronext market will be made for the new shares resulting from the exercise of founder's share warrants (BSPCEs).</p>	
Number of shares issued as of October 31, 2015	137,200	1,400	0
Maximum number of new shares that may be exercised*	308,270	143,600	30,000

Maximum dilution of shares and % resulting from the exercise of warrants	536,900 shares, i.e., a maximum dilution of approximately 7.80%*
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* Based on the exercise of all diluting instruments (i.e., the BSAs and BSPCEs) and the number of shares outstanding as of 10/31/2015, i.e., 6,903,041

As of the date of the Update, there are no longer any “guaranteed value” (ratchet) share subscription warrants. The previously outstanding 233,855 warrants were canceled by the General Shareholders’ Meeting of April 2, 2013.

15.1.4 Authorized capital not issued

The General Shareholders’ Meeting of May 21, 2012 decided on a maximum issue of:

- 30,034 share subscription warrants (BSA₂₀₁₂) with elimination 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 Gil Beyen BVBA,
- 33,788 founder’s share subscription warrants (BSPCE₂₀₁₂) with elimination 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 BSAs₂₀₁₂ and BSPCEs₂₀₁₂.

The Board of Directors used this delegation:

- in its meeting of July 17, 2014 and awarded 1,000 BSA₂₀₁₂ and 13,176 BSPCE₂₀₁₂ to the Company's top managers and corporate officers;
- in its meeting of April 29, 2015 and awarded 2,150 BSA₂₀₁₂ to the independent members of the Company’s Board of Directors.

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 elimination of the preferential subscription right through offerings as established under Article L.411-2(II) of the French Monetary and Financial Code.

The Board of Directors used this delegation:

- in its meeting of January 22, 2014 and issued 22,500 BSPCE₂₀₁₄ to the benefit of the Company’s top managers and corporate officers;
- in its meeting of December 4, 2014 to convert 3,000 BSPCE₂₀₁₄ into 3,000 BSA₂₀₁₄ to the benefit of the Chief Medical Officer of its subsidiary, ERYTECH Pharma Inc.;
- in its meeting of June 23, 2015 and awarded 3,000 BSA₂₀₁₄ to the Chief Medical Officer of its subsidiary, ERYTECH Pharma Inc. and 2,500 BSPCE₂₀₁₄ to the employees of the Company;
- in its meeting of August 31, 2015 and awarded 3,585 BSA₂₀₁₂ to the members of the Board of Directors.

As of October 31, 2015, 5,503 warrants remained to be granted, and 48,187 warrants granted but not exercised, i.e., a total of 53,690 warrants to be exercised.

The General Shareholders' Meeting of June 23, 2015 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	Duration	Use	Maximum nominal amount remaining
6/23/2015	Capital increase to remunerate contributions in kind, granted outside of a public exchange offer (9 th resolution)	€68,827.61		26 months 8/23/2017	None	€68,827.61
6/23/2015	Increase in share capital through the issuance of common stock and/or securities giving access to common stock while maintaining the preferential subscription right (10 th resolution)	€1,000,000 €80,000,000 (debt securities)		26 months 8/23/2017	None	€1,000,000 €80,000,000 (debt securities)
6/23/2015	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with elimination of the preferential subscription right of shareholders to the benefit of categories of investors* (11 th resolution)	€500,000 €80,000,000 (debt securities)		18 months 12/23/2016	None	€500,000 €80,000,000 (debt securities)
6/23/2015	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with elimination of the preferential subscription right of shareholders to the benefit of categories of investors* (12 th resolution)	€100,000 €80,000,000 (debt securities)		18 months 12/23/2016	None	€100,000 €80,000,000 (debt securities)
6/23/2015	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with elimination of the preferential subscription right of shareholders to the benefit of categories of investors** (13 th resolution)	5% of the Company's share capital		18 months 12/23/2016	None	5% of the Company's share capital

6/23/2015	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with elimination of the preferential subscription right, by way of public offering (14 th resolution)	€500,000 up to a limit of €1,000,000*** €80,000,000 (debt securities)		26 months 8/23/2017	None	€500,000
6/23/2015	Capital increase through the issue of shares and/or securities giving immediate or future access to common shares, with elimination of the preferential subscription right of shareholders to the benefit of categories of investors through an offering described in Article L.411-2(II) the French Monetary and Financial Code (15 th resolution)	20% of share capital (per 12-month period) up to a limit of €1,000,000*** €80,000,000 (debt securities)	€1,000,000	26 months 8/23/2017	None	20% of share capital
6/23/2015	Increase in the number of shares to be issued in the event of a capital increase with or without elimination of the preferential subscription right (17 th resolution)	Limited to 15% of the initial issue pursuant to the 11 th , 12 th and 13 th resolutions of the General Meeting of June 23, 2015		18 months 12/23/2016	None	
23/06/2015		Limited to 15% of the initial issue pursuant to the 10 th , 14 th and 15 th resolutions of the General Meeting of June 23, 2015		26 months 8/23/2017	None	
6/23/2015	Increase in the number through the issue of common shares and securities giving access to common shares in the event of a public exchange offer initiated by the Company (18 th resolution)	€1,000,000 (allotted to the ceiling fixed by the 14 th and 15 th Resolutions of the General Meeting of June 23, 2015)		26 months 8/23//2017	None	€1,000,000
6/23/2015	Capital increase by incorporation of reserves, profits or premiums (20 th resolution)	€1,000,000		26 months 8/23/2017	None	€1,000,000

6/23/2015	Authorization to grant stock options to the benefit of employees and/or corporate officers of the Company and ERYTECH PHARMA Group companies (21 st resolution)	5% of share capital	38 months 8/23/2018	None	5% of share capital
6/23/2015	Authorization to award existing or new bonus shares (22 nd resolution)	5% of share capital	38 months 8/23/2018	None	5% of share capital

*Individuals or legal entities under French or foreign law habitually investing in health-related securities.

** Corporate officers and employees of the Company and persons bound by a service or consultant agreement to the Company.

*** Within the limit of a total nominal ceiling of €1,000,000 for the maximum nominal amount of capital increases and €80 million for the maximum nominal amount of debt securities.

15.1.5 Evolution of the shares

The Company's share price as of October 30, 2015 and since the initial listing of its shares on the regulated NYSE Euronext market in Paris can be summarized in the table below:

Since listing

high	Wednesday, August 4, 2015	€40.20	i.e., for	6,896,791	shares	a value of	€277.2 m
price at	Friday, October 30, 2015	€29.52	i.e., for	6,903,041	shares	a value of	€203.8 m
low	Monday, December 16, 2013	€8.58	i.e., for	5,548,112	shares	a value of	€47.6 m
			number of shares traded:	20,804,073			

2013

high	Tuesday, May 7, 2013	€12.07	i.e., for	5,539,952	shares	a value of	€66.9 m
low	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

high	Wednesday, October 1, 2014	€34.97	i.e., for	5,584,272	shares	a value of	€195.3 m
low	Thursday, January 2, 2014	€10.16	i.e., for	5,558,952	shares	a value of	€56.5 m
			number of shares traded:	10,114,646			

2015

high	Tuesday, August 4, 2015	€40.20	i.e., for	6,896,791	shares	a value of	€277.2 m
low	Tuesday, February 3, 2015	€25.20	i.e., for	6,882,761	shares	a value of	€173.4 m
			number of shares traded:	9,824,784			

16 MAJOR CONTRACTS

16.1.1 Partnership agreements

16.1.1.1 [ERYTECH/Teva Group](#)

On March 28, 2011, ERYTECH signed a licensing and exclusive distribution agreement with Abic Marketing Limited (Teva Group), a global player in the pharmaceutical industry based in Israel, to distribute GRASPA[®] in that country. With revenues of over \$20 billion in 2013, 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, Teva Group will submit an application for approval of the drug in Israel and will provide for its marketing and long-term distribution in that country. ERYTECH is responsible for the manufacturing and transportation of the product directly to the consumer. Teva Group is responsible for all regulatory and marketing processes and has agreed to reimburse ERYTECH for part of its transportation expenses. ERYTECH does not expect that Teva Group will seek regulatory approval in Israel until a marketing approval has been issued for GRASPA[®] in the European Union.

Under the terms of this agreement, ERYTECH received an advance payment of €40,000 upon signing the contract and may receive up to €45,000 in milestone payments in the event of the completion of specific regulatory steps and a part of Teva Group's profits if it extends its distribution rights to other indications. ERYTECH will receive half of the profits of all sales of GRASPA[®] in Israel, calculated according to the terms provided in the agreement. The agreement is concluded for an initial term of ten years and will be automatically renewed for five successive years unless the parties give notice of non-renewal within six months. Early termination of the agreement may be requested by a party in the event of a transfer of control of the other party.

16.1.1.2 [ERYTECH/Orphan Europe \(Recordati Group\)](#)

On November 23, 2012, ERYTECH signed an exclusive licensing and 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 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[®] 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 in Europe's periphery and to other indications.

Under the terms of the agreement, ERYTECH is responsible for obtaining regulatory approval for GRASPA[®] for the treatment of ALL in the European Union and Orphan Europe is responsible for the regulatory processes for the 11 countries that are not EU Member States. Furthermore, Orphan Europe will seek marketing approval for GRASPA[®] for the treatment of AML in the 38 countries of Europe. If GRASPA[®] obtains this marketing approval, Orphan Europe will be tasked with assisting the Company in obtaining regulatory approvals for pricing and reimbursement. Orphan Europe has agreed, at its expense, to make reasonable commercial efforts to market and promote GRASPA[®] after it has been approved. ERYTECH has agreed to use reasonable commercial efforts to manufacture and deliver GRASPA[®] in the quantities requested by Orphan Europe, on the basis of forecasts that

Orphan Europe will transmit to ERYTECH. ERYTECH is responsible for the delivery of GRASPA[®] directly to consumers.

Under the agreement, Orphan Europe contributed €5 million upon signing. Orphan Europe will pay ERYTECH up to €37.5 million on future milestones depending on various clinical, regulatory, and commercial events. Orphan Europe will participate in the costs of the clinical development of GRASPA[®] in AML and 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.

The Company has granted Orphan Europe a right of first negotiation for the marketing of GRASPA[®] in additional indications, in addition to LAL and AML in Europe, and for marketing GRASPA[®] for all indications in other territories such as Turkey, Russia, specific states of the Middle East and throughout Africa. Orphan Europe has agreed not to be involved in the development and marketing of any competitor product containing L-asparaginase for the treatment of ALL and AML.

The term of the agreement varies by country. For EU Member States, the period is ten years from the marketing approval date for GRASPA[®] for the treatment of ALL and will be automatically extended by 10 years from the date of the marketing approval for the treatment of AML if it occurs before the end of 2019. For countries that are not part of the European Union, the period is 10 years from the marketing approval date for GRASPA[®] for the treatment of either ALL or AML, but it can be extended to more than three years after the expiry of the term for the Member States of the European Union. At the end of the contract, Orphan Europe is entitled to request an additional 10-year renewal if it is in accordance with the terms of the agreement. If the Company refuses to renew the agreement under specific circumstances, the Company may be subject to financial penalties as provided in the agreement. In addition, the agreement stipulates that Orphan Europe can automatically terminate the contract, require the reimbursement of certain expenses and lower milestone payments in the event that the intellectual property for which the Company was granted a license is deemed invalid.

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 on the Euronext Paris regulated market (*see also Section 18.1 of the 2014 Reference Document*).

16.1.2 ERYTECH/Medac

ERYTECH and medac, a German company, have signed 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 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 could develop 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 Update to 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.

The second contract contains some clauses providing that ERYTECH may have to refrain from any form of promotion of ERY-ASP/GRASPA[®] if such product was produced from a new formulation of asparaginase, registered and marketed before ERY-ASP / GRASPA[®] as the first-line treatment. It is specified that any restriction against promotion will 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 will 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 marketing-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 candidate drugs.

17 DOCUMENTS ACCESSIBLE TO THE PUBLIC

Copies of this Update and the 2014 Reference Document are available free of charge at the Company's headquarters, 60 avenue Rockefeller, 69008 Lyon, France. The Update and the 2014 Reference Document can also be found on the Company's website (www.erytech.com) and the AMF's website (www.amf-france.org).

The Articles of Incorporation, General Meeting minutes, and other Company documents, as well as the historical financial information and all assessments 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, free of charge, at the Company's registered office.

These documents are also available in paper format upon a simple request to the Company.

Additionally, pursuant to Article 221-3 of the General Regulations of the French *Autorité des Marchés Financiers* (AMF), regulated information within the meaning of Article 221-1 of the same General Regulations is available on the Company's website (www.erytech.com).

18 CONCORDANCE TABLE FOR THE UPDATE TO THE REFERENCE DOCUMENT

(Appendix 1 of European Regulation 809/2004 dated April 29, 2004)

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