

KEDRION
B I O P H A R M A

KEDRION GROUP
CONSOLIDATED FINANCIAL STATEMENTS
AS AT DECEMBER 31, 2018



Kedrion S.p.A.

Joint-stock company

Fully paid-up share capital Euro 55,186,279.00.

Registered office: Località Ai Conti - 55051 BARGA (LU), fraz. Castelvecchio Pascoli,

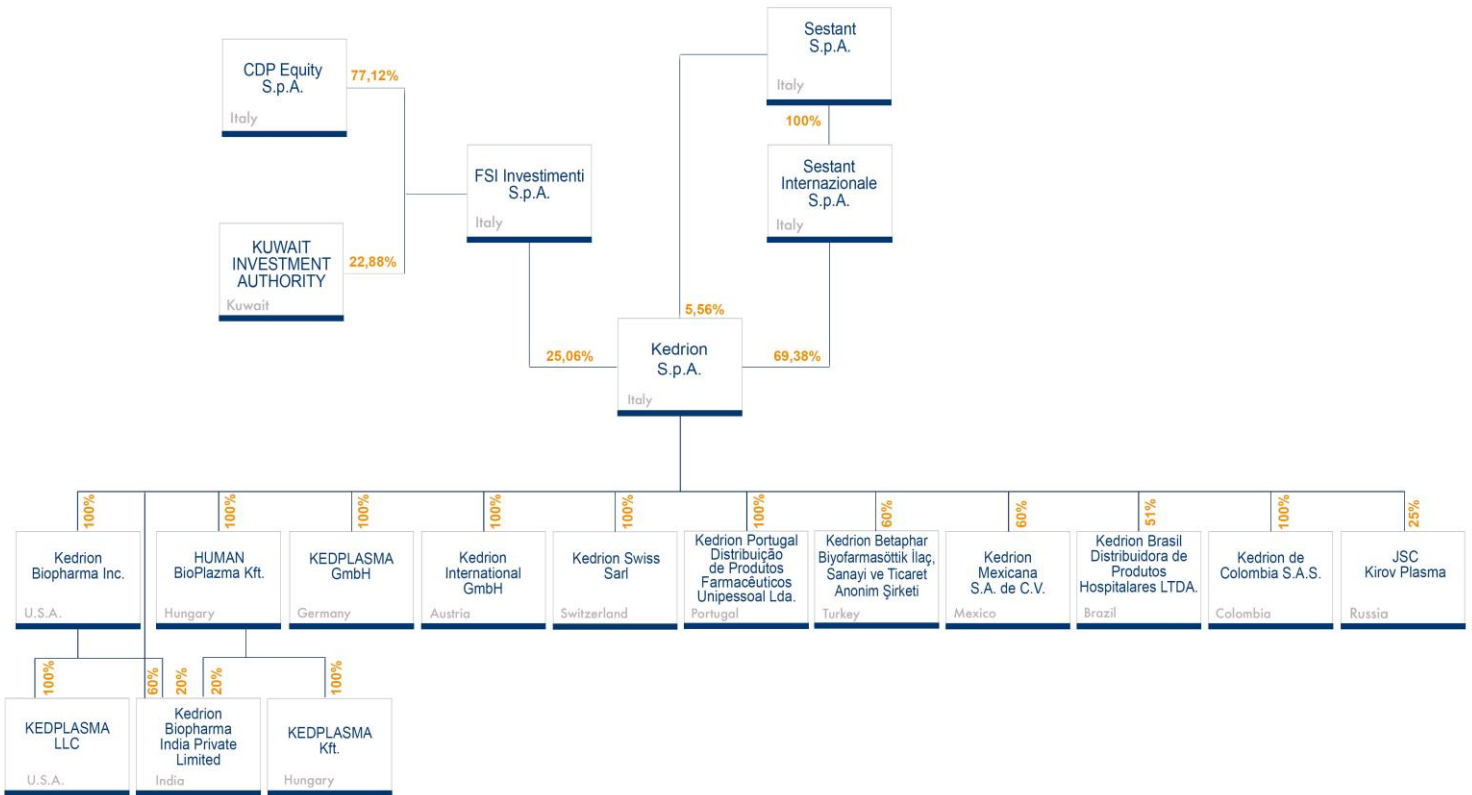
Production facility: 55027 GALLICANO (LU) – frazione Bolognana
80029 S.ANTIMO (NA)

Tax Code – VAT No. – Reg. Of Companies of Lucca No. 01779530466 – Economic & Administrative Index No. 170535.

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1. GROUP STRUCTURE



2. PARENT COMPANY BODIES

BOARD OF DIRECTORS

In office until approval of the financial statements for the year ended 31 December 2020.

Paolo Marcucci	Chairman and Managing Director
Rodolfo De Dominicis	Deputy Chairman
Maria Lina Marcucci	Director
Andrea Marcucci	Director
Remo Grassi	Director
Guido Rivolta	Director
Matteo Fanciullacci	Director in office since 4.02.2019
Massimo Perpoli	Secretary

REMUNERATION COMMITTEE

Guido Rivolta	Chairman
Rodolfo De Dominicis	
Remo Grassi	

BOARD OF STATUTORY AUDITORS

In office until approval of the financial statements for the year ended 31 December 2020.

Fabrizio Redaelli	Chairman
Francesco Cirillo	Standing Auditor
Marco Miccinesi	Standing Auditor
Alessandro Bicchi	Alternate Auditor
Giuseppe Paternò	Alternate Auditor

INDEPENDENT AUDITORS

The statutory audit assignment was awarded by the ordinary Shareholders' Meeting of 27 April 2015 and expires at the time of the Meeting called to approve the financial statements for the year ending 31 December 2022.

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THE COMPANY'S BOARD OF DIRECTORS

a) Role and functions

In compliance with Article 20.1 of the Statute, the Board of Directors is vested with full powers for the ordinary and extraordinary management of the Company, without any exceptions, and may perform all deeds, including provisions, that it deems necessary for achieving the corporate purpose, excluding only those that the law or the Statute specifically reserve to the Shareholders' Meeting or in any event which require a shareholder decision.

b) Composition

The Company is managed by a Board of Directors composed of 7 (seven) members.

c) Delegation and powers

The Board of Directors has delegated certain powers to individual directors. In particular:

- the Managing Director is invested with powers relating to ordinary administration for the purposes of achieving the corporate purpose and other specific powers.

ORGANISATIONAL MODEL PURSUANT THE LEGISLATIVE DECREE 231/2001

The Company has implemented the Organisational Model in compliance with the provisions of Legislative Decree No. 231/2001.

Kedrion set up a Privacy System to ensure compliance with the EU Regulation 2016/679 and D.lgs. 196/293 as last amended by the D.lgs. 101/2018.

3. REPORT OF THE INDEPENDENT AUDITOR

3.1. REPORT ON CONSOLIDATED FINANCIAL STATEMENTS



Kedrion S.p.A.

Consolidated financial statements as at December 31st,
2018

Independent auditor's report pursuant to article 14 of
Legislative Decree n. 39, dated 27 January 2010, and article
10 of EU Regulation n. 537/2014



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Independent auditor's report pursuant to article 14 of Legislative Decree n. 39, dated 27 January 2010 and article 10 of EU Regulation n. 537/2014 (Translation from the original Italian text)

To the Shareholders of
Kedrion S.p.A.

Report on the Audit of the Consolidated Financial Statements

Opinion

We have audited the consolidated financial statements of Kedrion S.p.A. and its subsidiaries, ("Kedrion Group" or "Group"), which comprise the consolidated statement of financial position as at December 31, 2018, and the statement of profit or loss, the statement of profit or loss and other comprehensive income, the statement of changes in consolidated shareholders' equity, the statement of cash flows for the year then ended, and explanatory notes to the consolidated financial statements, including a summary of the significant accounting policies.

In our opinion, the consolidated financial statements give a true and fair view of the financial position of the Group as at December 31, 2018, and of its financial performance and its cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union and with the regulations issued for implementing art. 9 of Legislative Decree n. 38/2005.

Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (ISA Italia). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are independent of Kedrion S.p.A in accordance with the regulations and standards on ethics and independence applicable to audits of financial statements under Italian Laws. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

We identified the following key audit matter:

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P.IVA 00891231003
Iscritta al Registro R revisori Legali al n. 70945 Pubblicato sulle G.U. Suppl. 13 - IV Serie Speciale del 17/2/1998
Iscritta all'Albo Speciale delle società di revisione
Consob al progressivo n. 2 delibera n.10831 del 16/7/1997

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Key Audit Matter	Audit Response
<p>Impacts from the refitting process of the Melville plant</p> <p>The consolidated financial statements of the Group reflect the impacts from the refitting process of the Melville plant; the project, which required a total investment of over 100 million US dollars, involved the shutdown of the plant since April of 2016, with the restart of the production during the year 2018 and the approval of the US Authority received in the first months of 2019.</p> <p>The processes and methodologies for assessing and determining the direct and indirect accounting implications of the refitting process on the consolidated financial statements as at December 31, 2018 required the use of the Directors' judgment, in particular with reference to: (i) the identification of the capitalization requirements of the expenses related to the refitting process during the year, for Euro 3.9 million, (ii) the beginning of the investments' amortization period from the date of the availability for use, as well as the definition of their useful life, (iii) the identification and write-down of the stock of semi-finished products no longer usable as a consequence of such project, for Euro 35.4 million, and (iii) the identification of additional charges attributable to the refitting project which, together with the aforementioned write-down costs, are disclosed as non-recurring costs for a total of Euro 76.0 million.</p> <p>In consideration of the judgment involved and the accounting implications to the Group's consolidated financial statements, we considered that this area represents a key audit matter.</p> <p>Such matters are reported in the report on operations and in the explanatory notes, in particular with reference to notes 6.2 "Period's significant events", 6.3.7 "Discretionary assessments and significant accounting estimates", 6.4.1 "Property, plant and equipment", 6.4.10 "Inventories" and 6.5.11 "Significant non-recurring, unusual and atypical transactions".</p>	<p>Our audit procedures in response to the key audit matter included, among others:</p> <ul style="list-style-type: none"> - the assessment of the documentation prepared by the Group for the analysis and monitoring of the refitting project, the minutes of the Board of Directors and relevant supporting documentation, and the correspondence with the US Authority (Food & Drug Administration); - the execution of substantive testing, on a sample basis, on additions to the investments made in connection with the project; - the assessment of the evidence used by the Directors to determine the beginning of the amortization period of the tangible and intangible assets related to the project's investments, and the definition of their useful life; - the test of the completeness of the write-down of semi-finished products' inventories from productions made before the shutdown of the plant, including discussions with the Directors to assess the rationale for such policy election; - the assessment of the methodologies for identifying and presenting the non-recurring costs related to the project. <p>Lastly, we evaluated the adequacy of the information provided in the notes in relation to the Melville plant's "refitting" process.</p>



Responsibilities of Directors and Those Charged with Governance for the Consolidated Financial Statements

The Directors are responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union and with the regulations issued for implementing art. 9 of Legislative Decree n. 38/2005, and, within the terms provided by the law, for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

The Directors are responsible for assessing the Group's ability to continue as a going concern and, when preparing the consolidated financial statements, for the appropriateness of the going concern assumption, and for appropriate disclosure thereof. The Directors prepare the consolidated financial statements on a going concern basis unless they either intend to liquidate the Parent Company Kedrion S.p.A. or to cease operations, or have no realistic alternative but to do so.

The statutory audit committee ("Collegio Sindacale") is responsible, within the terms provided by the law, for overseeing the Group's financial reporting process.

Auditor's Responsibilities for the Audit of the consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with International Standards on Auditing (ISA Italia) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with International Standards on Auditing (ISA Italia), we have exercised professional judgment and maintained professional skepticism throughout the audit. In addition:

- we have identified and assessed the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, designed and performed audit procedures responsive to those risks, and obtained audit evidence that is sufficient and appropriate to provide a basis for our opinion; the risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- we have obtained an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control;
- we have evaluated the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Directors;
- we have concluded on the appropriateness of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern; if we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to consider this matter in forming our opinion; our conclusions are based on the audit evidence obtained up to the date of our auditor's report;



however, future events or conditions may cause the Group to cease to continue as a going concern;

- we have evaluated the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- we have obtained sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements; we are responsible for the direction, supervision and performance of the group audit; we remain solely responsible for our audit opinion.

We have communicated with those charged with governance, identified at an appropriate level as required by ISA Italia, regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We have provided those charged with governance with a statement that we have complied with the ethical and independence requirements applicable in Italy, and we have communicated with them all matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, we have determined those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We have described these matters in our auditor's report.

Additional information pursuant to article 10 of EU Regulation n. 537/14

The shareholders of Kedrion S.p.A., in the general meeting held on April 27, 2015, engaged us to perform the audits of the consolidated financial statements for each of the years ending December 31, 2014 to December 31, 2022.

We declare that we have not provided prohibited non-audit services, referred to article 5, par. 1, of EU Regulation n. 537/2014, and that we have remained independent of the Group in conducting the audit.

We confirm that the opinion on the consolidated financial statements included in this report is consistent with the content of the additional report to the audit committee (Collegio Sindacale) in their capacity as audit committee, prepared pursuant to article 11 of the EU Regulation n. 537/2014.

Report on compliance with other legal and regulatory requirements

Opinion pursuant to article 14, paragraph 2, subparagraph e), of Legislative Decree n. 39 dated 27 January 2010 and of article 123-bis, paragraph 4, of Legislative Decree n. 58, dated 24 February 1998

The Directors of Kedrion S.p.A. are responsible for the preparation of the Report on Operation and of the specific section on Corporate Governance, as provided for by paragraph 2, subparagraph b) of the article 123-bis of Legislative Decree 24 February 1998, n. 58, of Group Kedrion as at December 31, 2018, including their consistency with the related consolidated financial statements and their compliance with the applicable laws and regulations.

We have performed the procedures required under audit standard SA Italia n. 720B, in order to express an opinion on the consistency of the Report on Operations and of specific section on Corporate Governance as provided for by paragraph 2, subparagraph b) of the article 123-bis comma



4 of Legislative Decree 24 February 1998, n. 58, with the consolidated financial statements of Kedrion Group as at December 31, 2018 and on their compliance with the applicable laws and regulations, and in order to assess whether they contain material misstatements.

In our opinion, the Report on Operation and the above mentioned specific section on Corporate Governance are consistent with the consolidated financial statements of Kedrion Group as at December 31, 2018 and comply with the applicable laws and regulations.

With reference to the statement required by art. 14, paragraph 2, subparagraph e), of Legislative Decree n. 39, dated 27 January 2010, based on our knowledge and understanding of the entity and its environment obtained through our audit, we have no matters to report.

Statement pursuant to article 4 of Consob Regulation implementing Legislative Decree n. 254, dated 30 December 2016

The Directors of Kedrion S.p.A. are responsible for the preparation of the consolidated disclosure of non-financial information pursuant to Legislative Decree n. 254, dated 30 December 2016. We have verified that non-financial information have been approved by Directors.

Pursuant to article 3, paragraph 10, of Legislative Decree n. 254, dated 30 December 2016, such non-financial information are subject to a separate compliance report signed by us.

Florence, April 12, 2019

EY S.p.A.
Signed by: Lapo Ercoli, partner

This report has been translated into the English language solely for the convenience of international readers.

3.2. REPORT ON CONSOLIDATED DISCLOSURE OF NON-FINANCIAL INFORMATION IN ACCORDANCE WITH D. LGS. 254/2016



Kedrion S.p.A.

Independent auditors' report on the consolidated disclosure of non-financial information in accordance with Article 3, par. 10, of Legislative Decree 254/2016 and with Article 5 of CONSOB Regulation adopted with Resolution n. 20267 of January 18, 2018



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Independent auditors' report on the consolidated disclosure of non-financial information in accordance with Article 3, par. 10, of Legislative Decree 254/2016 and with Article 5 of CONSOB Regulation adopted with Resolution n. 20267 of January 18, 2018

(Translation from the original Italian text)

To the Board of Directors of
Kedrion S.p.A.

We have been appointed to perform a limited assurance engagement pursuant to Article 3, paragraph 10, of Legislative Decree 30 December 2016, n. 254 (hereinafter "Decree") and article 5 of CONSOB Regulation adopted with Resolution 20267/2018, on the consolidated disclosure of non-financial information of Kedrion S.p.A. and its subsidiaries (hereinafter the "Group") for the year ended on 31st December 2018 in accordance with article 4 of the Decree, presented in the specific section of the Management Report and approved by the Board of Directors on 29th March 2019 (hereinafter "DNF").

Responsibilities of Directors and Board of Statutory Auditors for the DNF

The Directors are responsible for the preparation of the DNF in accordance with the requirements of articles 3 and 4 of the Decree and the "Global Reporting Initiative Sustainability Reporting Standards" defined in 2016 by GRI - Global Reporting Initiative (hereinafter "GRI Standards") identified by them as a reporting standard.

The Directors are also responsible, within the terms provided by law, for that part of internal control that they consider necessary in order to allow the preparation of the DNF that is free from material misstatements caused by fraud or not intentional behaviors or events.

The Directors are also responsible for identifying the contents of the DNF within the matters mentioned in article 3, par. 1, of the Decree, considering the business and the characteristics of the Group and to the extent deemed necessary to ensure the understanding of the Group's business, its performance, its results and its impact.

The Directors are also responsible for defining the Group's management and organization business model, as well as with reference to the matters identified and reported in the DNF, for the policies applied by the Group and for identifying and managing the risks generated or incurred by the Group.

The Board of Statutory Auditors is responsible, within the terms provided by the law, for overseeing the compliance with the requirements of the Decree.

Auditors' independence and quality control

We are independent in accordance with the ethics and independence principles of the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants, based on fundamental principles of integrity, objectivity, professional competence and diligence, confidentiality and professional behavior. Our audit firm applies the International Standard on Quality

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Control 1 (ISQC Italia 1) and, as a result, maintains a quality control system that includes documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable laws and regulations.

Auditors' responsibility

It is our responsibility to express, on the basis of the procedures performed, a conclusion about the compliance of the DNF with the requirements of the Decree and of the GRI Standards. Our work has been performed in accordance with the principle of "International Standard on Assurance Engagements ISAE 3000 (Revised) - Assurance Engagements Other than Audits or Reviews of Historical Financial Information" (hereinafter "ISAE 3000 Revised"), issued by the International Auditing and Assurance Standards Board (IAASB) for limited assurance engagements. This principle requires the planning and execution of work in order to obtain a limited assurance that the DNF is free from material misstatements. Therefore, the extent of work performed in our examination was lower than that required for a full examination according to the ISAE 3000 Revised ("reasonable assurance engagement") and, hence, it does not provide assurance that we have become aware of all significant matters and events that would be identified during a reasonable assurance engagement.

The procedures performed on the DNF were based on our professional judgment and included inquiries, primarily with company's personnel responsible for the preparation of the information included in the DNF, documents analysis, recalculations and other procedures in order to obtain evidences considered appropriate.

In particular, we have performed the following procedures:

1. analysis of the relevant matters in relation to the activities and characteristics of the Group reported in the DNF, in order to assess the reasonableness of the selection process applied in accordance with the provisions of article 3 of the Decree and considering the reporting standard applied;
2. analysis and evaluation of the criteria for identifying the consolidation area, in order to evaluate its compliance with the provisions of the Decree;
3. understanding of the following aspects:
 - o Group's management and organization business model, with reference to the management of the matters indicated in the article 3 of the Decree;
 - o policies adopted by the Group related to the matters indicated in the article 3 of the Decree, results achieved and related key performance indicators;
 - o main risks, generated or suffered related to the matters indicated in the article 3 of the Decree.

With regard to these aspects, we obtained the documentation supporting the information contained in the DNF and performed the procedures described in item 4. a) below.

4. understanding of the processes that lead to the generation, detection and management of significant qualitative and quantitative information included in the DNF.

In particular, we have conducted interviews and discussions with the management of Kedrion S.p.A. and with the personnel of Human BioPlazma Kft. and we have performed limited documentary evidence procedures, in order to collect information about the processes and procedures that support the collection, aggregation, processing and transmission of non-financial data and information to the management responsible for the preparation of the DNF.



Furthermore, for significant information, considering the Group activities and characteristics:

- at Group level
 - a) with reference to the qualitative information included in the DNF, and in particular to the business model, policies implemented and main risks, we carried out inquiries and acquired supporting documentation to verify its consistency with the available evidence;
 - b) with reference to quantitative information, we have performed both analytical procedures and limited assurance procedures to ascertain on a sample basis the correct aggregation of data.
- For the site of Gödöllő of Human BioPlazma Kft. that we have selected based on its activity, relevance to the consolidated performance indicators and location, we have carried out a site visit during which we have had discussions with management and have obtained evidence about the appropriate application of the procedures and the calculation methods used to determine the indicators.

Conclusion

Based on the procedures performed, nothing has come to our attention that causes us to believe that the DNF of the Kedrion Group for the year ended on 31st December 2018 has not been prepared, in all material aspects, in accordance with the requirements of articles 3 and 4 of the Decree and the GRI Standards.

Other Information

The comparative information presented in the DNF for the year ended on 31st December 2016 has not been examined.

Florence, 12th April 2019

EY S.p.A.

Signed by: Lapo Ercoli, partner

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4. REPORT ON OPERATIONS



Dear Shareholders,

The financial year ended 31 December 2018 generated a turnover for the Kedrion Group of Euro 687.9 million (Euro 602.5 million in 2017) with an increase of 14.2% compared to the previous year thanks to the consolidation of its international position through an integrated business model that allowed to realize turnover in about 100 countries with an export share that in 2018 stood at 75%. The United States remains the leading market thanks to a share of 41% of turnover, followed by the European Union countries with 36% and the Rest of the World with 23%.

Profitability stood at 21.6% (23.2% in 2017), with a slight dilution compared to 2017 due to the higher weight of the plasma segment. In fact, this lower-margin segment showed extraordinary growth of 65% compared to 2017. EBITDA reached Euro 148.7 million (Euro 139.9 million in 2017), while net profit for the year, which was affected by the significant amount of non-recurring costs mainly related to the US plant refitting, was Euro 11.6 million (Euro 6.2 million in 2017), equal to 1.7% of turnover.



The financial statements for the year ended 31 December 2018 include the statement of financial position, statement of profit or loss, statement of profit or loss and other comprehensive income, cash flow statement, statement of changes in shareholders' equity and the related explanatory notes, drawn up in compliance with the IFRS adopted by the European Union.

The consolidated statement of financial position shows a distinction between current and non-current assets and liabilities. The presentation format for the consolidated statement of profit or loss for the year as at 31 December 2016 is illustrated on a by function basis, the format considered more representative than the presentation by nature of expense. The adopted format, in fact, complies with internal reporting and business management methods. The cash flow statement was prepared according to the indirect method and is presented in compliance with IAS 7, thereby classifying cash flows under operating, investment and financing activities.

4.1. SEGMENT PERFORMANCE

Kedrion's reference market is that of biopharmaceutical products derived from human plasma, a segment forming part of the more extensive pharmaceutical market, and is characterized by a wide range of products to treat conditions such as immunodeficiency, haemophilia, infectious diseases and other serious illnesses. The main customers are government authorities, the national health services (through tender awards) and private distributors.

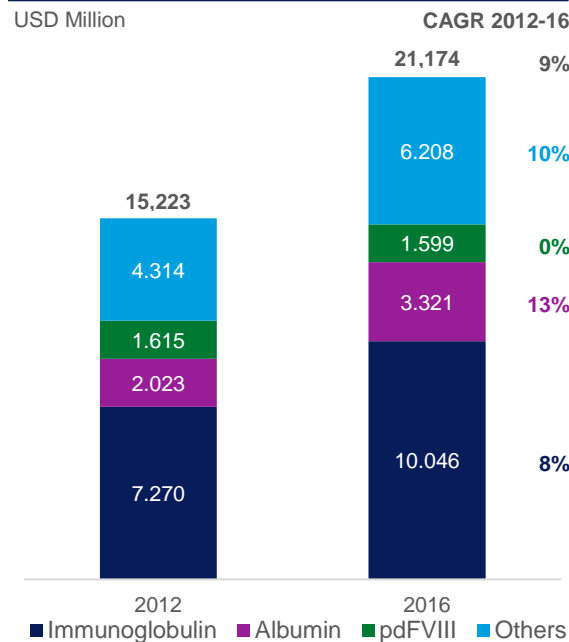
In the last 20 years the market has faced a progressive consolidation phase, which led the three main producers of plasma products - CSL Behring, Shire and Grifols - to hold an overall market share of approximately 67%, with Kedrion in fifth position, with a share of 3%.

According to the latest estimates, the global plasma product market has exceeded 21 billion dollars in 2016¹, with an average annual growth rate of 8.6% for the period 2012-2016, favored by the increase in diagnosis, aging of the population and the increase in healthcare spending per capita.

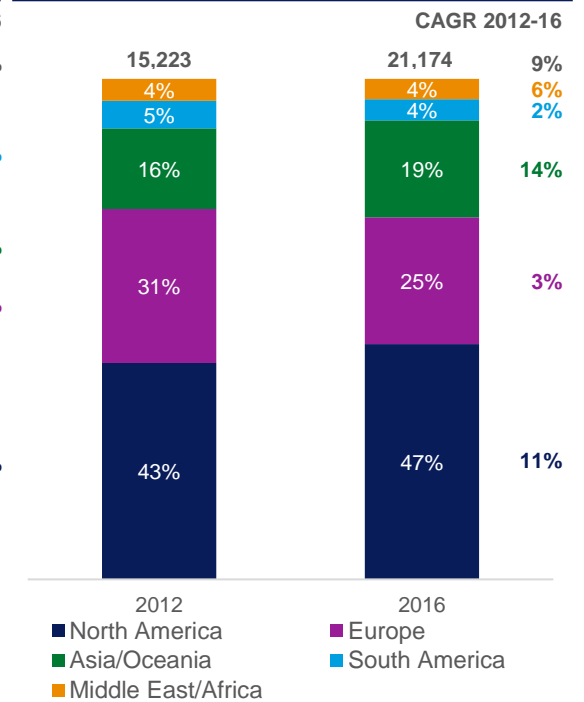
At product level, the market is dominated by Immunoglobulin, which, with over 10 billion dollars, represents about 47% of the total market, with an average annual growth of 8.4% since 2012, thanks to the approval of new therapeutic indications, especially in the neurological field, to the increase in patients diagnosed with primary immunodeficiencies and greater penetration in emerging countries.

The second product by value is represented by Albumin, with over 3 billion dollars of value estimated in 2016, an increase of 13.2% on average per year since 2012, driven by demand in China. The third product is Factor VIII, which represents 7.6% of the market, equal to 1.6 billion dollars, stable compared to 2012 due to the increase in the use of recombinant products.

MARKET TREND BY PRODUCT



MARKET TREND BY AREA



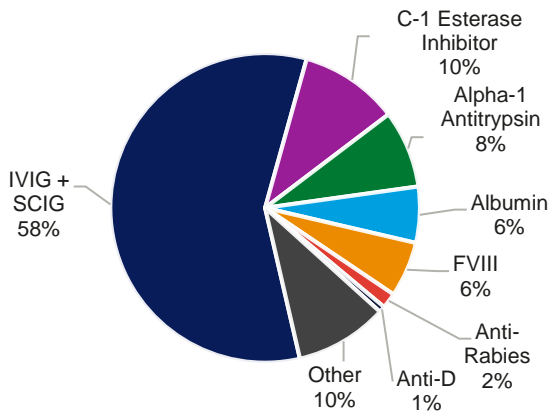
From a geographical point of view, 72% of the market is concentrated in North America and Europe. The United States, with approximately 9.5 billion dollars², is the most important market with an average annual growth of 11.6% since 2012. As shown in the following graphs, even in the US Immunoglobulin has the largest share of market with around 57%. The three main players - Shire, CSL Behring and Grifols - hold 88% of the American market together, while Kedrion is fifth with a 2% share.

¹ Source: Marketing Research Bureau "The Worldwide Plasma Proteins Market 2016". Recombinant not included.

² Source: Marketing Research Bureau "The Plasma Proteins Market in the United States 2016". Recombinant not included.

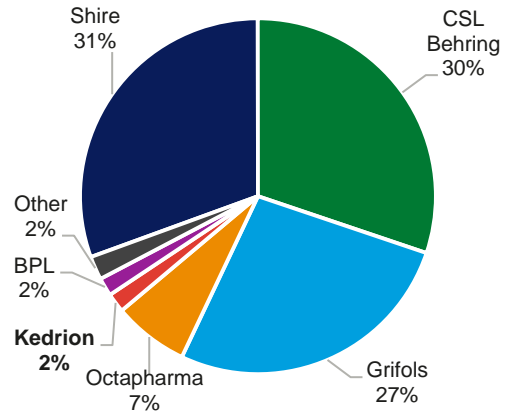
US MARKET BY PRODUCT

100% = 10.2 billion of Dollars (2017)



US MARKET BY COMPANY

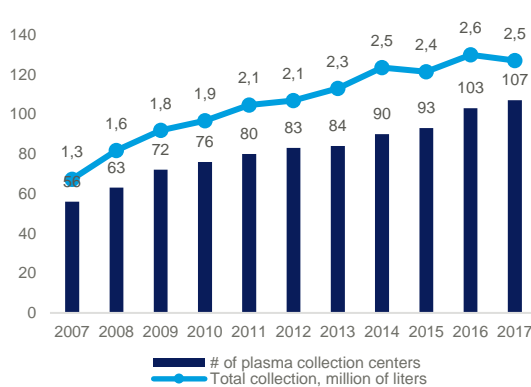
100% = 10.2 billion of Dollars (2017)



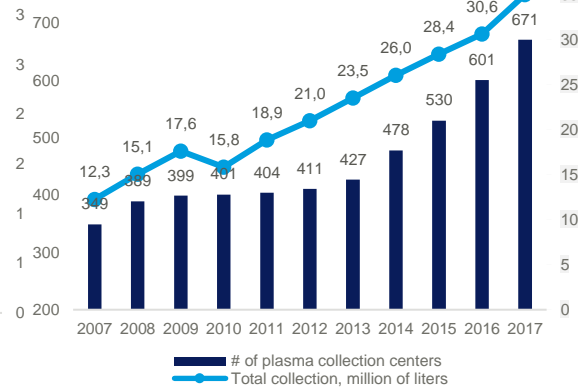
The United States are the world's first market for plasma collection, with approximately 35 million liters collected in 2017, increasing of 10.8% per year compared to 2012 and a total of 671 collection centers³. The latest updated data also confirms this growth trend in the United States, with the number of centers increasing to 778 in November 2018³. In Europe, considering the countries where plasma collection is managed by private companies - Germany, Czech Republic, Hungary and Austria - 2.5 million liters were collected in 2017, with an average annual increase of 3.5 % compared to 2012, for a total of 107 centers⁴.

Also in plasma collection activities, there has been a gradual consolidation in the last few years, with Grifols, CSL Behring and Shire owning 60% of the European and American centers⁵. This consolidation is due to the need of the main fractionators to ensure the raw material supply, in the light of plans to increase production capacity, which see the capacity for total splitting going from the 51 million liters estimated at the end of 2017 to 77 million liters in 2022, of which 65% held by the three main players⁶.

EUROPE PLASMA COLLECTION 2007-2017



US PLASMA COLLECTION 2007-2017



³ Source: PPTA. Plasma figures include plasma collected by plasmapheresis.

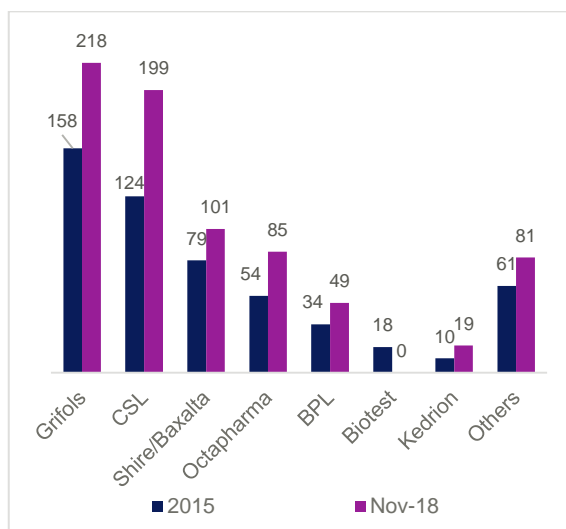
³ Source: PPTA 2017

⁴ Source: PPTA. Plasma figures include plasma collected by plasmapheresis.

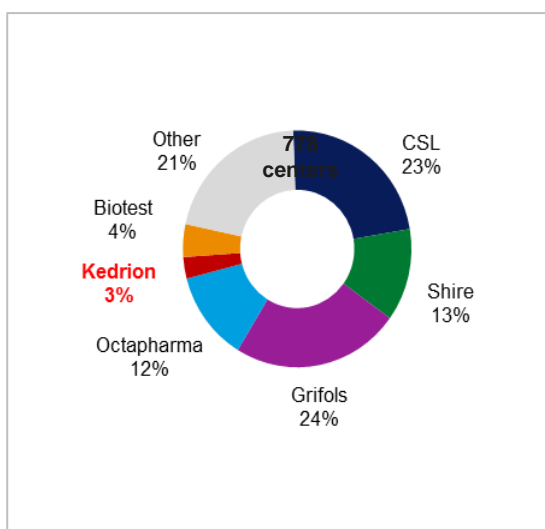
⁵ Source: Goldman Sachs Research as of 19th March 2018, FDA data.

⁶ Source: Bank of America Merrill Lynch Global Research, 6 aprile 2017.

US PLASMA COLLECTION CENTERS



EUROPE AND US PLASMA COLLECTION CENTERS BY COMPANY (% YEAR 2017)



The Italian plasma derivatives market is divided into the processing of plasma on behalf of the Italian Regions within the framework of the national self-sufficiency program and the commercial market.

The new principles established by the law n. 219/2015 provide that the Regions, individually or in a consortium, confer the plasma collected at the Transfusion Services and the Collection Units to authorized companies on the basis of tenders. Currently, the companies authorized to carry out the processing of the national plasma, identified on the basis of the Ministerial Decree of 5 December 2014, are CSL Behring, Baxter (Shire), Grifols, Kedron and Octapharma. Following the entry into force of the new regulatory regime, three tenders were awarded: the first, banned by the Veneto Region on behalf of the NAIP group⁷, was assigned to CSL Behring in March 2016; the second tender, organized by the Emilia Romagna Region on behalf of the RIPP group⁸, was assigned in September 2017 to a temporary association made up of Grifols and Kedron and on the same is pending an administrative dispute. The third, announced by the Region of Tuscany on behalf of the PLANET⁹ group, was assigned in June 2018 to a temporary association between the companies of the Baxter Group, and an administrative dispute is also pending over it. Kedron currently continues to work with plasma on behalf of the Regions that have not yet launched tenders under the new regulations, as well as on behalf of the Regions of the groups headed by Tuscany and Emilia Romagna, as supplies, on the basis of the new tenders assigned, have not yet been started.

In 2018, in Italy, about 840 thousand kilos of plasma were collected, increasing of 0.4% over the previous year¹⁰, reaching important levels of self-sufficiency.

In terms of products, in recent years a steady growth has been observed for the main plasma products, in line with international markets, with the exception of factor VIII and Anti-Trombine, which have a constant demand.

On the whole, based on the most recent estimates by MRB, PPTA and IMS, the Italian market in 2018 (including the recombinant market) exceeded 800 million of Euro (Kedron share is 21%);

⁷ Abruzzo, Basilicata, Friuli Venezia Giulia, Liguria, Umbria, Valle d'Aosta, Veneto, Provincia Aut. di Trento, Provincia Aut. di Bolzano.

⁸ Emilia-Romagna, Puglia, Calabria, Sicilia.

⁹ Toscana, Campania, Lazio, Marche

¹⁰ Source: Centro Nazionale Sangue.

excluding instead the recombinant market (both commercial and contract work) is equal to 460 million of Euro and Kedrion is the leader with approximately 35%.

4.2. BUSINESS OPERATIONS

Kedrion is one of the leading international groups in the development, production and distribution of a wide range of products derived from human plasma. Its life-saving products are used to treat patients with haemophilia, immunodeficiencies, infectious diseases and other serious conditions in around 100 countries worldwide.

Its global presence is articulated through an integrated business model that ensures the constant availability of the raw material thanks to 27 collection centers owned between Europe and the United States, 6 production plants and a rigorous quality control on the entire production chain. The production plants are subject to constant technological development geared towards excellence and upgraded periodically to ensure the highest safety standards at all levels of production. The plant in Bolognana (LU) is the only plant in Italy capable of producing the whole range of blood products, while that of Sant'Antimo (NA) is specialized in the production of specific immunoglobulins and inactivated plasma viruses. The Godollo plant (Budapest) was originally dedicated to supplies for the European and Asian markets and, following an important renovation that has more than doubled its capacity, since the end of 2012 it also produces intermediates for the Bolognana plant, where they are then brought to the finished product. The Melville US plant, purchased during 2012, subject to a major restructuring during the years 2016-2017, now fractionates plasma mainly for the U.S. market of Kedrion. In addition to these plants, there is another small plant in Siena dedicated to the research and development of orphan drugs and the new plant in Castelvecchio Pascoli (LU), currently being completed, which will be dedicated to the purification of the 10% immunoglobulin (KIg10).

The Group operates in three business segments:

- *Production and sale of plasma derivatives*, i.e. proteins extracted from human plasma such as albumin, standard and specific immunoglobulins, and coagulating factors;
- *Collection and sale of plasma*. The Group has some collection centers that have primarily secured the supply of the plasma needed to cover the needs of the plasma-derivatives segment, then allocating the surplus to the sale to third parties;
- *Other activities* including the toll manufacturing of intermediates and other products and the marketing of other pharmaceutical specialties including recombinant factor VIII, benefiting from the strong positioning of the Kedrion distribution network.

The Group operates worldwide, segmenting its markets into four geographical macro areas: Italy, European Union, United States and Rest of the World.

4.3. SIGNIFICANT EVENTS DURING THE YEAR

4.3.1. "PRODUCTION AND SALE OF PLASMA DERIVATIVES" SEGMENT

MELVILLE PLANT'S REFITTING COMPLETION

With regard to the plasma derivatives segment, the main (expected) situation that affected the performance of the year is represented by the conclusion of the project which saw the total shutdown of the Melville US plant from April 2016 to the first half of 2018 (so-called "refitting") for (i) the complete restructuring of the existing splitting line with the aim of completing the integration and harmonization of this plant with the other plant of Kedrion Group, as well as implementation of some recommendations received from the US Food & Drug Administration (FDA), and (ii) the

construction of a fractionation and purification line of the anti-D immunoglobulin (RhoGAM), aimed at internalizing the production of this specialty.

The project, which involved investments of Euro 3.9 million in 2018 for the Group (which add up to approximately Euro 83.6 million already invested in 2016-2017), has been completed from an industrial point of view with the operational restart of the fractionation in the second half of the year with about 80.000 liters fractionated. In August 2018, the fractionation plant was inspected by the FDA, which led to its final approval by the U.S. authorities in February 2019. The new line dedicated to the RhoGAM product was also inspected by the FDA in November 2018 and the operational start-up of this line, initially for filling and packaging activities, is expected in the first half of 2019, having received FDA approval in March 2019.

The partial activity of Melville plant led to a significant impact on the income statement for the year, due to the non-absorption of costs of the plant (which only from the time of the restart found partial correspondence in production) and the write-down of inventory of intermediates and finished products realized before the plant shutdown, for a total of Euro 876.0 million, as well as for the reduction in sales margins due to the outsourcing at Grifols of the production for the US market.

NEW CASTELVECCHIO PASCOLI PLANT FOR THE PURIFICATION OF IMMUNOGLOBULIN 10% (KLG10)

During the year the project for the realization of the 10% immunoglobulin purification plant (Klg10) was continued with the chromatographic method at Castelvechio Pascoli (LU).

In December 2018, the IND (Investigational New Drug) application for the development of KIG10 was submitted to the FDA and approved the following month, the date from which Kedrion is authorized to begin clinical trials. Currently, production for clinical studies is carried out at the Godollo plant and, once these studies have been completed, at the Castelvechio plant (for the purification phase, while fractionation will be carried out at the Melville plant).

Melville plant refitting delayed the completion of the preparatory activities to obtain the necessary authorizations and the registration of the product, generating an increase of start-up costs. Costs, which have not found a balance in production and related revenues yet, are equal to 8.4 million. Furthermore, following the 2018 innovation agreement between the Ministry for Economic Development, the Region of Tuscany and Kedrion S.p.A, for which part of the investment program for this project is financed by the Mise and the Region of Tuscany, grant for Euro 1.8 million was recorded as other non-recurring income.

NEW PRODUCT KEDRAB

Sales of KEDRAB, a concentrated anti-rabies hyperimmune immunoglobulin developed in partnership with Kamada, an Israeli pharmaceutical company, began in early 2018. Kedrion is the exclusive distributor of this product in the United States market and the turnover of the first year of activity was Euro 12.9 million.

PRICE TRENDS

Sales prices of plasma derivatives products in this year have been characterized by a slight recovery, in particular for immunoglobulin. In fact, in some European markets, the price of immunoglobulin has increased between 5 and 10%, while in the United States it has increased by about 3%. Other markets, such as Russia, Turkey and Mexico, were significantly affected by the weakness of the local currency.

4.3.2. "COLLECTION AND SALE OF PLASMA" SEGMENT

GREATER PLASMA AVAILABILITY

The Plasma segment was characterized in the year by an increase in the volumes available for the Group, generated mainly by the greater quantities of plasma collected in the owned centers and also those supplied by BPL Plasma. The growth in available plasma volumes has led, once the internal production requirements have been met, to a substantial increase in sales to third parties, generating segment sales for Euro 155.1 million compared to Euro 93.9 million in 2017, realizing therefore a growth of 65%.

SALES AND PURCHASES/START UP OF OWNED COLLECTION CENTERS

On the one hand, the segment saw, during this financial year, the sale to the Grifols Group of six plasma collection centers deemed not strategic, on the other hand, the purchase/start-up during the year of eight centers in the United States and a center in Hungary, for a total of 27 owned centers at the end of the year.

The sale to Grifols of the six collection centers contributed significantly to the result for the period, recording an amount equal to approximately Euro 28 million among other income.

SALES PRICE

The selling prices of plasma during the year have seen significant growth that, with regard to standard plasma, was about 4%.

4.3.3. FINANCIAL OPERATIONS

FOREIGN EXCHANGE TREND

The exchange rate fluctuation (in particular the US dollar, which rose from 1.1993 at 31 December 2017 to 1.1450 at 31 December 2018) generated a positive impact on the income statement due to exchange differences realized and unrealized for Euro 9.3 million (last year the effect on the result was negative for Euro 17.0 million), as well as an increase of the shareholders' equity of the Group and of third parties Euro for 8.3 million due to the change in the conversion reserve.

4.4. BUSINESS PERFORMANCE

(In thousands of Euro)	Year ended 31 December				
	2018	% of total revenues	2017	% of total revenues	Difference 2018/2017
Revenues	687,939	100.0%	602,501	100.0%	14.2%
Cost of sales	518,482	75.4%	427,831	71.0%	21.2%
Gross margin	169,457	24.6%	174,670	29.0%	(3.0%)
Other income	37,494	5.5%	52,887	8.8%	(29.1%)
General and administrative expenses	83,659	12.2%	80,757	13.4%	3.6%
Sales and marketing expenses	46,314	6.7%	51,785	8.6%	(10.6%)
Research and development costs	48,127	7.0%	35,045	5.8%	37.3%
Other operating costs	8,286	1.2%	8,325	1.4%	(0.5%)
EBIT	20,565	3.0%	51,645	8.6%	(60.2%)
Financial expenses	27,678	4.0%	43,750	7.3%	(36.7%)
Financial income	15,387	2.2%	1,953	0.3%	687.9%
Financial operations	12,291	1.8%	41,797	6.9%	(70.6%)
INCOME BEFORE TAXES	8,274	1.2%	9,848	1.6%	(16.0%)
Income taxes	(3,367)	0.5%	3,657	0.6%	(192.1%)
NET INCOME (LOSS) FOR THE PERIOD	11,641	1.7%	6,191	1.0%	88.0%
Net income (loss) attributable to non-controlling interest	1,476	0.2%	1,003	0.2%	47.2%
GROUP NET INCOME (LOSS)	10,165	1.5%	5,188	0.9%	95.9%

4.4.1. REVENUES

A breakdown of turnover by business segment and geographical area is provided in the following tables.

REVENUES (In thousands of Euro)	Year ended 31 December				
	2018	% of total revenues	2017	% of total revenues	Difference 2018/2017
Plasma derivatives	513,920	74.7%	490,016	81.3%	4.9%
Plasma	155,110	22.6%	93,905	15.6%	65.2%
Other	18,909	2.7%	18,580	3.1%	1.8%
TOTAL	687,939	100.0%	602,501	100.0%	14.2%

“PRODUCTION AND SALE OF PLASMA DERIVATIVES” SEGMENT

Revenues for the production and marketing of plasma-derived drugs as at 31 December 2018 amounted to Euro 513.9 million (74.7% of total revenues) with an increase of around 4.9% mainly due to the introduction of the new anti-rabies immunoglobulin on the U.S. market, an increase in the volume of albumin sold and higher prices for standard immunoglobulin. The plasma derivatives US market raises of about 14% related to the previous year, and all the other strategic markets are growing, driven by Italy, Germany and Mexico; within this segment, the US market retains leadership compared to the Italian market.

In addition, in 2018, the weight of this segment contracted to about 75% as a result of strong growth in the plasma segment.

“COLLECTION AND SALE OF PLASMA” SEGMENT

Revenues in the plasma collection and commercialization segment at December 31, 2018 amounted to Euro 155.1 million, with an increase of 65.2% compared to the previous year. This excellent performance was made possible by the increase in the volumes of plasma available, both purchased from third parties and generated by a growing collection in American and European owned centers (managed by the Plasma Business Unit to which KEDPLASMA LLC, KEDPLASMA GmbH and the plasma division in the Hungarian company HUMAN BioPlazma Kft belong to), the number of which, despite the sale of six centers during the year 2018, increased thanks to the purchase/start-up of eight owned centers in the United States and a center in Hungary.

“OTHER ACTIVITIES” SEGMENT

Revenues for this segment at 31 December 2018 amounted to 18.9 million Euro and relate to the sale of synthetic products and production on behalf of third parties.

One of the synthetic products is the Nuwiq, the recombinant factor VIII obtained in exclusive distribution for Italy by Octapharma with a ten-year agreement. The turnover of this product during this year (Euro 11.9 million) increased by +29% compared to 2017.

In 2018, the sale of CERUS products continued, with exclusive distribution in Italy from 2017 of biomedical products used for the viral inactivation of human platelets and plasma: the activity was launched both for the commercial synergy with the current Kedrion positioning in the plasma derivatives industry and for the possible development of the red cell inactivation segment for transfusion use, for which CERUS plans to obtain authorization in the coming years. In 2018,

CERUS products sales, generated revenues of Euro 1.6 million, compared to Euro 0.2 million in 2017.

The production on behalf of third parties carried out at the Melville and Godollo plants for some operators in the industry, is Euro 4.8 million, compared to 8.5 million in 2017: this segment too has been slowed down by the refitting activity of Melville plant, while the European production, carried out at the Godollo plant, is increased from last year by 11%.

The breakdown of revenues by geographical area is as follows:

REVENUES (In thousands of Euro)	Year ended 31 December				
	2018	% of total revenues	2017	% of total revenues	Difference 2018/2017
USA	282,109	41.0%	244,389	40.6%	15.4%
Italy	174,209	25.3%	163,589	27.1%	6.5%
Rest of the World	156,435	22.8%	136,124	22.6%	14.9%
European Union	75,186	10.9%	58,398	9.7%	28.7%
TOTAL	687,939	100.0%	602,501	100.0%	14.2%

USA

The turnover of this area, reached Euro 282.1 million, maintaining its position as the leading market for Kedrion with 41% of total revenues. Plasma sales were the main driver of revenue growth this year, followed by the new anti-rabies immunoglobulin, albumin, standard immunoglobulin and anti-D (RhoGAM) immunoglobulin, while factor VIII contracted in volumes sold.

In addition to sales of plasma-derived products, there is also sales in this area for activities carried out for third parties at the Melville plant, which decreased as they were affected by the restart of the plant.

ITALY

At 31 December 2018, the Italian market increased by 6.5% compared to the previous year with a turnover of Euro 174.2 million, equal to 25.3% of total revenues, achieved through the sale of finished products on the commercial market and the toll manufacturing for the National Health System. The increase compared to the previous year is mainly due to the growth in contract manufacturing volumes invoiced to the National Health System and the higher turnover of the recombinant factor VIII Nuwiq and CERUS products.

EUROPEAN UNION

Revenues in the European Union as at 31 December 2018 amounted to Euro 75.2 million, equal to 10.9% of total revenues, recording a significant increase of 28.7% compared to 2017 thanks to the increase in plasma sales to European customers (mainly in Germany) which amounted to Euro 7.4 million, and especially to higher volumes placed at rising prices of standard immunoglobulin in Germany, Austria, Poland and Portugal, which constitute, together with Hungary, the main European markets of 2018.

REST OF THE WORLD

Revenues for this geographical area as at 31 December 2018 amounted to Euro 156.4 million, with an increase of 14.9% compared to 2017 and representing 22.8% of total revenues. Mexico overcomes Turkey (despite the fact that both these countries also suffer from the weakness of the local currency in 2018) and becomes the leading market in this area in terms of turnover, reaching Euro 28.4 million, followed by Switzerland (mainly for plasma sales) and Turkey; moreover, together with Russia, Saudi Arabia, Vietnam, Israel and the United Arab Emirates, they cover approximately 73% of total revenues in the area.

4.4.2. OPERATING COSTS

Raw material, i.e. plasma, also recorded a price increase in 2018 in line with those highlighted in recent years. However, the long-term contracts for the purchase of plasma signed in previous years enabled to mitigate this increase and thanks to the continuous development of internal collection, which is less expensive than the plasma purchased from third parties, the increase in the average cost of plasma in the current year has been contained.

The partial activity of the Melville plant during 2018 resulted in a high level of unabsorbed costs, as well as the maintenance of the outsourcing production contract for the American market at Grifols had a negative impact in terms of sales margins. These two elements led to a reduction in gross margin from 29.0% in 2017 to 24.6% in 2018.

Overall, other operating costs were slightly down, with the exception of R&D costs, which increased by about 37% compared to 2017 as a result of new product development and internalization projects of the US production.

In order to further improve this situation, the Group is constantly engaged in the continuous search for efficiency through specific control actions and reduction of the weight of operating costs.

4.4.3. ALTERNATIVE PERFORMANCE INDICATORS

In addition to the conventional indicators required under IFRS, this Report on Operations presents some alternative performance indicators used by Kedrion Group management to monitor and assess business performance. Since these indicators are not identified as an accounting measure for IFRS purposes, they should not be considered an alternative means of measuring Group performance. As the breakdown of the alternative performance indicators (EBITDA, adjusted EBITDA, adjusted Gross Margin, Net Capital Invested, Net Working Capital, Net Financial Position) is not regulated by the reference accounting standards, the calculation criterion applied at Group level might not coincide with that adopted by other parties and is therefore not comparable.

EBITDA

The 2018 EBITDA stood at Euro 46.5 million (6.8% of turnover), down compared to the previous year (Euro 77.2 million) due to a very high level of non-recurring costs in agreement with the definition below the following table. In fact, as better detailed in the specific section (note 4.12), this item includes approximately Euro 102.2 million of non-recurring costs with an impact on the EBITDA, of which 73.4 million euros referring to the plant's refitting project Melville.

Adjusted EBITDA (calculated excluding the impact of these non-recurring items) reached Euro 148.7 million (21.6% of turnover), with a significant increase compared to 2017 (+6.3%).

Depreciation and amortization amounted to Euro 26.3 million, bringing operating profit to Euro 20.6 million, equal to 3.0% of turnover.

(In thousands of Euro)	Year ended 31 December				
	2018	% of total revenues	2017	% of total revenues	Difference 2018/2017
Operating Income	20,565	3.0%	51,645	8.6%	(60.2%)
+ Amortisation and depreciation	26,295	3.8%	25,895	4.3%	1.5%
- Plant and machinery grants	(356)	(0.1%)	(342)	(0.1%)	4.1%
EBITDA(*)	46,504	6.8%	77,198	12.8%	(39.8%)
Non-recurring items	102,181	14.9%	62,677	10.4%	63.0%
ADJUSTED EBITDA(*)	148,685	21.6%	139,876	23.2%	6.3%

(*) EBITDA is represented by the operating income gross of amortization/depreciation and plant and machinery grants. The adjusted EBITDA does not take into account certain one-off costs and revenues such as penalties, acquisition costs, new plants and plasma centers start-up costs, refinancing costs, employee incentives, transactions and contractual penalties. EBITDA and adjusted EBITDA defined in this manner are a measurement used by company management to monitor and assess business performance. EBITDA is not identified as an accounting measure for IFRS purposes and therefore cannot be considered an alternative means of measuring Group performance. Given that the breakdown of EBITDA is not regulated by accounting standards of reference, the calculation criterion applied at Group level might not coincide with that adopted by others and is therefore not comparable.

ADJUSTED GROSS MARGIN

Analysis of Gross Margin by business segment for the years ended 31 December

(In thousands of Euro)	Segment Adjusted Gross Margin (*)			
	Plasma derivatives production and marketing	Plasma collection and commercialization	Other activities	TOTAL
YEAR ENDED 31 DECEMBER 2018	198,849	29,997	5,551	234,396
% of total revenues of the business segment (**)	38.7%	9.4%	29.4%	34.1%
% of total Adjusted Gross Margin	84.8%	12.8%	2.4%	100.0%
Difference 2018/2017	8.4%	22.7%	(11.1%)	9.5%
YEAR ENDED 31 DECEMBER 2017	183,455	24,455	6,243	214,152
% of total revenues of the business segment (**)	37.4%	10.9%	33.6%	35.5%
% of total Adjusted Gross Margin	85.7%	11.4%	2.9%	100.0%

(*) The segment Adjusted Gross Margin is represented by the revenues of the segments less the production costs that may be directly allocated to the segments not considering non-recurring production costs such as the unabsorbed resulting from the refitting of the plants or the acquisition/opening of new plasma centers. With regard to costs directly allocated to sectors, the Group books direct and indirect production costs relating to the business sector, including production amortization and all the other costs making up the cost of sales. The commercial costs, general and administrative costs, research and development costs and other operating costs are not attributed to the sectors. The segment margin defined in this way is a measurement used by Group management to monitor and assess its business performance and is not identified as an accounting measure for IFRS purposes and therefore cannot be considered an alternative means of measuring Group performance. Given that the breakdown of the sector margin is not regulated by the accounting standards of reference, the calculation criterion applied at Group level might not coincide with that adopted by others and is therefore not comparable.

(**) Calculated on segment revenues before inter-segment eliminations.

Plasma derivatives production and marketing

This segment's Gross margin amounted to 198.8 million Euro, equal to 38.7% of total segment revenues and represents 84.8% of the Group's total adjusted gross margin.

The slight increase in the margin from 37.6% in 2017 to 38.7% in the current year is mainly due to the rise in prices, primarily in Europe and the USA, of standard immunoglobulin and to the ever-increasing weight of the more profitable American market.

Plasma collection and commercialization

Adjusted Gross Margin of the plasma collection and distribution segment went from 10.9% of total segment revenues in 2017 to 9.4% in 2018, with a significant growth weight reaching 12.8% of the Group's Adjusted total Margin. In fact, during the 2018 financial year, the volumes of standard plasma available both for the growth of internal collection and purchases from third-party operators increased considerably and this explains the increased size of this segment. The slight decrease in margins is attributable to the greater weight of the less profitable sales of standard plasma compared to those of hyperimmune plasma (anti-D, anti-Tetanus, anti-rabies and anti-hepatitis) while the average increases in the cost of plasma were reversed on in sales prices.

Other activities

This last residual segment's Adjusted Gross Margin decreased to 29.4% of the total revenues of the sector for the year ended 31 December 2018 compared to 33.6% of the previous year. The slight dilution of margins is linked to the reduction of production activities on behalf of third parties in the various production plants, which guarantee better absorption of production costs, while revenues from the exclusive commercialization in Italy of both the recombinant factor VIII, under licence from Octapharma, and the products under licence from CERUS increased. The weight of this segment in terms of margins decreased from 2.9% to 2.4% as a result of the performance of the activities described above.

4.4.4. FINANCIAL OPERATIONS

Financial charges amounted to Euro 27.7 million in 2018, compared with Euro 43.8 million in 2017, and mainly include interest payable to banks and bondholders, financial charges on leasing contracts, and the recognition of foreign exchange losses.

The decrease compared to the previous year is due to lower exchange losses and the absence of financial costs related to refinancing operations (Bond and RCF extension) concluded during 2017.

Financial income increased in this year 2018 to Euro 15.4 million compared to Euro 2.0 million in 2017 and is largely attributable to the positive impact of the appreciation of the U.S. dollar which generated exchange gains on the value in Euro.

The incidence of financial operations (excluding losses and exchange gains) on turnover was 3.2%, compared to 4.1% in 2017.

Profit before taxes amounted to Euro 8.3 million, equal to 1.2% of turnover, net profit for the year amounted to Euro 11.6 million, equal to 1.7% of turnover, while Group profit amounted to Euro 10.2 million (1.5% of turnover).

4.5. STATEMENT OF FINANCIAL POSITION

Reclassification of statement of financial position, based on financial criteria, is as follows:

(In thousands of Euro)	31.12.2018		31.12.2017	
INVESTMENTS				
Net Working Capital (*)	296,452	33.7%	285,634	35.1%
Fixed assets and other long-term assets (**)	587,591	66.8%	538,034	66.2%
Short-term liabilities	(1,450)	(0.2%)	(598)	(0.1%)
Long-term liabilities	(2,694)	(0.3%)	(9,442)	(1.2%)
Net invested capital	879,899	100%	813,628	100%
SOURCES				
Net Financial Position (***)	496,396	56.4%	444,620	54.6%
Shareholders' equity	383,503	43.6%	369,008	45.4%
Total sources of financing	879,899	100%	813,628	100%

(*) Net working capital is calculated as current assets net of current liabilities, except for overdrafts and loans maturing within 1 year and financial as-sets and liabilities. Net working capital is not identified as an accounting measurement for either Italian accounting principles or for the IFRS adopted by the European Union. The calculation method applied by the Group might not coincide with that adopted by other groups, and therefore the balance recorded by the Group may not be comparable with that of others.

(**) This item includes the assets held for sale referred to in note 6.4.17.

(***) Net Financial Position is calculated as the sum total of overdrafts and loans maturing within one year and non-current financial liabilities, net of cash and cash equivalents, current and non-current financial assets and fair value of financial derivatives. Net Financial Position is not identified as an accounting measurement for either Italian accounting principles or for the IFRS adopted by the European Union. The calculation method applied by the Group might not coincide with that adopted by other groups, and therefore the balance recorded by the Group may not be comparable with that of others.

A breakdown of movements in investments is provided in the following table:

(In thousands of Euro)	31.12.2018	31.12.2017
Due from customers/contract assets	125,709	127,969
Inventories	344,118	280,180
Trade payables	(170,959)	(122,522)
Other current assets/(liabilities)	(2,417)	7
NET WORKING CAPITAL	296,451	285,634
Tangible assets	268,365	253,601
Goodwill	230,554	219,318
Other intangible assets	83,331	62,034
Assets held for sale	1,554	0
Investments in associates and other companies	2,525	2,426
Other non-current assets	1,262	655
FIXED ASSETS AND OTHER LONG-TERM ASSETS	587,591	538,034
Employment severance indemnity	(9,028)	(6,738)
Provisions for risks and charges	(922)	(959)
Deferred tax liabilities and prepaid tax assets	12,341	6,089
Other non-current liabilities	(5,085)	(7,834)
LONG-TERM LIABILITIES	(2,694)	(9,442)
Provisions for risks and charges	(1,450)	(598)
SHORT-TERM LIABILITIES	(1,450)	(598)

4.5.1. INVESTMENTS

In 2018, the Group made net investments of 79.9 million of Euro, primarily concerned the following:

- **Melville plant (NY, USA)** for a total amount of Euro 4.9 million, mainly relating to the completion of the refitting project for the fractionation line and the new fractionation and purification line for the production of the specialty RhoGAM;
- **Bolognana Plant (LU, Italy)** for a total of 6.7 million of Euro, mainly for works and improvements to existing buildings and plants;

- **Sant'Antimo Plant (NA, Italy)** for a total of Euro 5.5 million for works and improvements to existing buildings and plants;
- **Godollo Plant (Hungary)** for a total amount of Euro 1.8 million relating to work on improvements to existing plants;
- **Plasma collection centers in Germany, Hungary and United States** for a total of Euro 47.0 million, of which Euro 44.8 million for the completion of the purchase of eight new US centers and downpayments for the purchase of eleven other US plasma centers, Euro 0.3 million for the opening of a new Hungarian center and the rest for works and improvements in the other centers.
- **Castelvecchio Pascoli (LU, Italy)** for a total of Euro 8.2 million mainly referred to the Kig10 project (7.1 million of Euro) for the construction of a new generation immunoglobulin production unit, while the rest refers to works and improvements of the warehouse and nearby buildings.
- **Other investments** for a total Euro 5.8 million, mainly referred to IT hardware and software investments, among which the SAP implementation in the company that manages plasma collection in the United States and a new Group information system to improve data collection and management.

Considering the investments described above, the capital invested rises to Euro 879.9 million.

4.5.2. NET WORKING CAPITAL

Net working capital increased from Euro 285.6 million in 2017 to Euro 296.5 million this year, with a percentage on turnover that fell to 43.1% compared to 47.4% in 2017. The increase in absolute value compared to the previous year is mainly due to the growth in inventories (+ Euro 63.9 million) linked to the restart of the Melville plant, partly offset by an increase in trade payables (+ Euro 48.4 million) due to the peak in purchases of plasma at the end of the year and to investments for the maintenance activities of the plants during the year-end shutdown. Analyzing the other components, it should be noted that the item receivables from customers/contract assets decreased by Euro 2.3 million compared to the previous year thanks to the effective credit management policies.

4.5.3. FINANCIAL OPERATIONS

The structure of the debt remained stable compared to the structure reshaped in 2017 when, taking advantage of the favorable conditions on the capital markets, the Group completed a series of operations aimed at refinancing a large part of its medium/long-term debt.

In July 2017, Kedrion S.p.A. issued a new 350 million Euro bond with a 5 years maturity, placed with leading international investors and listed on the Irish Stock Exchange. The bond was issued below par at a price of 99.43 with a coupon of 3%, for a yield of 3.125%. The proceeds from this new issue were partially used to repurchase, through a tender offer, Euro 91 million of the remaining Euro 149 million of the 4.625% coupon bond issued in 2014, the remaining Euro 58.204 million of which will be repaid on 24 April 2019.

In that refinancing context, Kedrion also extended from April 2019 until April 2022 the expiries of two of the revolving credit facilities (Euro 158 million and Euro 30 million. In December 2017, the Parent Company also signed a new 60 million Euro revolving credit facility, expiring in December 2021.

The following table shows the data of medium-long term loans granted to the Group and outstanding at December 31, 2018.

Description	Maturity	Global amount (in thousands of Euro)	Outstanding principle as at 31.12.2018 (in thousands of Euro)	Interest rate as at 31.12.2018
Bond	24.04.2019	58,204	58,204	4.625%
Bond	12.07.2022	350,000	350,000	3.000%
Revolving Credit Facility	31.12.2021	60,000	-	Euribor + 2.000%
Revolving Credit Facility	02.04.2022	30,000	30,000	Euribor 6 Months + 1.650%
Revolving Credit Facility	22.04.2022	158,304	138,304	Euribor 1 Month + 1.750%
TOTAL		656,508	576,508	

The weighted average maturity of medium/long-term loans is three years and two months. The cost of borrowing, including short-term credit lines, is about 3.5%, stable compared to 2017. As can be seen from the table below, as at 31 December 2018 the net financial position stood at Euro 496.4 million, compared to Euro 444.6 million in 2017, because of the high level of investments and unabsorbed costs incurred during this year. Compared to 2017, the current portion of debt is growing mainly due to the maturity of the 2014 bond issue by the end of the year (April 2019) and to the greater use of short-term bank credit lines to support working capital.

(In thousands of Euro)	31.12.2018	31.12.2017
Medium/long-term debt towards banks and other lenders - current portion	64,915	7,036
Current financial liabilities towards banks and other lenders	68,001	41,248
Current borrowing	132,916	48,284
Medium/long-term debt towards banks and other lenders- non-current portion	490,126	511,932
Other non-current financial liabilities	515	346
Non-current borrowing	490,641	512,278
TOTAL GROSS BORROWING	623,557	560,562
Cash and cash equivalents	(116,325)	(104,522)
Other current financial assets	(712)	(564)
Other non-current financial assets	(10,124)	(10,856)
NET FINANCIAL POSITION (*)	496,396	444,620

(*) Net Financial Position is calculated as the sum total of overdrafts and loans maturing within one year and non-current financial liabilities, net of cash and cash equivalents, current and non-current financial assets and fair value of financial derivatives. Net Financial Position is not identified as an accounting measurement for either Italian accounting principles or for the IFRS adopted by the European Union. The calculation method applied by the Group might not coincide with that adopted by other groups, and therefore the balance recorded by the Group may not be comparable with that of others.

4.5.4. FINANCIAL INDICATORS

	31.12.2018	31.12.2017
Short-term ratio <i>Short-term financial payables and current share of long-term debt/Net Financial Position</i>	26.8%	10.9%
Long-term ratio <i>Long-term financial payables/Total Net Financial Position</i>	98.8%	115.2%
Ratio - Net Financial Position/Shareholders' Equity	1.29x	1.20x
Ratio - Net Financial Position/Total sources of financing	56.4x	54.6x
Leverage Ratio <i>(NFP/Adj. EBITDA)</i>	3.34x	3.18x
Net Interest Cover Ratio <i>(EBITDA adj./ Financial operations)</i>	6.85x	7.13x
ROE	3.0%	1.7%
ROIC	1.8%	4.8%
ROA	81.2%	77.9%
ROS	2.2%	6.2%

As regards financial ratios, there was a significant increase in the weight of short-term debt compared to long-term debt as a result of the upcoming maturity of April 2019 of the remaining Euro 58 million of the 2014 bond.

The Net Financial Position/Shareholders' Equity ratio slightly increase as the net financial position has increased due to the need of financing Melville plant restart and the acquisition of new plasma centers. The Leverage Ratio and the Net Interest Cover Ratio deteriorate slightly but continue to show strong financial solidity.

Moving on to the other indicators, a growth was recorded by ROE, which shows the profitability of the investment in the Company's capital, while ROIC (which can be broken down into ROS, representing profitability of sales, and ROA, representing profitability of assets), which measures the remuneration of invested capital, worsened significantly due to the reduction in operating profit as a result of the high level of non-recurring costs, as shown by the trend in ROS.

Looking at the cash flows summarised in the table below, we note that:

- In the financial year 2018 there was an operating cash flow of Euro 36.3 million, stable compared to a generation of Euro 36.8 million in the previous year. This positive flow is linked to the optimisation of the net working capital that took place in this financial year despite the physiological increase in inventories due to the restart of the Melville plant; in particular, the incidence of net working capital fell by 4.3 percentage points compared to the previous financial year following a better management of trade receivables and payables to suppliers, as already detailed in the specific section..
- In 2018, in addition to the normal level of investments required to carry out periodic efficiency improvements to ensure the highest safety standards, important projects were completed by an industrial point of view: such as Melville plant's refitting and those intended to internalize the process production of the new 10% immunoglobulin (K1g10) and the RhoGAM specialty. Moreover, during the year, the acquisition of eight U.S. plasma collection centers was completed, another was opened in Hungary, while 11 other

U.S. centers are in the process of being acquired, continuing the project to increase the level of self-sufficiency related to the raw material. The absorption of cash flow by these projects and the other previously detailed investment activities amounted to Euro 65.2 million.

- Financing activities generated total cash of Euro 40.5 million thanks to the greater use of the revolving credit facility from Euro 158 million and of short-term credit lines. During the year, the Group paid Euro 7.4 million in leases, approximately Euro 20.3 million in interest and Euro 7.5 million in dividends.

(In thousands of Euro)	Year ended 31 December	
	2018	2017
Net cash flow from operating activities	36,309	35,536
Net cash flow from investment activities	(65,226)	(91,350)
Net cash flow from financing activities	40,478	93,765
TOTAL NET CASH FLOW	11,561	37,951
Cash and cash equivalents at the beginning of the year	104,522	66,508
Net effect of conversion of foreign currencies on cash and cash equivalents	240	62
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	116,323	104,521

4.6. MAIN RISKS AND UNCERTAINTIES TO WHICH THE GROUP IS EXPOSED

The Group's main risks are foreign exchange risk, interest rate risk, credit risk and liquidity risk. Risk management is centralized in the Corporate Finance function that, in close collaboration with the Group's operational functions, identifies, assesses and hedges financial risks in compliance with the directives established by the related policy approved by the Board of Directors.

4.6.1. EXCHANGE RATE RISK

The Group is internationally active and is therefore exposed to exchange rate risk arising from the various currencies in which the Group operates. Exposure to currency risk derive from commercial and financial transactions in currencies other than the accounting currency, mainly the US dollar and, to a lesser extent, the Hungarian forint.

The sensitivity analysis performed to assess the Group's exposure to currency risk was conducted by assuming reasonably possible changes in the exchange rates of the US dollar and the Hungarian forint against the euro. The following tables show the impact on pre-tax income due to changes in the fair value of current assets and liabilities, keeping all the other variables fixed. In addition to current assets and liabilities of a commercial nature, for the financial year 2018 financial items have been included, mainly represented by the balances of intragroup financial receivables and payables in currencies other than the accounting and which constitute the main greatness of this analysis.

Year ended	Change in US Dollar	Effect on income before taxes (In thousands of Euro)
31 December 2017	+ 10%	15,311
	- 10%	(12,309)
31 December 2018	+ 10%	23,179
	- 10%	(19,156)

Year ended	Change in Hungarian forint	Effect on income before taxes (In thousands of Euro)
31 December 2017	+ 10%	4,984
	- 10%	(4,070)
31 December 2018	+ 10%	5,183
	- 10%	(4,241)

4.6.2. INTEREST RATE RISK

Kedrion has two outstanding bonds (Euro 58.2 million and 350 million) with a fixed rate and two revolving credit facilities (Euro 158.3 million and 30 million) with a variable rate, both currently covered by Interest Rate Swaps (the first one up to April 2019, the second one up to 2022), which represent the majority of medium/long-term financial debts. Interest rate risk that the Group is exposed to, therefore is now mainly limited to short-term loans. The Group monitors financial market conditions on interest rates in order to assess opportunities for hedging to further reduce risk exposure. Please see point 6.6.4 of the notes to the financial statements for the corresponding sensitivity analysis.

4.6.3. LIQUIDITY RISK

The Parent company closely manages liquidity risk by means of strict control of the elements comprising net working capital and maintains an adequate level of cash and funds obtainable by various banking institutions. At December 31, 2018, the Group had available and unused credit lines of Euro 135.2 million, of which 40% was short-term.

In order to make cash flow management more efficient, avoiding the dispersion of cash liquidity and minimizing financial charges, the Group also adopted concentration and centralized management systems of main Group companies' cash liquidity on Kedrion S.p.A's accounts (cash pooling).

4.6.4. CREDIT RISK

Most of the Group's receivables from Europe are due from hospital authorities and other public institutions, whose credit rating is considered to be reasonably sound; the Group has never, in fact, recorded losses on receivables, with the exception of the waiving of default interest. Similarly, receivables due from US customers, given the extremely short payment times and the financial strength of these customers, are considered reasonably certain and solvent. The residual receivables are mainly due to foreign customers (Middle East, Asia, Africa and South America) with consolidated knowledge relationships and long-term collaborations, while in the case of new commercial relationships, in particular on new markets, coverage is generally

required with letters of credit or other guarantees. In addition, all receivables are constantly monitored by a recently implemented dedicated central structure, capable of preventing exposures that are not in line with Group policies, such as unauthorized shipments in a context of overdue positions or excess of the commercial credit granted. The Group therefore believes that it does not need to implement specific credit risk management policies given the low risk of insolvency of its customers.

4.6.5. OTHER RISKS

Other possible risks to which the Group could be exposed are related to the macroeconomic environment, the performance of the Group and the industry's regulation.

- **Risks related to the high degree of regulation in the industry**
The Group operates in a highly regulated industry and requires government authorizations to carry out its activities. The inability of the Group to obtain such authorizations for new products or to maintain such authorizations for existing products could damage its business.
- **Risks inherent to international business**
The Group's international operations expose it to risks inherent in international activities, each of which could affect the Group's operating results.
- **Risks related to increased competition in the Italian market**
The presence of competitors operating in the Italian market could reduce the company's access to Italian plasma and its splitting activities on behalf of Italian regional authorities.
- **Risks related to the production process and to requirements under Good Manufacturing Practices (GMP)**
Plasma and plasma-derived products are fragile products and production processes are complex. Any improper manipulation of plasma and plasma-derived products or non-compliance with GMPs could have a negative impact on the Group's activities.
- **Risks related to interruptions of the normal operations of production facilities and collection centers**
Any interruption of the normal operation of the production facilities, shipping or distribution channels of the Group or of the plasma collection centers may adversely affect its activity.
- **Risks related to increased pressure on pricing**
The Group operates in a highly competitive industry with increasing price pressure. Furthermore, fluctuations in plasma or plasma derivatives supply or demand may influence the activities of the Group.
- **Risks related to technological changes**
Technological changes in plasma-derivatives production and the development of alternative products could make the Group's production processes and products uneconomic.

4.7. DIVIDEND POLICY

Pursuant to Art. 30.3 of the Articles of Association of Kedrion S.p.A., net profits as reported in the financial statements duly approved by the Shareholders' Meeting will be allocated as follows: a) at least 5% to the legal reserve until this reaches one fifth of share capital; b) no less than 50% distributed as dividend, subject to a resolution of the Shareholders' Meeting and the Board of Directors' verification of compliance with any contractual restriction.

4.8. PERSONAL DATA PROCESSING

Kedrion adopted a Privacy System to ensure compliance with EU Regulation 2016/679 (hereinafter also "GDPR") and Legislative Decree 196/2003 as last amended by Legislative Decree 101/2018 (hereinafter collectively also "Regulations").

The Privacy System is part of the principles and elements of the internal control system adopted by the company; it includes:

- Code of Ethical Conduct; SA8000 social responsibility system; adherence to the Ten principles of the Global Compact on human rights, labour, environment and fight against corruption; Management policy for Ethics in Business Affairs renewed annually by Kedrion through the issue of a special document; Legality rating in accordance with the Regulation of the Antitrust Authority, Model 231, whistleblowing system - *elements that constitute the ethical reference scenario of the existing Corporate Privacy System*;
- Organisational structure of responsibilities around privacy area - *appointment of internal data processors, or internal contact persons, or "Designated" in accordance with the Privacy Code as amended by Legislative Decree 101/2018, of persons allowed to process data, of Data Protection Officer (hereinafter also "DPO"), of System Administrators, of Head of Video Surveillance*;
- Principle of segregation of duty in the design and surveillance of the system - *for which the surveillance of the Privacy system, and the design of the system, with respect to the prerogatives of the Owner, are implemented by different independent figures although operating in close synergy*;
- Principle of prevention and control of conflict of interest, authority and independence in the identification of the supervisory body - *for which the DPO has been identified, in accordance with the principles set out in Articles 37-38-39 of the GDPR, in the corporate figure already Head of Internal Audit*;
- Principle of accountability - *to which the technical and organizational measures put in place by the company to ensure and be able to demonstrate that the processing of personal data is carried out in accordance with the Regulations conform*;
- Data processing register - *in order to have an updated picture of the processing operations in place within the company that can be maintained and used by the parties involved - Owner, DPO, and Managers (Internal Contact Persons or "Designated", persons authorized to processing, system administrators, video surveillance manager), Interested parties*;
- Provision of specific information to the Interested Parties - *to whom the personal data refer, in accordance with the principle of transparency and usability for the Interested Party and of the protection of the rights of the person concerned*;
- Data processing - *which is based on the explicit, free and informed consent of the interested party*;
- Principle of "data protection by default and by design" for the purposes of the processing configuration - *for which the indispensable guarantees for the purposes of protecting the rights of the data subject, also considering the overall context in which the processing takes place and the risks to the rights and freedoms of the data subject, are considered from the outset in the processing configuration*;
- Annual plan of Training on the Regulations and on the company Privacy System and implementation of the same for DPO;

- Information flows to the DPO and Communication System with the Data Controller and the DPO - *through specific addresses disclosed with the documents of the privacy system (such as information, letters of appointment, agreement with third parties), and from the company web and intranet;*
- Privacy Compliance Audit from the DPO;
- Monitoring of regulatory and organisational changes - *in order to assess and implement the need to adapt the Privacy System;*
- Periodic meetings of the DPO with company functions;
- DPO mandate and periodic report of the DPO to the Owner on the carried out activities and proposal of the Annual Plan of Activities and Privacy Compliance Audits.

4.9. THE MAIN FEATURES OF THE INTERNAL RISK MANAGEMENT AND CONTROL SYSTEM IN RELATION TO THE FINANCIAL RE-PORTING PROCESS, ALSO CONSOLIDATED (INFORMATION PURSUANT TO ARTICLE 123-BIS, PARAGRAPH 2. B) OF LEGIS-LATIVE DECREE 58/98)

The completeness, correctness and timeliness of the financial information is ensured by the adoption of an internal control system by Kedrion S.p.A, effective and efficient, object of constant improvement and adaptation to the evolution of business activities, the regulatory framework and the economic-social context. The components described below must be considered as integral parts of the internal control system.

4.9.1. ORGANISATIONAL, MANAGEMENT AND CONTROL MODEL PURSUANT TO ITALIAN LEGISLATIVE DECREE NO. 231/2001

Kedrion has, as of 2004, adopted a specific Organisational, Management and Control Model pursuant to Art. 6 of Italian Legislative Decree 231/2001 (hereinafter also referred to as the Model 231) to prevent the risk of committal of crimes set forth in the above Decree and, at the same time, to spread and consolidate a culture of transparency and integrity in addition to assuring fair conditions in doing business and conducting corporate activities while protecting its position and image and the expectations of those who are interested in its actions.

Model 231 is intended for all those who work towards achieving the Company's corporate purpose.

The Model 231 is sent to company bodies, directors, employees, and third parties who work for Kedrion in various capacities.

The effective adoption and implementation of Model 231 by Kedrion entails that all recipients of Model 231, when performing their duties, engage in fair and transparent conduct, in compliance with the Decree, with the control measures set forth in Model 231 itself and with the Ethical-Social Values embodied in Kedrion's Code of Ethical Conduct.

Moreover, the effective adoption and implementation of Model 231, required Kedrion itself:

- to supplement Model 231 with the pre-existing internal control system, also with the purpose of better monitoring and protecting all corporate processes and functions in order to prevent any conduct not complying with the law and therefore with Legislative Decree 231/2001;
- to make anyone who operates in the name and on behalf of Kedrion:
 - fully aware of the scope and effects of Italian Legislative Decree No. 231/2001;
 - fully aware that conduct must always comply with Kedrion's code of ethics, which is aimed at condemning any conduct, engaged in by whomever, prohibited by legal provisions and contrary to Kedrion's Ethical-Social Values, represented by its Code of Ethical Conduct.

The purposes, principles, and contents of Model 231 are communicated to the recipients thereof through training courses and ongoing communications and information from and to the Supervisory Body.

Moreover, those third parties who have contractual relationships with the Company must undertake to comply with the Model 231 by signing a special termination clause in the related contract, which will be enforced in the event of violations of the Model's regulations by said third party.

The objectives and the principles specified above were operatively articulated in the following elements of internal control, which also define the contents of the Model 231 adopted by Kedrion:

- Analysis of Enterprise Risk Management;
- Analysis and Mapping of Risks with respect to the crimes identified by Legislative Decree 231/2001;
- Operating procedures and control protocols for the areas potentially at risk;
- Code of Ethical Conduct;
- Internal disciplinary/sanction system defined under Legislative Decree 231/2001
- Whistleblowing system;
- Management control system and accounting handbook (related to the Act 262/2005) and procedures on the financial statements also for the monitoring of cash flows;
- Management control system and system of Management and control of the Area "Financial Statements" (related to the Act 262/2005), including:
 - Tasks and Responsibilities of the person in charge of the preparation of the accounting documents;
 - Operating procedures and specific protocols on preparation of corporate accounting documents, and on relations with foreign companies;
 - Audit and control plan;
- Corporate Transfer Pricing Policy in line with the provisions of the specific regulations;
- Group Cash Pooling system and Treasury Policy;
- SAP management information system, regulations for the use and management of the system, validation system;
- Antitrust Compliance Program;
- Compliance with the Regulation from the Italian Competition Authority (AGCM);
- Privacy Management Internal System to ensure compliance with EU Regulation 2016/679 and Legislative Decree 196/2003 as last amended by Legislative Decree 101/2018;
- Social Accountability System for ethics in the relationship with employees of Kedrion and in the supply chain based on the SA8000 standard - certified by an accredited independent organization;
- Workplace Health and Safety Management System based on the OHSAS18001 standard - certified by an accredited independent organization;
- Environmental Management system in compliance with current laws and regulations, the ISO 14001 standard and the EMAS format – certified by an accredited independent organization;
- Scientific Reporting System on the basis of the guidelines issued by Farmindustria - certified by an accredited independent organization;
- Models of Quality/Safety Assurance in compliance with the best practice of the sector - Good Manufacturing Practices, Good Distribution Practices, Good Laboratory Practices, Good Clinical Practices, Good Pharmacovigilance Practices;
- Quality Management System based on the ISO 9001 standard - certified by an accredited independent organization;
- System for the allocation of roles and responsibilities; system for the allocation of mandates, powers of attorney, and spending powers; corporate organisation charts; job descriptions;

- System for the recruiting of personnel and contractors;
- System for the assessment of employees' performance and allocation of targets;
- Compensation Policy and system for the calculation and accounting of variable pay;
- Corporate Policy for Business Ethics, updated each year by Kedrion through the issue of a specific document;
- Activity of internal and external communication on the system;
- Activity of training on the system;
- Ten Global Compact principles on human rights, work, the environment and the fight against corruption;
- Regulations (or articles of association) of the Supervisory Body;
- Appointment of the Supervisory Body of Kedrion with specific tasks to ensure the monitoring, update and correct operation of the Model;
- Procedure regulating internal information flows to the Supervisory Body.

We note in particular that the Board of Directors of Kedrion S.p.A. has established, implementing Legislative Decree 231/2001, the Supervisory Body, which has been granted the powers and the responsibilities needed to carry out the activities pertaining to it pursuant to the Decree with regard to the operation, effectiveness, adequacy and compliance with the Organisational, Management and Control Model adopted by the Board of Directors.

Kedrion has a special System of Communication with the Supervisory Body in place that enables anyone (employees and third parties) - through specific and dedicated channels and in the manners regulated by a procedure - to:

- ask questions or raise doubts on the principles set forth in the Code of Ethical Conduct of Kedrion and Model 231;
- ask questions or raise doubts beforehand on the activities carried out or to be carried out for Kedrion and therefore on conduct that, in performing any such activities, might involve, even if just hypothetically, an offence and the committal of the crimes identified in Italian Legislative Decree 231/2001;
- report alleged or suspected breaches of ethical principles set forth in the Code of Ethical Conduct adopted by Kedrion and the measures set out in the Model 231;
- report any other information related to the elements and contents of the Model 231.

4.9.2. BUSINESS ETHICS MANAGEMENT SYSTEM

Kedrion adopted a Business Ethics Management System (hereinafter referred to as the "System") to raise awareness, disseminate and consolidate a culture of transparency, integrity, lawfulness and fairness in the conduct of business and corporate activities.

The organisational structure of this System, which operates on the basis of specific regulations, is a guarantor towards the Corporate Bodies; in this regard, the Board of Directors of Kedrion S.p.A. has established and confirmed over time, with the right delegation, the following functions:

- Ethics Officer;
- Internal Audit;

In 2018, the Board of Directors also introduced the Enterprise Risk Management and Antitrust Compliance Officer functions; the Board also established, in implementation of Legislative Decree 231/2001 (hereinafter the "Decree"), the Supervisory Body which has been assigned the powers and responsibilities necessary to carry out the activities entrusted to it by the Decree with regard to the functioning, effectiveness, adequacy and observance of the Model of Organisation, Management and Control adopted by the Board of Directors.

4.9.3. COMPLIANCE WITH THE REQUIREMENTS OF ITALIAN LAW 262/2005

Kedrion has defined and kept active its own system for the internal control on the basis of the criteria and standards set forth in Italian Law 262/2005, believing that such methodology is valid and in line with the best practices - although Kedrion does not have any obligation to comply with such regulation.

Kedrion's internal control system provides for the following:

- Identification of the tasks and responsibilities of the function responsible for preparing the accounting documents;
- Operating procedures and specific protocols on the preparation of corporate accounting documents, and on relations with subsidiaries; with a view to strengthening the supervision and control over financial processes and administrative management processes, Kedrion has also adopted a specific corporate Transfer Pricing Policy in line with the provisions of the specific regulations, and the Group Cash Pooling Management System with its Treasury Policy;
- Training activities for those who, for various reasons, operate in the corporate and financial reporting processes;
- Appointment by resolution of the Board of Directors of the Head of Internal Audit, who has been assigned the powers and responsibilities necessary to carry out the activities assigned to him by a specific mandate for the assessment of the adequacy and effectiveness of the Internal Control System;
- Audit and control activities of the Internal Audit system, which include:
 - ✓ Annual Audit Plan and its implementation
 - ✓ Verification of the status of updating of company procedures
 - ✓ Monitoring of the state of implementation of the requests for actions made by the audits
 - ✓ Verification of the state of implementation of the Enterprise Risk Management process and synergy with the proposed annual audit plan
 - ✓ Relationships with the Supervisory Body, the DPO and the Antitrust Compliance Officer for the implementation of integrated audits
 - ✓ Reconnaissance of the elements of the internal control system - *Code of Ethical Conduct; Antitrust Compliance Program; Model 231; procedures of the control system of the budget area; SAP company management information system;*

budget definition, approval, monitoring and control system; quality and safety assurance system in accordance with the standards of the pharmaceutical sector; Privacy company management system for compliance with EU Regulation 2016/679 and Legislative Decree 196/2003 as last amended by Legislative Decree 231/2001. 101/2018; Occupational Health and Safety Management System and voluntary certification OHSAS 18001; Environmental Management System and voluntary certification/registration ISO 14001 and EMAS; Scientific information management system and voluntary certification according to Farmindustria guidelines; Social responsibility system, voluntary certification SA8000 and activities of the Ethics Officer; quality system and voluntary certification ISO 9001; adherence to the Global Compact; Legality rating; Ethics Committee;

- ✓ Proposals for changes, updates and additions to the internal control system
- ✓ Evaluation of the risk management, control and governance processes of the company
- ✓ Periodic reporting to the Board of Directors on the activities carried out and on the proposal of the Annual Audit Plan

4.10. PARENT COMPANY AND CONSOLIDATED SUBSIDIARIES/ASSOCIATES

4.10.1. KEDRION S.P.A.

Kedron is a pharmaceutical company operating in the production and marketing of plasma-derived products.

In 2018 the Company continued its strategy of preserving its leadership on the Italian market and expanding in the international markets, generating a 4.7% increase in sales, equal to 333.2 million of Euro (318.3 million of Euro in 2017).

In this year, sales growth was driven mainly by an increase in sales of recombinant factor VIII (+29% compared with 2017), anti-D immunoglobulin (+16%), antitetanus immunoglobulin (+20%) and standard immunoglobulin (+7%).

Margins are slightly up thanks to the positive price trend of standard immunoglobulin, while other revenues are down and operating costs are slightly up. Adjusted EBITDA therefore amounts to Euro 46.7 million (Euro 45.3 million in the previous year), EBIT amounts to Euro 13.0 million (Euro 12.9 million in 2017), while in financial management approximately Euro 15.6 million of lower costs/greater revenues were recorded, mainly thanks to a positive management of exchange rates in the current year and to the absence of the costs for the financial restructuring completed by the company as parent company in 2017, which allowed the extension of the average life of existing loans and medium/long-term bank credit lines.

Finally, net profit rises to Euro 16.6 million (Euro 5.1 million in 2017) thanks also to the reduction in taxes following the use of the tax credit on research and development costs.

4.10.2. KEDRION BIOPHARMA INC.

This company incorporated under US law, originally called Kedron Melville Inc, a wholly-owned direct subsidiary, owns a production facility with a fractionation capacity of approximately 1 million litres bought as part of a framework agreement with Grifols signed in 2011 that has also provided access through Kedron Biopharma Inc. (later incorporated), to the most important market of the sector. In 2012 the acquisition of the proprietary medicinal product “RhoGAM” was then perfected. On 1 January 2015, the Company incorporated Kedron Biopharma Inc., establishing a single US company dedicated to pharmaceutical production and distribution mainly targeting the US market.

The company name was later changed to Kedrion Biopharma US. From the 1 December 2016, Kedrion Biopharma merged Haemopharm INC, formerly holding of the business unit responsible for plasma procurement. The merger simplifies the corporate structure on the American market and Kedrion Biopharma acquires 100% of Ked Plasma LLC, to directly control the plasma supply for the American market required for its production needs.

In the first half of 2018 Melville plant's industrial restructuring was completed, bringing to the realization of a new fractionation plant and a new production line for the RhoGAM specialty. The fractionation plant was inspected by the FDA in August and then received final approval from the U.S. authority in February 2019 allowing it to process about 80,000 liters in the second half of 2018. The new line dedicated to the RhoGAM product was also inspected by the FDA in November 2018 and the operational start-up of this line, initially for filling and packaging activities, is expected in the first half of 2019.

The partial use of the Melville plant during the current financial year was offset, in terms of product availability for the American market, by an agreement for outsourced production at Grifols, which enabled sales to reach USD 206.9 million (compared with USD 191.0 in the previous year), with sales of standard immunoglobulin followed by anti-D immunoglobulin (RhoGAM), anti-rabies immunoglobulin developed in partnership with Kamada and entering the U.S. market in early 2018, factor VIII and albumin. Adjusted EBITDA was USD 46.7 million compared to USD 44.8 million in 2017, while the partial activity of the Melville plant resulted in a significant increase in one-off costs linked both to the failure to absorb plant costs (which only from the moment of restart found partial correspondence in production) and to the write-down of inventories of intermediates and finished products produced before the plant shutdown, for a total of USD 89.8 million (EUR 76 million). Because of these significant non-recurring costs, the net result for the year shows a loss of USD 55.8 million (against a loss of USD 36.9 million in the previous year).

4.10.3. HUMAN BIOPLAZMA KFT.

Kedrion S.p.A. acquired 100% of the shares in Human Bioplazma Kft on 31 December 2007, thus increasing its overall production capacity due to the plant located in Godollo, near Budapest. In the second half of 2012, the new plant also started operations, increasing the overall fractionation capacity to 550,000 litres per annum, ensuring a more efficient absorption of production costs. In April 2015 the assets of the subsidiary Plazmaferesis Kft, were transferred to Human Bioplazma, while the Company Plazmaferesis went into receivership.

Plasma collection gave a good performance, increasing the volumes of plasma available in the centers by approximately 20%, all used for the production of plasma derivatives, thanks to the opening of a new center and the implementation of another one opened during 2017 (to date, 7 collection centers have been set up in Hungary). The turnover in 2018 was equal to Euro 44.7 million (against Euro 43.4 million in 2017), showing a small increase with respect to the previous year, due higher volumes of contract work for third parties with a net profit of Euro 2.1 million (Euro 2.1 million in 2017).

During the financial year 2017, the National Blood Transfusion Service (NBTS) sued HUMAN BioPlazma for a value of approximately Euro 37 million to be recognized as price difference between the one actually agreed and paid on plasma purchases made until 2015 and the highest one that NBTS considers established by a Legislative Decree of 1992. The litigation during 2018 continued at the Court of Budapest and the law firm assisting the Company found the request to be unfounded and therefore believes that the possibility of losing the case in the legal proceedings is remote.

4.10.4. KEDRION INTERNATIONAL GMBH

This company, incorporated under Austrian law and wholly owned by Kedrion S.p.A., operated as a distributor of Kedrion products in the European Union and within some important Asian markets. At the end of 2016 Kedrion International undergo a reorganization process that involved the transfer of the German market to Ked Plasma Gmbh (effective from 1 January 2017) and all the other markets, except those of Austria and Poland (effective from 1 November 2016), and the investments held in Kedrion Portugal and Kedrion Swiss in Kedrion S.p.A.

The financial statements as at 31 December 2018 show an increase in turnover of 23% reaching Euro 18.7 million (Euro 15.2 million in 2017) thanks to the strong increase in sales in the Austrian and Polish markets, mostly due to the higher volumes of albumin and standard immunoglobulin sold with significant price increases, especially for the latter product. Net income for the year, which also increased, reached Euro 2.1 million (Euro 1.6 million in 2017).

4.10.5. KEDRION SWISS S.A.R.L.

Established in 2008 and 100% owned by Kedrion International until 2016, it is mainly involved in the marketing of Kedrion products in Switzerland. Following the reorganisation of Kedrion International, the investment in Kedrion Swiss was transferred to Kedrion S.p.A. In 2018, sales reached Euro 0.5 million (Euro 0.2 million in 2017) with sales almost exclusively of standard immunoglobulin but with volumes, although growing, still modest, which led to a closure in substantial break-even.

4.10.6. KEDRION PORTUGAL - DISTRIBUIÇÃO DE PRODUTOS FARMACÊUTICOS UNIPESSOAL, LDA

Kedrion Portugal, with headquarters in Alges (Lisbon), was acquired by Kedrion International in December 2010 with the objective of distributing Kedrion products in the Portuguese market. Following the reorganization of Kedrion International the participation in Kedrion Portugal was also transferred to Kedrion. In 2018 the company increased its presence on the local market thanks to the benefits of using a direct sales force. In fact, the turnover, equal to Euro 7.4 million, is in strong growth compared to Euro 5.3 million of the previous year thanks to the growth in volumes and prices, achieving a profit for the year of Euro 0.5 million.

4.10.7. KEDRION MEXICANA S.A. DE C.V.

This company, incorporated under Mexican law, was set up in June 2008 for the purpose of distributing Kedrion products in Mexico. Kedrion S.p.A. holds 60% of the share capital, while the remaining 40% is held by a local partner, Medici Pharma, S.A.P.I. de CV.

Sales in 2018 increased by 14% to Euro 28.5 million (Euro 25.1 million in 2017) thanks mainly to higher sales of albumin and standard immunoglobulin, closing the year with a net profit of Euro 3.6 million, up from Euro 2.8 million in the previous year.

4.10.8. KEDPLASMA LLC

This American company, of which Haemopharm acquired the remaining 50% of the share capital in October 2008 (while the first 50% was acquired at the end of 2004), increased plasma collection in its centers by approximately 29% compared to the previous year. The company currently owns sixteen collection centers, which are already operational based on the acquisition of a further eight centers and the sale of six centers to Grifols during the current financial year. This growth trend in collection is linked to the Kedrion Group's commitment to cover, on the one hand, the production needs of the plasma-derived products segment and, on the other hand, to increasingly

develop the plasma market, both through long-term agreements with third-party operators for the sale of plasma and through trading in centers that are no longer considered strategic.

In accordance with this strategy, in 2018 the Company achieved total sales of over 1.8 million litres for a total amount of USD 320.3 million (USD 203.3 million in 2017), with a significant increase (+ 58%) compared to the previous year thanks to the higher volumes of plasma available, to important sales agreements with the main market operators and benefiting from favourable price dynamics. Trading on plasma collection centers generated other revenues of USD 33.6 million, contributing to the growth of adjusted EBITDA, which stood at USD 46.5 million (USD 41.3 million in 2017). Net income was USD 35.3 million.

4.10.9. KEDPLASMA GMBH

This company, incorporated under German law and wholly owned by Kedrion S.p.A. (following the transfer from Haemopharm in June 2016), was set up in June 2008 for the purposes of managing the three plasma collection centers purchased and opened in Bavaria at the end of the same year. In 2017 the Company, consolidated its collection centers, thanks also to the opening of the new centre of Augsburg, optimized its trading activities (German, Austrian, Polish and Czech suppliers), with the objective of lowering the average cost for liter of plasma and started the marketing of plasma derivatives in the local market: in fact, with effective transfer from 1 January 2017, the Company acquired the German market from Kedrion International GmbH. Therefore, the company generated sales of Euro 69.7 million in 2018 (compared with approximately Euro 67.0 million in 2017), with an increase in sales both in the plasma segment, with an increase in sales in the four proprietary centers of around 10% compared with the previous year, and in the plasma-derived segment. In this segment, in fact, sales increased by approximately 14% compared to 2017 thanks to the higher volumes of standard immunoglobulin placed at increasing prices, which allowed the Group to achieve a net profit of Euro 2.7 million (loss of Euro 0.2 million in 2017).

It should also be noted that on 12 March 2019 an agreement was reached to sell to HAEMA AG the 4 German plasma collection centers belonging to KEDPLASMA GmbH for a total of Euro 20.5 million.

4.10.10. KEDRION BETAPHAR BIYOFARMASÖTİK İLAÇ SANAYİ VE TİCARET ANONİM ŞİRKETİ

In November 2012, Kedrion S.p.A. purchased a stake of 42.5% in this Company, with registered office in Ankara, Turkey. On 2 September 2015 Kedrion S.p.A increased its stake in the Company from 42.5% to 60%, becoming therefore the majority shareholder. In 2015 the company began distributing pharmaceutical products, achieving in 2018 a turnover of Euro 2.6 million, in significant increase compared to the previous year (Euro 1.2 million), with a small profit at the end of the year.

4.10.11. KEDRION BRASIL DISTRIBUIDORA DE PRODUTOS HOSPITALARES LTDA

Since November 2013, this company, 51% owned by Kedrion S.p.A. and 49% owned by a local partner FBM Farma Industria Farmaceutica LTDA, has been officially registered with the Chamber of Commerce of the State of Goias in Brazil. Kedrion Brasil has obtained in 2014 the authorization to import organic products in Brazil and in 2017 the registration of albumin, first step of the regulatory process that also foresees the registration of standard immunoglobulin during 2019. Since 2014 the company has been distributing products of other pharmaceutical companies and in 2018 it achieved a turnover of approximately Euro 0.8 million (Euro 0.2 million in the previous year) thanks to the entry into the market of albumin Kedrion, closing with a result in substantial break-even.

4.10.12. KEDRION BIOPHARMA INDIA PRIVATE LIMITED

On 6 December 2013 this new Company in India was established, held by Kedrion S.p.A. for 60%, by Human Bioplasma Kft for 20% and by Kedrion Melville Inc for the remaining 20%. This Company, after applying to obtain the necessary authorisation to the import and distribution, began in 2015 to sell the Kedrion products on the Indian market, especially in the specific immunoglobulin sector. The turnover in 2018 was equal to Euro 1.5 million (Euro 1.8 million in 2017) and the company closed the year with a loss (Euro 0.9 million) caused by the low local market sales margin and an allocation of Euro 0.6 million to the bad debt provision.

4.10.13. KEDRION DE COLOMBIA S.A.S.

Kedrion De Colombia was established in Colombia to consolidate the Kedrion presence in Latin America and in particular, in this important market. The procedures for the establishment of the Company were completed on 26 October 2015 and the Company, wholly owned by Kedrion S.p.A., is based in Bogotá.

In 2017, the Company began direct distribution of Factor VIII, generating in 2018 a turnover of Euro 1.6 million (Euro 0.7 million last year), closing the year with a slight profit (Euro 0.1 million).

4.10.14. JSC KIROV PLASMA

On 23 March 2017 a new company was set up in Russia, JSC Kirov Plasma, as envisaged by the Understanding Memorandum signed in the past between the Russian companies National Immunobiological Company (Nacimbio) and Pharmastandard, and Kedrion S.p.A. (the latter with a 25% share). This Italian-Russian partnership aims to create a joint program for the production of plasma-derived drugs in the Russian Federation and, in particular, to complete the construction of a production plant in Kirov, Russia. To date, the company is not yet operational because the project has been delayed and the agreements between the partners will have to be renewed.

4.10.15. RELATIONS WITH PARENT COMPANIES AND INVESTING COMPANIES

The shares of Kedrion S.p.A. are held by:

- Sestant Internazionale S.p.A. (69.38%);
- FSI Investimenti S.p.A. (25.06%);
- Sestant S.p.A. (5.56%).

4.10.16. EQUITY INVESTMENTS

Paolo Marcucci, Andrea Marcucci and Marialina Marcucci each hold respectively 22.74% (17.64% in full ownership and 5.10% in bare ownership with voting rights); 22.74% (17.64% in full ownership and 5.10% in bare ownership with voting rights) and 22.73% (17.64% in full ownership and 5.09% in bare ownership with right) of Sestant S.p.A.'s share capital, which directly holds 5.56% of Kedrion S.p.A and 100.00% of Sestant Internazionale S.p.A.'s share capital, which holds 69.38% of Kedrion S.p.A.

The remaining members of the Board of Directors, the members of the Board of Statutory Auditors and key executives do not hold equity investments in Kedrion S.p.A.

4.11. SIGNIFICANT EVENTS AFTER YEAR END

KEDPLASMA LLC acquired two new centers (Hickory and Anderson) in the United States from Immunotek Biocenters LLC in January and March 2019, respectively.

In January 2019 the IND (Investigational New Drug) application for the development of KIG10 was approved by the FDA. From this date Kedrion is authorized to begin clinical trials. Currently, production for clinical studies is carried out at the Godollo plant and, once these studies have been completed, at the Castelvecchio plant (purification phase, while fractionation is carried out at the Melville plant).

In February 2019, following the inspection in August 2018, the FDA reactivated the authorization of the Melville fractionation plant for the production of the intermediates Fraction II+III, Fraction V and Cryo Paste.

On March 12, 2019, an agreement was reached to sell to Haema AG four German plasma collection centers belonging to KEDPLASMA GmbH for a total of Euro 20.5 million.

On March 19, 2019, the FDA approved the new filling and packaging line for the RhoGAM product at the Melville plant.

None of these events has an impact on the 2018 financial statements.

4.11.1. PERFORMANCE IN THE FIRST TWO MONTHS OF THE YEAR AND BUSINESS OUTLOOK

The objective for 2019 is to continue the international development through the growth of the plasma-derived products segment, achieved through the higher volumes available thanks to the restart of the Melville plant and also benefiting from price increases expected for some plasma-derived products, especially standard immunoglobulin. In particular, significant sales growth is expected in the United States and in other strategic markets such as Germany, Russia, Mexico and Turkey. Further growth is also expected in the plasma segment, made possible by the higher volumes of plasma available, by long-term contracts already stipulated with third-party operators and by a slight increase in prices for standard plasma.

To recover margins, the Company continues to strive to increase the efficiency of its production plants and decrease the cost of raw material by progressively increasing the number of directly owned plasma centers, as well by constant monitoring to contain costs.

In the first two months of 2018, consolidated sales were approximately Euro 85 million, up compared to previous year (Euro 72 million) and in line with sales forecasts in the main markets,.

4.12. NON-RECURRING TRANSACTIONS

Following the summary of significant non-recurring costs and revenues, as defined on note 4.4.3 (see explanatory notes for non-recurring costs in compliance with Consob regulation n. 15519 of 27/07/2006).

In 2018 a few non-recurring transactions were carried out, for a total value of Euro 107.1 million of which Euro 102.2 million with effect on EBITDA. These mainly refer to:

- Completion of the refitting of the Melville plant, consisting of the unabsorbed costs of both the fractionation and the new production line dedicated to the RhoGAM (which only since the restart of the fractionation have found partial correspondence in production) for Euro 38.0 million, the write-down of inventories of intermediate and finished products made before the refitting of the plant for Euro 35.4 million and the higher depreciation as part of the project for Euro 2.6 million, for a total of Euro 76.0 million;
- Start-up costs relating to both the Klg10 project (Euro 6.6 million as net balance composed of Euro 8.4 million of costs and Euro 1.8 million of other income relating to grants for the innovation agreement with the Ministry of Development and the Region of Tuscany) for the construction of a plant dedicated to the production of the new generation immunoglobulin at 10% and the costs necessary for the registration of the product itself, the new plant dedicated to the production of Plasminogen (Euro 7.9 million) and, finally, the higher costs of plasma collection incurred in the new open or acquired centers that are not yet fully operational (Euro 7.0 million);
- Litigation and contractual penalties mainly represented by the expenses incurred for the arbitration in progress against the supplier BPL Plasma responsible for the non-compliance with certain contractual conditions (Euro 0.8 million), by a settlement with Biotest for some contractual breaches raised by the German company relating to the supply of intermediates produced in the Godollo plant (Euro 0.7 million), by the legal costs incurred in the various appeals raised on the award of tenders for the processing of Italian plasma as well as the costs of the positive verification of compliance with competition regulations (Euro 0.5 million), from the transaction with the company Bio&Bio for the early termination of the contract for the development of a new product (Euro 0.4 million), from the transaction with a former employee of a plasma collection center (Euro 0.1 million), from the partial write-down of some foreign receivables (Euro 1.6 million) related to country risk and disputes still in progress that do not allow the recovery of sums in a certain time, and finally from other penalties applied by customers and suppliers for failure to supply products in the contractual procedures defined;
- Non-recurring incentives to employees for a total value of Euro 3.3 million;
- Non-recurring donations and promotional activities for Euro 0.7 million;
- Strategic consultancy relating to corporate restructuring operations and revision of the organisational structure of certain functions with the goal to increase efficiency for a total of Euro 1.4 million.

The table shows the impact of these transactions on the profit and loss statement and the balance sheet.

	Cost of sales	Other income	General and adm.ve cost	Distribution and marketing cost	R&D cost	Other operating costs	Total	Effect on EBITDA
(In thousands of Euro)								
Melville plant's refitting	63,621				12,416		76,037	73,449
Start-up costs KIG 10		(1,837)			8,400		6,562	4,256
Start-up costs Plasminogeno		(354)			8,303		7,949	7,792
Start-up costs new plasma centre	1,162				5,848		7,011	7,011
Settlements and contractual penalties			4,037		400		4,437	4,437
Non-recurring incentives to employees	89		2,238	623	302	39	3,290	3,290
Strategic consultancy			1,449				1,449	1,449
Non-recurring donations			453	259			712	712
Net contingencies	67	(685)	266	80	52	6	(214)	(214)
TOTAL	64,939	(2,876)	8,443	962	35,721	45	107,234	102,181

4.13. TRANSACTIONS WITH RELATED PARTIES

In 2018, Group companies were party to various types of transactions with other companies of the same Group and with other related parties identified on the basis of the principles established by IAS 24 and specified in detail in the notes to the financial statements.

The conditions under which these transactions were actually carried out are deemed consistent with arm's length conditions. However, there is no guarantee that, if said transactions had been concluded between or with third parties, they would have negotiated or executed the transactions at the same conditions and with the same procedures.

4.14. RECONCILIATION OF NET PROFIT AND GROUP EQUITY WITH THE ANALOGOUS VALUES OF THE PARENT COMPANY

The following table shows the reconciliation between the net result for the period and the group equity with the corresponding values of the parent company:

Reconciliation of Net Profit and Equity					
	2017 Equity	2018 Net profit	2018 OCI	2018 other Equity movements (Dividends)	2018 Equity
(In thousands of Euro)					
Kedrion S.p.A. Financial Statement	282,014	16,642	128	(4,849)	293,935
Intercompany dividend distribution	(22,919)	(2,313)	0	0	(25,232)
Kedrion Biopharma US Inc. Group post-formation result (2011)	120,631	(17,374)	0	0	103,257
Kedrion International post-establishment result (2006)	(1,190)	2,087	0	0	897
HUMAN BioPlazma Group post-acquisition result (2007)	10,510	2,266	0	0	12,776
Kedrion Mexicana post-establishment result (2008)	13,864	3,597	0	0	17,461
Kedrion Brasil post-acquisition result (2013)	(406)	(68)	0	0	(474)
Kedrion India post-establishment result (2013)	(1,417)	(936)	0	0	(2,353)
Kedrion Colombia post-establishment result (2015)	132	99	0	0	231
Kedrion Betaphar post-establishment result (2015)	(230)	176	0	0	(54)
KEDPLASMA GmbH post-establishment result (2008)	786	2,687	0	0	3,473
Kedrion Portugal post-acquisition result (2010)	163	601	0	0	764
Kedrion Swiss post-establishment result (2008)	(305)	(61)	0	0	(366)
Gains on inventories write-off	3,838	1,558	0	0	5,396
Other intercompany profits write-off	(29,491)	1,204	0	0	(28,287)
Other provisions	(7,822)	0	8,147	0	325
TOTAL OWNED BY GROUP	368,158	10,166	8,275	(4,849)	381,750
Amount owned by minority shareholders	850	1,476	108	(681)	1,753
TOTALE GROUP BALANCE SHEET	369,008	11,642	8,383	(5,530)	383,503

4.15. CONSOLIDATED DISCLOSURE OF NON-FINANCIAL INFORMATION IN ACCORDANCE WITH LEGISLATIVE DECREE 254/2016

CEO Statement

Dear Readers,

since last year, Kedrion has been drawing up a Consolidated Non-Financial Disclosure (DNF). The DNF is prepared in accordance with the provisions of Legislative Decree 254/2016, which transposed in Italy the European Directive 2014/95.

The document that we are presenting this year, far from constituting only a legal obligation, represents for our Group the confirmation of our attention to the issues on environmental sustainability, compliance with the rules and principles of ethics in business, attention to the development of people, interaction with local communities in which our plants, plasma centers, laboratories and offices insist.

This year's document is more complete and better representative of the non-financial activities carried out by our company in accordance with the Legislative Decree 254/2016. For these reasons, the DNF 2018 was drawn up in accordance with the GRI-Core option, evolving from last year's GRI-referenced one.

The text we are presenting is the result of a broad global matrix, in which the main legal entities and numerous functions have contributed - under the coordination of the Finance department - to drawing the picture of the impact of our activities in the five areas that make up the DNF: Environment, People, Social, Anti-bribery, Human Rights.

For each of these areas we have described, from a qualitative and quantitative point of view, the organization put in place for their efficient management, as well as the processes, policies and related risk analysis (including initiatives for their mitigation). In addition, again this year the DNF contains a lot of general information about our group and its way of contributing, together with our most important stakeholders, to the improvement of the natural, economic and social environment of which we are part.

I am pleased to recall that in 2018 Kedrion recorded a growth of almost 5% of its employees, confirming a slight majority of female staff; during the year we provided around 22,000 hours of training worldwide and expanded the scope of our personal development and performance management tools.

From an environmental point of view, while aware of the fact that in 2018 our facilities were more widely used, Kedrion has confirmed and refined its impact mitigation policies.

Our activities for the social communities have been mapped all over the world and show the profile of a company that frequently and naturally interacts with its territories of reference; lastly, the company confirms its prevention and supervision activities all over the world, including through offices and independent bodies, in the areas of legal compliance and equal treatment and non-discrimination.

I am therefore pleased to invite you to read the DNF on the events of 2018, with a commitment to further improve our processes and our organization on issues that are part of the founding values of our company.

Paolo Marcucci

4.15.1. INTRODUCING KEDRION GROUP

Kedron is an Italian biopharmaceutical company that collects and splits human plasma in order to develop, produce and distribute plasma-derived drugs for the treatment of patients with haemophilia, immunodeficiency and other forms of serious disease. Kedron is the bridge between donors and caregivers, and works globally to extend patients' access to available therapies.

Headquartered in Italy and with a commercial presence in over 100 countries worldwide, it is the fifth largest player in the world and the first in Italy in the plasma-derived sector.

Kedron manages the entire plasma transformation cycle (procurement, production and distribution) and is based on a vertically integrated business model. The company has six production plants: four in Italy, three in Tuscany (in Bolognana and Castelvecchio Pascoli, in the province of Lucca, and in Siena) and one in the province of Naples (in Sant'Antimo); one in Hungary (in Gödöllő, near Budapest); and one in the United States (in Melville, in the State of New York). All these production sites are internationally certified according to GMPs (Good Manufacturing Practices).

In Italy, Kedron is a long-standing partner of the Italian National Health System, with which it collaborates actively pursuing the objective of self-sufficiency in the supply of plasma-derived drugs; at the same time, the company puts its experience and commitment at the service of communities and health systems around the world to achieve this same goal. In Italy, about 1,800,000 donors donate on a voluntary, anonymous and unpaid basis in over 300 transfusion centers throughout the country. Many Italian regions entrust the plasma to Kedron, which transforms it into medicine that are then returned to hospitals so that they can meet the therapeutic needs of the population. Kedron's activities in Italy are aimed at improving plasma collection and contributing to the Italian Blood System's commitment to self-sufficiency.

Abroad, Kedron has plasma collection centers in Germany, Hungary and the United States. Here, in particular, the Buffalo (New York) center specializes in the collection of plasma with a high content of Anti-D antibodies, used in the production of a drug based on Immunoglobulin Anti-D, which has a history of more than half a century of effectiveness in the prevention of Haemolytic Disease Feto-Neonatal (MEFN).

The vertical integration of Kedron allows a very tight control on its supply chain, also in consideration of the important weight that the raw material (the human plasma) constitutes for its business. From this point of view, in 2018 there were no significant changes in processes and activities along the supply chain, which was made more efficient through the continuation of the strategy of rationalization of proprietary plasma centers in the United States (see below, in the section on people, how this has impacted on the rate of turnover and cessations).

As far as stakeholders are concerned, the company identifies the following as the main interlocutors, as is the case in situations of similar size and scope of activity:

- Employees and their representative organisations;
- Components of the global value chain (customers and suppliers);
- National, regional and local public institutions;
- Independent administrative and regulatory authorities;
- Local communities near productive plants;
- National and international financial community;
- Patient and medical community associations;
- Donor associations;
- Other non-profit associations (Farmindustria, PPTA, etc.).

The identification of the list of the main stakeholders takes place through interviews with the corporate functions and offices typically exposed to the outside world, and which also have the burden of their management and engagement in the corporate activities.

From this point of view, the management of the relationship with employees is essentially in the hands of the human resources function according to the laws and internal procedures intended for them; the relationship with public or regulatory institutions at all levels is the prerogative of the Presidency, which receives support from other functions (including Global Public Affairs, the Italy function, the Regulatory and Medical Area); relations with patients' associations are maintained by the marketing function under the strict supervision of the Medical Area; relations with donors are maintained by the plasma centers owned by the company or, in Italy, by the Donors Italy function; relations with local communities are mainly maintained by the Presidency, Global Public Affairs and the management of production sites; relations with associations such as Farindustria and PPTA (Plasma Protein Therapeutics Association) are maintained by the Presidency of the company.

Regarding Kedrion's participation in associations, the two most important are those in Farindustria and in PPTA, the association that brings together the largest plasma-derived products and plasma collection companies in the world; the president of Kedrion is a member of the Farindustria Council and of the Global Board of Directors of PPTA, which he chaired in the three-year period 2013-2015.

In addition to these memberships, among other things Kedrion is a member of Aspen Italia, founder of the Fondazione Campus di Lucca and the Tuscany Life Sciences Foundation of Siena, member of the Fondazione VITA di Siena, the Fondazione Lucchese per l'Alta Formazione e la Ricerca (FLAFR) and the Civita association.

4.15.2. KEDRION GROUP 2018 DNF

In compliance with the terms of Legislative Decree 254/2016 (hereinafter also referred to as the Decree), which transposes European Directive 2014/95 into Italian law, this year Kedrion is again drawing up a consolidated disclosure of non-financial information (hereinafter referred to as the "DNF") relating to the events of 2018.

The Kedrion DNF has an annual frequency; the last DNF approved, which was also the first in its history, was approved by the Board of Directors on March 29, 2018.

This year's DNF did not expect any changes to the data presented in last year's disclosure and there are no particular changes in reporting arrangements.

As a qualifying note of this declaration, it should be noted that the greater completeness of the data collected, together with a more robust process of verification, has allowed the transition from last year's GRI-referenced option to this year's GRI-Core option. Kedrion 2018 DNF is prepared, therefore, in compliance with the Sustainability Reporting Standards published in 2016 by GRI – Global Reporting Initiative – on the basis of the in accordance-Core option.

If a DNF GRI-referenced means that the document is inspired by the standards and indices of the Global Reporting Initiative, the drafting of a DNF in accordance-Core implies that this year's disclosure is fully incorporated into the framework provided by the GRI standards.

In accordance with art. 5 paragraph 3a of the Decree, this DNF is contained in the Report on Operations of the Consolidated Financial Statements and was approved by the Board of Directors of Kedrion S.p.A. on 29 March 2019.

Precisely because it is included in the Report on Operations, DNF does not include the company's governance structure, which is described in detail there. It should be noted, of course, that the various legal entities are administered by boards, boards or managing directors assisted by supervisory boards.

The legislation requires the DNF to report on the main activities, policies and related results, organisational models adopted, risks generated and/or suffered and strategy to manage them, in the domain of environment, social, personnel, respect for human rights and fight against active and passive corruption, taking into account both what has been done directly by the company and what can be controlled on the supply chain and the repercussions for stakeholders.

From an organisational point of view, Kedrion's DNF 2018 was assigned by the CEO to the company's Finance area, which set up a multifunctional work group. The Finance function is the point of contact for any party interested in deepening the issues dealt with in the DNF and its construction process.

4.15.3. MATERIALITY ANALYSIS

The Decree provides that the DNF covers – in the necessary measure to ensure the understanding of Company activity, its performance, its results and the impact produced by it – five thematic areas: “Employment”, “Social”, “Environment”, “Anti-Corruption” and “Human Rights”.

As provided by the Decree, in order to write the DNF, first and foremost Kedrion drafted a materiality analysis, which has the task of establishing, for each of the five areas, the topics that the Company deemed most relevant, of priority and high impact; topics for which it has drafted policies and organisational structures intended to oversee them appropriately.

The materiality analysis was approved by the departments involved and by the Chairman and Chief Executive Officer of the Company.

The material topics identified in the materiality analysis were the following:

“Employment” Area:

- Managerial development
- Employer branding
- Company well-being
- Injuries (Occupational health and safety)

“Social” Area:

- Relationship with local communities
- Research activities and expanded access

“Environment” Area:

- Water consumption and water cycle
- Renewable and non-renewable energy consumption
- Direct and indirect emissions
- Waste production

Topics relating to human rights and anti-corruption and bribery matters were also deemed material.

As stated in 2017 DNF, during the year 2018 Kedrion continued its reflection on diversity issues, in particular with regard to equal opportunities and gender issues.

On this issue, although no specific policies have been adopted or ad hoc organizational models implemented, Kedrion recognized its interest on that theme and, although without ever considering it as material, the Company will continue to monitor it in view of specific and systematic, therefore detectable in a future DNF, development and improvement actions.

On the basis of benchmarking and listening activities, the functions involved in the definition of the material issues have determined them also taking into account the expectations of the main stakeholders of the company (mentioned in paragraph 1.1.1).

4.15.4. GENERAL APPROACH ON SUSTAINABILITY TOPICS

Kedrion, due to the specific nature of the products created, helps people, communities and institutions to attenuate and remove the obstacles which prevent to enjoying the right to life, liberty and security.

Kedrion contributes to transforming inherent right (life, freedom, safety) into the social right to live in the best possible conditions. For this reason, it collects, transforms, makes active and available the vital energy generated and regenerated, stored and transported in the blood, so that it can be transferred from human being to human being.

Kedrion contributes to the production and distribution of medicines derived from human plasma which are able to improve people's quality of life. It works to maintain excellent sector standards; it operates to consolidate its own role as a recognised representative of the medical and scientific, healthcare and institutional community.

Kedrion aims, in an international context, to strengthen its role as strategic partner of the healthcare systems in countries which seek to achieve self-sufficiency in the field of plasma derivatives. It produces wealth for investors, workers, and the territory, and does so in coherence with its own vision and the values of responsibility, transparency, trust and respect for people.

The company's founding values, ethical principles, reference standards and rules of conduct on sustainability issues and on its way of being in the world are set out, among other documents, in the Code of Ethics.

The policy adopted by Kedrion provides for risk analysis on sustainability issues and the adoption of prudential policies and processes to avoid accidents or non-standard behaviour; more specifically, for each of the following areas (Personnel, Social, Environment and Safety, Anti-Bribery and Human Rights), the functions involved have indicated the risks to which they are subject and the mitigation measures adopted to prevent and manage them.

4.15.5. "EMPLOYMENT" AREA

Kedrion believes that the management of its staff goes beyond contractual and legal obligations and operates - as described below - on several fronts to ensure their well-being and professional satisfaction. The company is convinced, for example, that investing in the training of people is essential for professional growth and that it must go beyond the simple professional requirements of the role: therefore, in 2018 Kedrion launched its own leadership model represented by the managerial skills and individual skills necessary for each employee to work at their best and - more generally - to implement the corporate strategy, guide individual development, direct performance.

Kedrion considers that making decisions in a joint manner not only allows its employees to be primary actors, but also leads to better decisions; and that personal and professional growth requires challenge and the possibility to move toward constructive criticism.

For example, the history of the Kedrion family Company leads it to recognise and promote a good balance between free time and work, placing a high value on diversity and at the same time, searching for common values.

Kedrion operates so that the health and safety of its employees are not left to chance nor good intentions, adopting a management system based on safety policies subject to frequent reviews during changes, including new processes, activities or production plants.

At 31 December 2018, Kedrion had a total of 2,571 employees, up from 2,456 at the end of 2017 (+4.7%). The group's corporate population is concentrated in Italy (45%), the United States (34%), Hungary (14%) and Germany (6%), countries where the production plants and plasma collection centers are located; a residual share (1%) is employed in other locations. In 2018, the number of women in the total workforce increased to 1,328, equal to 52% of the total (and +6.9% compared to the same figure in 2017), 22 of whom belonged to the professional category of "Directors".

Regarding to the age, 19.5% of staff age is under 30 years, while 20.4% is over 50 years.

Breakdown of employees by geographic area			
	2018	2017	2016
Italy	1,146	1,136	1,056
Hungary	368	360	311
Germany	158	145	133
Rest of Europe	13	14	33
USA	870	787	748
Latin America	5	3	3
Rest of the World	11	11	6
TOTAL	2,571	2,456	2,290

The form of contractualisation of the prevailing staff is permanent staff (95% of contracts). It should also be noted that 66% of the staff is covered by collective agreements, and the other part by individual contracts. More specifically, all employees are covered by national collective labour agreements or company collective agreements, except those in the United States, which enter into individual employment contracts.

Breakdown of employees by type of contract

Region	Fixed-term			Permanent		
	Men	Women	Total	Men	Women	Total
Italy	36	39	75	661	410	1,071
Hungary	4	12	16	165	187	352
Germany	7	31	38	25	95	120
Rest of Europe	-	-	-	6	7	13
USA	-	-	-	327	543	870
Latin America	-	-	-	4	1	5
Rest of the World	-	-	-	8	3	11
TOTAL	47	82	129	1,196	1,246	2,442

With reference to the breakdown by professional category, in 2018 the 44% of employees were concentrated in the “Blue Collars” category and 52% in “White Collars”. On the other hand, the “Directors” category represented 4% of total employees at 31 December 2018.

Kedron includes staff employed under management contracts, assimilated or assimilable, in the “Directors” category; employees in the offices or, if in a plant, in a supervisor or manager role (for example in the USA plasma centers) form part of the “White Collars”; employees employed for manual work (workers, those employed in logistics and the warehouse, other operators, etc.) are “Blue Collars”.

Total number of employees by category and gender at 31.12.2017 and 31.12.2018

Category	2018			2017		
	Men	Women	Total	Men	Women	Total
Directors	68	22	90	72	22	94
White Collars	579	765	1,344	560	700	1,260
Blue Collars	596	541	1,137	582	520	1,102
TOTAL	1,243	1,328	2,571	1,214	1,242	2,456

With regard to the trend, the increase in the number of women was mainly recorded among white collars (+9.2% compared to 2017) and blue collars (+4% compared to 2017), while it is stable among directors, whose number in 2018 was, however, reduced.

In 2018, the use of part-time work increased slightly, especially among women (+19%).

Total number of employees by type of contract at 31.12.2017 and 31.12.2018

Type of employment	2018			2017		
	Men	Women	Total	Men	Women	Total
Full-Time	1,224	1,212	2,436	1,192	1,145	2,337
Part-time	19	116	135	22	97	119
TOTAL	1,243	1,328	2,571	1,214	1,242	2,456

During 2018, the company saw 1,135 new entrants from Italy, Hungary, Germany and the United States; in the Rest of Europe, LATAM and ROW regions, only one entry was registered in 2018.

Total new entries by region and age group at 31.12.2018

Region	< 30	31-50	>51	Total
Italy	23	37	6	66
Hungary	28	44	4	76
Germany	18	22	13	53
USA	486	369	85	940
TOTAL	555	472	108	1,135

Compared to 2017, the number of admissions increased by 24.7%, from 910 to 1,135. In particular, female admissions increased by 26.5%, male admissions by 20.8%.

Total new entries by region and gender at 31.12.2017 and 31.12.2018¹²

Region	2018			2017		
	Men	Women	Total	Men	Women	Total
Italy	34	32	66	27	34	61
Hungary	21	55	76	35	61	96
Germany	13	40	53	17	34	51
USA	288	652	940	212	490	702
TOTAL	356	779	1135	292	618	910

¹² This figure includes all new entries, including those for temporary contracts that ended during the year. The figure should be read together with the following table referring to the exits of the year 2018.

The data on new entrants should be read together with the data on exits, the main causes of which were the resignation of employees (also read from the point of view of the turnover rate, see table below) and the sale and acquisition of plasma collection centers in the United States. The difference between the Group's hiring and retirement in 2018 does not coincide with the increase in the workforce between 2017 and 2018 shown in the table Breakdown of employees by geographical area. The difference derives from the fact that this table shows only employees as at 31 December, while the figures relating to hirings and terminations also include non-employees (e.g. temporary contracts, even of very short duration). The company often uses contracts of this type to meet seasonal and specific needs, especially in the case of plasma centers.

In 2018, the company recorded 993 leavings in Italy, Hungary, Germany and the United States. In the Rest of Europe, LATAM and ROW regions, there were 3 exits in 2018.

Total exits by region and age group at 31.12.2018

Region	< 30	31 - 50	> 51	Total
Italy	9	23	12	44
Hungary	21	39	9	69
Germany	7	11	17	35
USA	410	353	82	845
Others	0	3	0	3
TOTAL	447	429	120	996

Total exits by gender at 31.12.2018

Region	Women	Men	Total
Italy	17	27	44
Hungary	39	30	69
Germany	27	8	35
USA	599	246	845
Others	2	1	3
TOTAL	684	312	996

With regard to the types of leaving the company, the comparison between 2017 and 2018 (which is proposed in DNF for the first time) shows year-on-year differences that affect a reclassification of the reasons for staff leaving that will be completed during 2019.

Number of exits by cause as of 31.12.2017 and 31.12.2018

Cause	2018	2017
Resignation	331	374
Dismissal	20	142
Retirement	10	6
End of contract	17	58
USA centers sale	240	270
Other*	378	104
TOTAL	996	954

*Other includes terminations not classifiable in the previous categories (e.g. death, failure to pass the test period, etc.).

As for the turnover rate linked to resignations alone, which - particularly in the United States, Hungary and Germany - is significant, it is linked to dynamics typical of plasma collection centers, where the labour market, the competitive environment and the professional figures employed favour frequent job changes. In 2018, however, turnover fell slightly, from 15.5% to 12.7%.

Turnover rate due to resignations during considered period by region and gender¹³

Region	Turnover rate	Number of resigned people	Women resigned in the period	Men resigned in the period
Italy	2.0%	23	10	13
Hungary	15.2%	56	28	28
Germany	12%	19	16	3
USA	26.8%	233	153	80
TOTAL	12.9%	331	207	124

¹³ The figure includes and considers only voluntary resignations. Does not include:

- terminations of temporary contracts opened and closed during the year but, in any case, before 31.12.2018 (date on which the data are photographed);
- contract terminations due to the sale of 6 plasma collection centers in the United States;
- terminations due to other causes (retirement, dismissal and/or consensual termination).

Turnover rate due to resignations during considered period by region and age

Region	Turnover rate	Number of resigned people	< 30	31 - 50	> 51
Italy	2.0%	23	3	17	3
Hungary	15.2%	56	17	31	8
Germany	12%	19	7	8	4
USA	26.8%	233	107	96	30
TOTAL	12.7%	331	134	152	45

As regards the other reasons for exit, the US population was affected by the sale and acquisition of plasma centers in 2018.

Turnover rate due to other reasons during considered period by region and gender

Region	Turnover rate	Number of exits for other reasons	Women exit for other reason	Men exit for other reason
Italy	1.8%	21	7	14
Hungary	3.5%	13	11	2
Germany	10.1%	16	11	5
USA	70.3%	612	446	166
Others	27%	3	2	1
TOTAL	25.7%	662	475	187

Turnover rate due to other reasons during considered period by region and age

Region	Turnover rate	Number of exits for other reasons	< 30	31 - 50	> 51
Italy	1.8%	21	6	6	9
Hungary	3.5%	13	4	7	2
Germany	10.1%	16	3	8	5
USA	70.3%	612	302	258	52
Others	27%	3	0	3	0
TOTAL	25.7%	665	315	282	68

The main risks associated with Kedrion's personnel are linked to two factors: on the one hand, the technological content and complexity of the plasma processing processes; on the other hand, the geographical location of the plants and production sites. For both reasons, there are difficulties

in finding the right talent with the technical, scientific and experience skills required to cover key roles, and the pool of talent available in the company is relatively limited.

It is therefore important to carry out risk mitigation activities by taking care, on the one hand, of the accumulation of technical skills, obtained by investing in technical training and ensuring the permanence of people in the roles, and on the other hand, by using tools that promote retention for people with key know-how and not easily replicable. These mitigation activities are carried out through HR policies aimed at promoting wellbeing in the workplace, professional development and investment in the individual. The tools most often used are people review, individual development plan management and performance management

As far as Italy and Hungary are concerned, a further risk lies in the fact that there are very few competitors in the sector from which to draw for expert applications; in addition, the geographical location of the various sites does not facilitate the transfer or the so-called 'commuting' of candidates from other regions: in this sense, the efforts of attraction and retention, once again, leverage both on the aspects of remuneration and on those of development and training.

Kedrion is committed to continuous dialogue with workers' representatives at all levels: European, national and local.

Kedrion S.p.A., for example, applies and respects the provisions of the National Collective Labour Agreement for the pharmaceutical chemicals sector. In addition to the national collective bargaining agreement, Kedrion S.p.A. also has second-level agreements that provide for economic disbursements linked to the achievement of significant results, both in terms of profitability and productivity (performance bonuses).

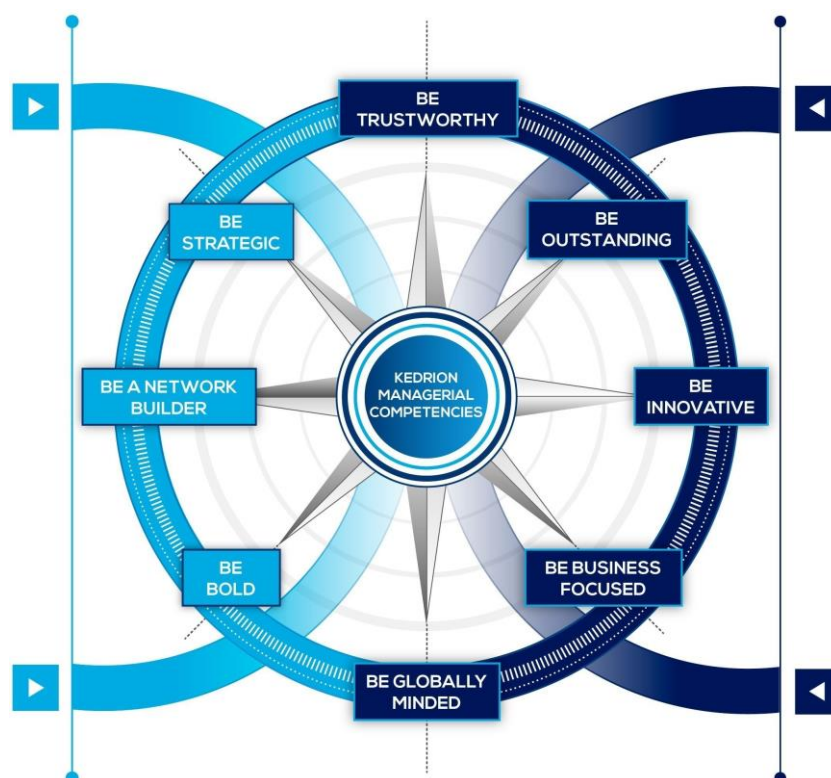
In support of its commitment, during 2018 and on the basis of the experience of 2017, Kedrion S.p.A., in order to further promote the Flexible Benefit instrument as an alternative rewarding lever, granted all workers at the Sant'Antimo site a donation through this institution. In addition, the Smart Working trial was extended to various departments in Italy, with the total involvement of about 200 people.

In addition, HUMAN BioPlazma has signed second-level agreements that provide for financial contributions aimed at making the company competitive in a dynamic and evolving labour market. The material topics identified for DNF 2018 in the "Personnel" area are four: managerial development, employer branding, company welfare and safety at work. Among these, the first and fourth are certainly the issues that have been given priority and relevance in terms of the policies adopted and the organisation made available. The issue of managerial development (such as employer branding and corporate welfare) is dealt with by the company's Global Human Resources function, while occupational safety is dealt with by the Global EHS function.

MANAGERIAL DEVELOPMENT

The success of the company and the growth of people's professionalism go hand in hand and both require the active contribution and daily commitment of everyone. To this end, thanks to active listening and involvement of people in the company, Kedrion has developed a new leadership model, adopted in 2018; the model is aimed at each member of the organization and is aimed at creating value and improving company performance as part of a policy of enhancement of human resources, talent management and the balance between work and private life.

This model, the result of an activity carried out internally and with the help of experts in managerial development, represents the way of understanding the virtuous behaviour that Kedrion expects from its people, as well as the axes of managerial development of resources in Kedrion, in Italy and abroad.



The topic of managerial development in this DNF will be expanded upon by describing training activities, the talent and performance monitoring system and the remuneration and rewarding policies.

Training activities

Kedrion pays particular attention to training, recognising the importance this plays in building knowledge and maximising both technical and specialist expertise of its resources and managerial expertise.

Through Scuola Kedrion (Kedrion School), a project carried out in collaboration with the Fondazione Campus di Lucca, the company supports the objectives of internationalization and evolution of teaching, also through the use of digital tools and the consolidation of the managerial and leadership model.

In 2018, the company developed, among other things, the following training and management development courses:

- The second edition of the Kedrion Management Development Program (KMDDP) continued and took place, aimed at talented people from all over the group: 18 managers, from 5 countries and from all company departments;
- Three plenary sessions addressed to the 100 key people of the company, dedicated to the themes of market orientation and business intelligence; the sessions included international speakers, round tables and discussions with the CEO;
- People Management Journey. A course for newly appointed managers, two classes for a total of 27 Italian people involved. 12 days of training between classroom, outdoor and webinar (6 days per group);
- TOYF - Think On Your Feet. Three-day classroom course for 15 participants on the topic of negotiation and argumentation during meetings;
- Finance for non-Financial People, two days in the classroom for 15 Italian middle managers and executives.

These training courses share an innovative training vision which sees collaborative learning, mentorship and project work experiences used together with traditional classroom and distance training techniques.

Moreover, thanks to the collection of a series of feedback received during the annual People Review, it was decided to invest in some critical phases of personnel management, namely the practice of feedback to employees and the preparation of effective individual development plans. This investment resulted in a training program, which first involved some representatives of the HR function through the train-the-trainer method, and then 85 managers in Italy and abroad. Finally, to support the inclusion of the leadership model in human resources management systems, a specific action was prepared aimed at learning and becoming familiar with the leadership model.

Through local initiatives, both through external providers and by exploiting the training skills of employees, Kedrion has made further significant investments in training to improve and update the skills necessary for the proper performance of activities related to the role held.

Summary of training hours carried out in 2017 and 2018 for gender¹⁴

Region	Men	Women	Total hours	Average hours per employee
2018	13,456.6	8,201.4	21,658	8.4*
2017	9,082	12,906	21,988	9.06

*The average is calculated on a total number of employees of 2,571

Summary of training hours carried out in 2018 for occupational category and gender

Region	Director	White Collar	Blue Collar	Total
Italy	1,116	13,611.5	134	14,861.5
Hungary	389	2,300	1,867	4,556
Germany	31.5	230	85	346.5
USA	n/a	n/a	n/a	1,894
TOTAL	1,536.5	16,141.5	2,086	21,658

During 2018 Kedrion provided almost 22 thousand hours of training, for an average of 8.4 hours per employee. Of this total, over 4,000 hours were dedicated to managerial and behavioral training, while about 8,600 hours were dedicated to technical and professional training.

Performance monitoring

In 2018, in continuity with previous years (Kedrion's performance evaluation system exist since 2009 and since 2014 has become a global system), the annual evaluation process of individual performance, of strategic importance in the development of human resources, was carried out. Compared to 2017, the population has increased from 1,146 to 1,733 people; as in 2016, the process involved 67% of the company population and 100% of executives and senior management, as MBO Eligible.

¹⁴ Data does not include On the Job training linked to the inclusion of new employees.

Number of employees involved in the Performance Management process in 2017 and 2018 for region and gender

Region	2018			2017		
	Women	Men	Total	Men	Women	Total
Italy	391	647	1,038	628	383	1,011
Hungary	10	22	32	22	10	32
Germany	4	4	8	5	4	9
USA	395	254	649	3	-	3
Others	2	4	6			
TOTAL	802	931	1,733	709	437	1,146

Number of employees involved in the Performance Management process in 2018 for occupational category and gender

Category	Women	Men	Total
Directors	19	66	85
White Collars	505	467	972
Blue Collars	278	398	676
TOTAL	802	931	1,733

The KedPMP (Kedrion Performance Management Process) provides that, depending on the different roles, employees are assessed on the basis of the achievement of departmental and individual objectives and the level of possession of the skills required by the leadership model. The system envisages homogeneous evaluation criteria at a corporate level for managerial roles, and homogeneous evaluation at country level, in respect of local requirements, for non-managerial roles.

An MBO system exists at corporate level, whose process is constructed in such a way so as to guarantee transparency in assigning and evaluating objectives and the greatest possible homogeneity in evaluation criteria and feedback management.

From 2017, Kedrion also introduced a global evaluation process for potential intersected with the performance evaluation: the process is named People Review, and following the 2016 pilot projects, assumed global validity in 2017. The process aims to increase management's capacity to identify dedicated training courses coherent with the Company's requirements in terms of succession plans and success planning. The population involved in 2018 (334 people worldwide) represents 19% of the Kedrion employees subject to performance evaluation and includes all Executives and Senior Managers.

Remuneration and rewarding policies

As regards Rewarding and Compensation, since the past years, Kedrion has already started a review of the work position assessment policies, which allows a segmentation of roles valid throughout the group and in compliance with local specificities, with the aim of promoting

remuneration, development and management policies for the people who give value to the principles of fairness and transparency.

Within the Group the remuneration policies are oriented towards guaranteeing competitiveness on the labour market, in line with the growth objectives and human resources retention, as well as differentiating remuneration tools on the basis of individual professionalism and competency. Kedrion has a differentiated system based on the employee's professional category and/or role held, which, as well as the fixed remuneration component, may also include incentive systems (short and long term) related to individual and Company objectives.

Within the company, according to corporate-type rules that are applied to local situations, an annual Salary Review process is provided for, connected to the output of the performance and potential management process.

Every legal entity of the Group has an employee benefits system in which, depending on the specifics of the role, context and local laws, reward choices can vary from supplementary insurance to life insurance, accident insurance; from the registration to supplementary pension funds to modifiable benefits packages to support family choices (study of minors, domestic assistance, medical visits, travel, etc.). The benefits are assigned based on local procedures and, within the same organisational category, are assigned to all employees independently of the duration and type of the contract. In particular, there are no differentiations between part-time and full-time employees.

EMPLOYER BRANDING

To bring talented young people closer together and encourage the integration of young graduates and new graduates into the company, in 2018 Kedrion further developed its Employer Branding programmes, through greater collaboration in specific projects with universities and training bodies in the areas with the greatest presence. Among the main ones, the Master in Pharmaceutical Marketing at Pin of Prato, a consortium managed by the University of Florence, where Kedrion also provided part of the teaching staff and managed an entire training module, is worth mentioning. In addition, the HR department has provided hours of teaching in the master's degree in Human Resources Development, organized by the Department of Political Science University of Pisa.

In addition, we remember the Master's Degree in Clinical Trials of Medicines in Internal Medicine, Oncology and Haematology (University of Pisa), in which Kedrion has been collaborating for 3 years now, welcoming trainees in the company.

At the same time, Kedrion continues to monitor the labour market through its participation in job fairs dedicated to the pharmaceutical world (Biopharmaday Genova and Biopharmaday Firenze), the activation of educational and orientation internships within various company offices (16 extra-curricular internships and 22 curricular ones) and a social presence, with respect to which Kedrion's page on social LinkedIn, with over 30,000 followers, is worthy of mention.

COMPANY WELL-BEING

Kedrion is committed to identifying and promoting initiatives that promote an ever greater balance between private and professional life.

For example, the following are some of the projects in this area.

- In the United States (KBI), in accordance with local laws, several Flexible Working Hours initiatives have existed for some years and were in force in 2018, providing that part of the work can be done remotely;
- in Italy (Kedrion S.p.A.), the pilot project on Smart Working was extended to a total of 200 employees, with the sole exception of personnel involved in laboratory activities and

production departments. In the manner established by Kedrion S.p.A., employees enjoy, in compliance with an agreed company regulation, the freedom to choose their preferred working method remotely (other company sites, their residence or domicile or other places as long as they are suitable in terms of compliance with occupational safety regulations). In addition, Kedrion has promoted an initiative to improve the local public transport service, in order to allow its workers to effectively use the Bolognana production site, financing part of its economic cost.

OCCUPATIONAL HEALTH AND SAFETY

The policies practised by Kedrion through its Environment, Health and Safety (EHS) at work department are intended to:

- Promote safety culture at every organisational level;
- Support initiatives intended to improve working conditions;
- Support local offices to manage safety in workplaces and monitor their performance.

The Italian and Hungarian offices have adopted an SSL management system which is certified according to the OHSAS 18001 standard.

In addition to preventing any accident or situation that might lead to damage to its own employees, visitors or external suppliers, in the event of an accident, Kedrion acts through an emergency structure to reduce any damages to the minimum; additionally, it tracks and analyses all incidents to study their causes and implement corrective and preventive actions.

The EHS Global structure supports the local departments to identify the causes, and shares the results of the analysis through a “safety alert” system with other sites so that everyone can learn from the errors and prevent new events from occurring.

The “Zero Accidents” objective was launched in the Operations department, which monitors accidents through indicators that measure their frequency and level of seriousness.

The distribution of events, days lost and frequency and severity indicators by geographical area in 2018 is shown in the table below:

Distribution of injury cases by geographical area at 31.12.2018				
Region	Number of events	Number of lost days	TIR*	LWR*
<i>Italy</i>	7	155	0,7	15.8
<i>USA</i>	30	258	4	34.3
<i>Hungary</i>	5	156	1,7	52.3
<i>Germany and rest of the world</i>	6	2	5,6	1.9
TOTAL	48	571	2,2	26.7

*Used indicators are Total Injury Rate (TIR) and Lost work days Rate (LWR)

The percentage of injuries to women is expressed as an interval because of the presence of 11 cases in American plasma collection centers, where gender distinction is not available for privacy reasons.

Therefore, the percentage ranges from 27% to 5%.

The following is the trend of accidents in the two-year period 2017-2018:

Index	2018	2017	Difference 2018/2017	2016
Number of injuries	48	42	+14%	50
Number of lost days	571	449	+27%	726
TIR	2.2	2.2	–	2.64
LWR	26.7	23.3	+15%	38.3

The overall figure for 2018, compared to the previous year, shows a slight increase in the number of events and days lost, a substantial invariance in the frequency indicator and a slight increase in the number of days lost. The figure, overall, shows an improvement compared to 2016. During the years 2017-2018 no mortal injuries occurred.

EXTERNAL PERSONNEL INJURIES

In 2018, there were no accidents involving external personnel (collaborators or contractors) working in areas under direct responsibility and/or following company directives.

PROFESSIONAL DISEASES

In Kedrion there exist some areas and activities in which risk factors for safety and health in particular are identified:

- Video terminal, microclimate and lighting, fire/explosion, work-related stress that are present in all activities, from administrative to productive/technical;
- Biological risk, chemical risk, manual handling of loads, noise risk, low temperatures and use of machinery and equipment (mechanical risk), which are added to the previous for production and technical areas (laboratories / plasma collection centers, logistics, maintenance);
- Work at height, work in confined areas, driving forklifts and mechanical equipment that are added in relation to specific tasks.

Risks are identified in accordance with current national regulations. In particular, sites in Italy are subject to Consolidated Law no. 81/08 and produce a Risk Assessment Document (DVR); Hungarian sites are subject to similar legislation and, in turn, produce a risk document similar to the Italian DVR.

The prevention and protection measures adopted in all areas guarantee the control of the above risk factors, keeping the level of risk below the limits set by the legislation and company policies. The data on accidents and occupational diseases of the last 5 years confirm the above, given that there have been no accidents with serious personal injuries or specific occupational diseases related to exposure to risks at work.

During the two-year period 2017-2018 there was only one case (relating to 2017 and reported in DNF last year) of recognition of occupational disease; the event involved an employee of Kedrion S.p.A. for loin disc arthrosis without limitation for the task currently performed.

ABSENTEEISM

The phenomenon of absenteeism is detected in a timely manner in Italy (Kedrion S.p.A), especially in consideration of its connection with the production of pay slips and acquired economic rights (in countries such as the United States this link is not, however, significant and

the company does not detect the rate of absenteeism, which would be an indicator substantially devoid of meaning and heuristic capacity).

In Kedrion S.p.A., the absentee rate is calculated as hours of absence (illness, maternity, injuries, social absenteeism, union absenteeism, other absenteeism) divided by hours scheduled to be worked.

In 2018, the absentee rate was the following:

Absentee rate 2018 - Kedrion S.p.A.

Workable hours	Hours of absence	Absenteeism Rate
2,223,248	109,384	4.9%

In general, Kedrion believes that the working environment of the various offices and factories of the group, as shown by the level of health of the employees (injuries and occupational diseases), is coherent with the average of its competitors and with manufacturing companies of a similar size; consequently, the risk on employees from this point of view is not considered relevant or greater with regard to comparable contexts.

4.15.6. "SOCIAL" AREA

The policies practised by Kedrion have as a main element the commitment to Social Responsibility, which extends to all communities with which the company has contact: from production factories to the environment, from donor communities to patient communities.

Kedrion strives to increase global awareness of the diseases it deals with and to improve their diagnosis, treatment and access to cures.

Kedrion pursues its objectives by supporting projects at a local level and through significant international product donations and collaborations of an educational and awareness-raising nature.

Relationship and engagement activities of local communities are not coordinated at central level, but entrusted to the main local realities. Thus, the production sites of Bolognana, Sant'Antimo, Godollo and Melville continuously carry out activities of listening and animating the local communities of reference; the activity of listening and engagement leads to the determination and execution of the social activities described below; in the same way, each of the plasma centers owned in Germany, Hungary and the United States engages the local communities of reference and, starting from the needs thus identified, commits itself to the activities of relating with the local communities.

Also this year the DNF describes the "Social" area through actions in support of local communities and research activities in the field of *orphan drugs*.

RELATIONSHIP WITH LOCAL COMMUNITIES

The theme of the relationship with local communities takes up the original and consolidated tradition of Kedrion to support the areas closest to its factories, plasma centers and offices. Starting from experience gained in Italy in the Company's area of origin, with the growth of the social boundary and the internationalisation of activities, this approach has been suggested, communicated and supported.

From an organisational point of view, the activities in support of local communities are prevalently concentrated at a central level, with the Parent company. Thus far, this choice has been dictated

by historical reasons and closeness to the Company's main office, and by the various national regulations on donating blood and blood components. As a matter of fact, if in Italy it is prohibited to give your plasma in return for payment, in the United States, Germany and Hungary (the office of the other major legal entities of the group), this remuneration, even if governed differently in each country, is required or permitted. For this reason, the Company activities that support communities in countries in which the plasma donors are compensated are usually recorded as marketing activities.

In view of the above, it should be noted that this year's DNF extends the information contained in that for the year 2017, listing in the following list most of the activities carried out for the benefit of local communities by the four main legal entities.

The main activities that the company carries out for the benefit of local communities are as follows:

KEDRION S.P.A.:

- Kedrion S.p.A. is by far the most significant employer in the areas in which its production facilities are located;
- Under the same economic and technical conditions, Kedrion's supply chain favours companies in the territories in which it has offices, also reducing the environmental impact related to transfers;
- Kedrion S.p.A. supports several activities with the Municipalities and schools in the area, including participation in a Higher Technical Institution (ITS) in Life Sciences and a teaching development project with the technical and professional secondary schools in Valle del Serchio (Borgo a Mozzano and Barga);
- Kedrion Group is one of the founders of the Fondazione Campus di Lucca, a non-profit training and cultural institution which carries out university and advanced training in tourism and the development of the territory and local economies;
- Kedrion encourages local traffic reduction measures through car-sharing and car-pooling initiatives;
- Kedrion supports the activities of stakeholders qualified in the health sector through impartial contributions. In 2018, the following non-profit institutions, among others, received contributions: Association of Primary Immunodeficiencies ONLUS, the Jeffrey Modell Foundation (at the Meyer Paediatric Hospital in Florence), World Federation of Haemophilia (WFH), the Italian Federation of Haemophiliacs (FedEMO) and Italian Association of Haemophilia cCenters (AICE), Paracelso Federation, the Italian Association for the Study of the Liver (AISF), Palermo and Milano university, Hospital of Palermo, AUSL of Viterbo, Carlo Erba Foundation, for the establishment of research awards in memory of Guelfo Marcucci;
- Kedrion is a bridge between plasma donor communities and patients who use human plasma derivative medicines. From the point of view of donors, in the countries in which Kedrion directly manages plasma centers, the group companies undertake to make the donor experience as safe, efficient and pleasant as possible; in countries such as Italy where plasma is processed on behalf of third parties and collected in public donor centers, Kedrion is at the service of the national blood systems in order to support principles such as national self-sufficiency in plasma derivatives, the efficient operation and quality of collection systems and training and information about donating (for example through the "Kedrion Incontra" (Kedrion Encounters) project at the Bolognana facility and the AVIS national training school for young managers, carried out together with the Fondazione Campus di Lucca).

KEDRION BIOPHARMA INC.:

- All participants of the KBI Sales & Marketing meeting attended the "Kedrion Cares" event, travelling to the scout camp in Savannah (Georgia), severely damaged during the hurricane, to contribute to its reconstruction and extraordinary maintenance.
- The Sales & Marketing team dedicated one day of the week in the last week of December 2018 to providing a socially useful service in their city. Employees have worked in soup kitchens, homeless shelters, animal shelters, "Meals on Wheels" and many other places of social entertainment.
- In October 2018, KEDPLASMA (a wholly owned subsidiary of KBI) organized a fundraiser for employees, their families and donors affected by Hurricane Michael.
- In September 2018, KBI employees at Fort Lee and Melville supported the GBS-CIDP Foundation's "Walk & Roll" event to raise awareness and support scientific innovation for faster diagnosis and better treatments for those with GBS, CIDP and its variants.
- In late September 2018, the Kedrion Biopharma Team participated in the "Gears for Good National 3 Ride" event in support of the Hemophilia Federation of America. Cyclists have thus supported communities that care for people with coagulation disorders in a financial crisis, so as to allow them better access to care.
- On October 21, 2018, Kedrion Biopharma participated in a walk organized by the Immune Deficiency Foundation in New York City and received the "Top Team" award.
- In November 2018, KEDPLASMA USA participated as a silver sponsor in the walk organized by the Immune Deficiency Foundation (IDF) in Atlanta, Georgia, thus providing funding for this patient association.

HUMAN BIOPLAZMA KFT.:

- "KM-collecting" campaign. On the occasion of the tenth anniversary of HBP's founding, the company launched a campaign to virtually reach the Kedrion factories on foot, by running, by swimming or by bicycle. From day zero, colleagues and their families went on a hike and recorded the kilometres travelled. By converting the km into Hungarian guilders, the company donated 500,000 flowers to the "Dr. Sándor Lumnicz" Foundation in Gödöllő to support local public health services.
- Visit to the facility open to donors and patient associations. The visits to the Gödöllő plant allow donors and patients to be aware of the plasma processing activities and the use of the biological raw material, to highlight the 'bridge' that the company forms between donors and patients. The donors were members of the Heroes' Club (at least 45 donations), while the patients were members of the MIBE (association of patients with immunodeficiency).
- Charity activities during the Christmas period. The company participated in a fundraiser promoted by a local organization and also donated animal food to a local foundation that deals with abandoned animals.
The company donated computer devices (PCs, screens, keyboards, printed matter and other devices) to the local primary school.

KEDPLASMA GMBH

- Cooperation with DSAI (German association of patients with hereditary immunodeficiencies). Support to the association through support to their magazine and the organization of workshops and seminars for their members.
- Organization and implementation of two initiatives that allowed the socialization of patients and plasma donors, which allowed the rapprochement of these two communities.

- The Augsburg Plasma Centre has been supporting the Bunte Kreis charity for years, which supports families of children suffering from cancer and serious illnesses. In 2018, in addition to the ordinary contribution, the plasma center donated 2 Euros for each donation of plasma collected in a week of December, for a total of 1,210 Euros donated.
- The same plasma center organized the charity sale of wooden objects, the proceeds were donated to the "Wald-Pavillon Freundeskreis", a cultural institution where the students on the trip receive a lot of information about the environment and forests.
- In Austria, the company participates in the International Week of Primary Immunodeficiencies event.

During 2018 Kedrion did not suffer any economic or non-economic sanctions related to the social area (stakeholders, local communities, patients, etc.).

As mentioned, this DNF has been able to collect the support activities to local communities carried out all over the world, completing the framework of 2017, mainly referred to only Kedrion S.p.A.; for the future the company will continue to systematize the various activities of Corporate Social Responsibility, also assessing their impact.

RESEARCH ACTIVITIES, ORPHAN DRUGS AND EXPANDED ACCESS

For the Kedrion Group, innovation represents an element of distinction within its industrial model, as well as one of its main strategic tools. Thanks to innovation, the Company succeeds in achieving excellent results, identifying technological and production solutions amongst the most advanced and effective currently available, and establishing a virtuous cycle of continuously improving products and processes.

Kedrion's research and development in previous years has taken various directions:

- An industrial research activity which aims to identify new products or new production processes;
- An industrial development activity tending towards optimising the production process and guaranteeing the highest quality and safety standards;
- An activity aimed to guarantee compliance in the context of safety from pathogens.

The development of orphan drugs and delivering expanded access has always been Kedrion's approach, coherent with its own values and the relationship that it tends to establish with the societies in which it operates.

It is noted that according to European legislation, orphan drugs are medicines intended to cure or treat diseases which pose a threat to life or chronic debilitation. In Europe, diseases are defined as rare if they affect 5 in 10,000 individuals. The economic commitment to the development and commercialisation of these drugs is important and risky; it is encouraged by specific laws which make approval times by competent bodies faster.

Patients affected by rare diseases who do not have the requirements needed to access a clinical study can access orphan medicines through expanded access, even if the drug has not yet been approved by healthcare authorities. The Ministerial Decree of 8 May 2003 "Therapeutic use of medicines subject to clinical trial" (Official Gazette n. 173 of 28 July 2003, General Series) provides for the extraordinary use of orphan drugs, which are subject to clinical trial, on patients with endangered life or affected by a debilitating disease. The value of these cures is significant: they allow patients with no other valid treatment opportunity to use a drug, which, although it has not yet received the approvals necessary for commercialisation, could bring benefits to the patient's quality of life.

The Company's commitment to orphan drugs has led to the development of a facility dedicated to the research, development and production of these products in Siena. IKOD (Impianto Kedrion

Orphan Drugs/Kedrion Orphan Drugs Facility) is the first facility of its kind in Europe and was built in collaboration with the Regione Toscana and Toscana Life Sciences.

Kedrion's commitment to orphan drugs and expanded access projects takes place in various ways, often linked to the close relationship that the Company maintains throughout the world with local and professional stakeholders: doctors, patients' associations, public and healthcare institutions. Once the Company decides to commit to a project of this kind, widely inter-departmental working groups are formed, whereas a Company department dedicated exclusively to expanded access does not exist (something which, for that matter, would perhaps make the Company less agile in initiating and conducting the various projects).

As in the case of plasminogen, the expanded access projects can provide for a future – albeit uncertain – return of an industrial and commercial kind; in other cases, as in that of administering factor V of coagulation, on the other hand, research on the drug is first and foremost made for the Company's sense of social responsibility.

It must be added that, especially in Italy, the centrality of the group in the plasma derivatives sector makes Kedrion almost ethically "obliged" to be at the disposal of the healthcare system and the requests relating to its area of activity; in some cases, actually, the risk connected to commitment in this area can depend on the fact that the expectations of the society and the patients towards the Company are very high; whereas – as is obvious – the Company cannot allocate resources to expanded access projects that are similar to those used for its main areas of business.

Kedrion's two main projects on orphan drugs are those on Plasminogen and the one on Factor V of coagulation.

Plasminogen Project

Kedrion is developing a project to increase expanded access of the human concentrate of plasminogen, a drug which has received orphan designation for the treatment of patients affected by ligneous conjunctivitis. Thanks to this project, a greater number of patients will be able to request the product and be treated before the drug is commercially available. In 2018, the number of patients who benefit from the possibility of receiving plasminogen for compassionate use increased from eight to eleven.

Plasminogen (PLG) is an important protein in the blood which plays a fundamental role in the dissolution of a coagulant, acting physiologically on fibrin and fibrinogen A chains. Where there is a lack of plasminogen in the blood, two types of deficiency can occur: deficiency type 1 and deficiency type 2.

Plasminogen deficiency type 1 or severe hypoplasminogenemia (HPG) is a very rare systemic disease which causes the formation of fibrin-rich pseudomembranes (with a wooden appearance) in the mucous membranes when a wound is healing. The most common clinical sign (manifested in 90% of cases) of HPG is the chronic inflammation of the conjunctiva (ligneous conjunctivitis), which can lead to blindness, but other sites can also be affected, such as the upper gastrointestinal tract, the respiratory tract, the female genital tracts, the central nervous system and the skin. The prevalence of HPG, although not properly determined to date, is estimated at around 1.6 cases per million of inhabitants. Clinical onset usually occurs in early childhood, but can manifest at any age and be brought on by repeated microtraumas (dust, foreign body), surgical interventions or local inflammation.

Since no approved drug is available yet for plasminogen replacement therapy in patients affected by HPG (and ligneous conjunctivitis in particular), it has been treated in previous years through the surgical resection of ocular lesions (pseudomembranes) and/or use of non-indicated drugs including corticosteroids, antibiotics and heparin. Each of these approaches, however, do not have entirely effective results, and have lesser resolving power.

At present, Kedrion S.p.A. is working to complete all preparatory phases for the Marketing Authorisation process of the product. In the meantime, the Company is, on the one hand, continuing to make the preparation available to patients who have taken part in the clinical study (currently 6 of 12) and, on the other and within the limits of current production capacity, is providing the product in expanded use treatment to 11 patients (8 in 2017) affected by ligneous conjunctivitis (4 in Italy, 1 in Spain, 1 in France, and 5 in the USA, where in 2017 they were only 2).

Kedrion intends to expand the expanded access programme and treat 30 patients worldwide in the next 3 years.

Factor V Project

Factor V is a plasma protein present in a concentration of around 7 µg/ml in healthy individuals. It carries out a crucial role in haemostasis: as a matter of fact, it has a pro-coagulant role in the coagulation cascade, participating in the formation of thrombin.

Congenital factor V deficiency, alone or in combination with factor VIII deficiency, is an extremely rare haemostasis disease which occurs in 1:1,000,000 of the population. Individuals affected by a lack of this protein manifest haemorrhaging in various areas and magnitudes: epistaxis, menorrhagia, haemarthrosis and haematomas, and those more serious, including intracranial and gastrointestinal.

To date, no specific factor V concentrate is available for which treatment of deficiency in this protein restores the deficient factor using fresh frozen plasma, which, however, leads to risks and complications including: allergic reactions, development of alloantibodies, overload of volume and viral infections. Treatment involves the administration of around 750-1,000 ml of fresh frozen plasma at least twice per week.

At the moment, there are no factor V concentrates available on the market. The low interest in developing these concentrates is due to the fact that the disease associated with this deficiency (parahaemophilia or Owren's disease) is very rare. Also, the natural history and spectrum of clinical manifestations are not entirely known, due to the scarcity of clinical cases to observe and study.

Kedrion is developing a factor V concentrate, currently the only company in the world to do so. Development of the concentrate is still in an initial research/development phase aimed at optimising the purification production process, with the first toxicity studies on animals estimated for the first quarter of 2019.

In 2018 Kedrion completed the first part of the development of the small scale PV concentrate. Further product development to achieve EU and US registration still requires time and investment. For this reason, Kedrion applied for access to public funds that could facilitate and speed up the production of PV concentrate; among these, Kedrion has, in particular, applied for funding at the MISE using the tool of the "Development Agreements".

4.15.7. "ENVIRONMENT" AREA

Kedrion's attention to the environment starts from the territory in which its employees operate. From the workplace, it extends to the communities which surround the Company, with a strong commitment to reducing environmental impact to a minimum. Conscious of man's responsibility in global climate change, Kedrion's environmental policy contributes to mitigating the consequences of human activity on the surrounding environment.

Kedrion employees are aware of environmental protection and operate to evaluate and monitor environmental aspects connected to activities carried out, pursuing opportunities for improvement.

The Kedrion management team undertakes to implement, maintain and document its processes and activities in compliance with the highest quality standards, including, for example:

- UNI EN ISO 14001 and EMAS Standard* (Eco-Management and Audit Scheme);
- BS OHSAS 18001 (Occupational Health and Safety Assessment Series).

Participation in Global Compact** involves a global commitment to improving environmental services, which are put into action in a strategy founded on principles of:

- Optimising resources and endorsing sustainable ones;
- Reducing negative impact;
- Spreading an environmental culture within and between external collaborators.

*EMAS, the EU Eco-Management and Audit Scheme, is a model to which companies and organisations, both public and private, based in the European Union and wishing to commit themselves to assessing and improving their environmental performance, can voluntarily adhere.

EMAS aims to improve the environment and to provide organisations, control authorities and citizens (the public at large) with a tool through which they can obtain information on the environmental performance of organisations.

The management system relating to the technical activities of EMAS registration, accreditation and surveillance of EMAS Environmental Auditors are carried out in accordance with the ISO 9001:2015 standard.

**The United Nations Global Compact is a United Nations initiative created to encourage companies around the world to adopt sustainable policies that respect corporate social responsibility and to make the results of the actions undertaken public. It is a framework that brings together ten principles in the areas of human rights, labour, environmental sustainability and anti-corruption. To pursue the ten principles of the Global Compact, companies cooperate with United Nations agencies, trade union groups, stakeholders and civil society in general.

The organisation has a “Global EHS” structure in the aim of supporting local offices to manage environmental aspects and monitor their performance. The Italian offices have adopted an environmental management system according to ISO 14001.

The offices in Lucca (Klg10 production site, Castelvecchio Pascoli warehouse, Bolognana site and administrative offices) and the Sant’Antimo (NA) site are certified ISO 14001 and registered EMAS.

In 2018, the environmental management system will also be extended to the Hungarian site with the objective of obtaining ISO 14001 certification in 2019.

The adopted model integrates the monitoring and control activities of environmental performance required by the Integrated Environmental Authorisations applicable to the sites mentioned.

The Italian offices have an Energy Management structure with the aim of optimising the use of energy resources through analysis and monitoring activities and promotion of initiatives

To improve its environmental performance, Kedrion is committed to increasing its understanding of its impacts by analyzing the life cycle of its products and extending control to the entire supply chain.

In 2018, the Life Cycle Assessment - previously applied to Factor VIII - was extended to two other products, IG Vena and Albumin, obtaining certification of the relevant Environmental Product Declarations, which will be made available to the public.

The availability of information on its environmental impacts and performance is also guaranteed by the publication of the Environmental Declaration for Italian EMAS registered sites.

WATER CONSUMPTION AND WATER CYCLE

Attention to water resources is concentrated on the use of water provided by the public utilities and water coming from wells and on wastewater production.

Water taken from production facilities is mainly used to power cooling systems, softeners, steam production, washes and sanitation. In the other offices, it is used as domestic hot water and for cleaning the workplaces.

The risks connected to the water resource depend on the presence of obligations required by legislation or specific authorisations. Water consumption can constitute a risk connected to the capacity of local infrastructures and the availability of the resource (aqueduct and wells), constituting a constraint with regard to any increases in production capacity. Furthermore, an increase in water consumption corresponds to an increase in wastewater, whose hydraulic load is governed by authorisation and/or technical/infrastructural limitations.

Wastewater derives from the processes of the six production sites, which is transferred to the public utilities in accordance with legislation and regulations in force in terms of hydraulic load and qualitative characteristics of the wastewater.

Discharge is prevalently of an industrial kind and a minor percentage of 10% is represented by domestic hot water-waste.

Contributions of the individual companies to the consolidated data is expressed in terms of percentage in the following table:

Water balance (water consumption and discharges in cubic metres) as at 31.12.2018

Water consumption from public utilities* Mc	Water consumption from well Mc	Total water consumption Mc	Wastewater** Mc
532,251	376,520	908,771	645,989

*The figure is the sum of measured consumption (Bolognana, S'Antimo, CVP Godollo, Melville, German plasma centers) and estimated consumption (Siena, American plasma centers and offices).

**Wastewater measured for Bolognana, S'Antimo, CVP, Godollo and Melville; estimated for Siena, Offices and plasma centers.

The largest contribution, equal to 65%, is given by Italy and due to the presence of the two main production plants, followed by Hungary (18%) and the United States (17%), which also include the production sites of Godollo and Melville.

Below is a table summarising water consumption and the quantities of wastewater discharged at a global level for the two-year period 2017-2018 (the figure for 2016 is left for the sake of completeness of information):

Water balance 2017-2018

Index (Mc)	2018	2017	Delta 2017/2018	2016
Water consumption from public utilities *	532,251	423,678	+26%	428,127
Water consumption from well	376,520	331,350	+14%	363,867
Total water consumption	908,771	755,028	+20%	821,994
Wastewater**	645,989	566,092	+14%	584,342

*The figure is the sum of measured consumption (Bolognana, S'Antimo, CVP Godollo, Melville, German plasma centers) and estimated consumption (Siena, American plasma centers and offices).

**Wastewater measured for Bolognana, S'Antimo, CVP, Godollo and Melville; estimated for Siena, Offices and plasma centers.

The increase in the consumption of mains water is essentially due to the greater use of the Melville plant, which in 2017 was in the revamping phase, and - to a lesser extent - to the Bolognana and Castelvechio Pascoli plants, which are continuing the preparatory phases for the start of production.

The increase in the consumption of well water is due to the higher consumption of the Bolognana and Sant'Antimo sites.

RENEWABLE AND NON-RENEWABLE ENERGY CONSUMPTION

The production sites mainly use energy sources for the production of cold, heat and steam, as well as to power the factories and for lighting.

The provision of electric energy presents constraints related to the infrastructures which can impact on the continuity of the service and on any production developments, even if there are emergency generator systems for the most critical equipment.

The Bolognana facility produces part of the electric energy consumed through a cogeneration system, which, in addition to having lower environmental impact, guarantees improvement in the quality of the supply even if it does not reduce the risks related to any interruptions from the grid. No particular constraints of a legal/authorising type exist for the various sites.

Monitoring and related energy diagnosis, required by the Integrated Environmental Authorisations and by the legislation on the reasonable use of energy, represent an opportunity for interventions intended to optimise consumption.

The use of natural gas, both for the production of electric energy and steam, is the best source of non-renewable energy in terms of greenhouse gas emission and therefore an opportunity to improve the sector's environmental impact; nevertheless, it presents risks related to possible short or prolonged interruptions to the supply due to any technical problems of the grid infrastructures or the supplier, with significant impact on business continuity of the production facilities: this is true in particular for the Bolognana site, which uses methane to produce a large part of the electric energy consumed.

Electricity from the grid

The Bolognana factory has a 3 MW cogeneration system capable of meeting part of the factory's electric energy demand, returning a small part of it to the grid (in 2018, the quantity of energy released to the grid was 515.4 GJ, equal to 2% of the energy purchased).

Consumption of electricity from the grid by company at 31.12.2018*

GJ

185,380

*The figure is the sum of measured consumption (Bolognana, S'Antimo, CVP, Godollo, e Melville e centri plasma ungheresi tedeschi) and estimate consumption (Siena, Uffici e Centri plasma americani).

The largest contribution to total consumption is given by the Italian, American and Hungarian production plants, which account for 40, 31 and 17% respectively, for a total of 88%.

Fossil fuels

The absolute values and contributions of the individual companies to the consolidated data on the consumption of methane, expressed in terms of percentage, are shown in the following table:

Methane gas consumption* as at 31.12.2018

GJ

442,485

* The figure is the sum of measured consumption (Bolognana, S'Antimo, CVP, Godollo, and Melville and Hungarian German plasma centers) and estimated consumption (Siena, American plasma offices and centers).

**The figure includes natural gas for the cogeneration plant at the Bolognana site.

The largest contribution to total consumption is made by the Italian, US and Hungarian production plants, which account for 74, 12 and 9% respectively, for a total of 95%.

Below is a table that summarizes the consumption of electricity, natural gas and gas oil, expressed in GJ at global level for the two-year period 2017-2018 (the figure of 2016 is left for the sake of completeness of information):

Energy balance 2016-2018 three-year period

Index (GJ)	2018	2017	Difference 2018/2017	2016
Electricity from the grid	185,380	151,042	+ 23%	159,426
Methane	442,485	417,748	+6%	425,397
Gas Oil	13,635	7,776	+75%	8,501
Total energy	641,500	576,566	+11%	593,324

The table shows an increase in both the consumption of electricity from the grid and gas oil fuel for motor vehicles and generating sets, and an increase in the consumption of methane.

The greater increase is due to the greater use of the Melville site, followed by the new Castelvechio Pascoli plant and the Bolognana site.

The increase in gas oil consumption is due to the temporary installation of electric generators to support the production of the Melville site.

DIRECT AND INDIRECT EMISSIONS

Kedrion calculates carbon footprint in order to identify the greenhouse gas emissions generated by its activities, considering the direct emissions coming from the consumption of natural gas and other fuels and by refrigerant gas losses (Scope I) and indirect ones coming from the consumption of electricity (Scope II).

The following table shows contributions to the total CO₂ equivalent emission (Scope I) and the trend in the two-year period 2017-2018 (the figure for 2016 is left for the sake of completeness of information).

Carbon Footprint 2016-2018 three-year period – Scope I				
CO₂ equivalent (Ton)	2018*	2017**	Delta 2018/2017	2016**
CO _{2e} from refrigerant gas losses (refilling)	12,512	22,062	-43%	7,562
CO _{2e} from consumption of natural gas	24,580	23,737	+3%	24,172
CO _{2e} from consumption of gas oil	1,013	574	+77%	632
Total CO₂ eq.	38,105	46,373	-17%	32,365

* DEFRA emission factor version 2018.

** DEFRA conversion factor version 2017.

The data show a decrease in CO₂ emitted by refilling of refrigerant gases (in 2017 there was a higher emission due to leaks on some plants and the rupture of a pipeline at the plant in Bolognana).

The increase in CO₂ from gas oil, even if not very significant on the total, is due to the production support generators temporarily installed in Melville.

Below is the graph that represents the contributions to the total CO₂ equivalent emission (Scope II).

Carbon Footprint 2016-2018 three-year period – Scope II (*)				
Ton CO₂ eq	2018*	2017**	Delta 2018/2017	2016
CO _{2e} from consumption of electric energy from the grid	19,116	16,447	+16%	18,358
Total CO₂ eq.	19,116	16,447	+16%	18,358

* TERNA emission factor version 2017

** DEFRA emission factor version 2015

WASTE PRODUCTION

The amount of waste from the production sites represents the prevalent quota of all waste produced by the Group, equal about to 88%; collection centers contribute in a small significant way (12%); administrative activities contribute in a marginal way.

The waste – when not given to the municipally-owned companies as urban waste is – is managed according to the legislation of the country in which the production site is located, for its classification and packaging and its disposal.

The presence of obligations required by legislation or specific authorisations or voluntarily assumed obligate the company to pay strict attention in terms of classification, packaging, time and quantitative limitations defined by legislation and by any local regulations/authorisations.

The possibility of any interruptions to transport and disposal services related to incorrect classification or packaging, unavailability of suppliers (technical, authorising and contract problems) make waste management an extremely significant environmental aspect.

In addition to legislative compliance and business continuity, Kedrion's attention is turned towards the safety of people, who on various grounds can come into contact with the material (internal staff, operators in the waste sector and communities), and towards the environment in general; this leads the company to favour sustainable disposal methods (energy recovery or recycling material).

Waste production as at 31.12.2018

Non-hazardous waste Kg	Hazardous waste Kg	Total waste Kg
1,228,935	5,086,959	6,315,894

Waste balance for geographical area as at 31.12.2018

Region	Non-hazardous waste Kg	Hazardous waste Kg	Total waste Kg
Italy	641,054	1,008,833	1,649,887
USA	265,461	637,308	902,769
Hungary	231,240	3,440,818	3,672,058
Germany and RoW	91,180	0	91,180
TOTAL	1,228,935	5,086,959	6,315,894

The table below shown the values for 2018 compared to the data for 2017 (the data for 2016 is left for the sake of completeness of information):

Waste balance 2017-2018 two-year period net of waste disposed of by road

Type (kg)	2018	2017	Delta 2018/2017	2016
Non-hazardous waste	1,228,935	773,529*	+59%	1,528,691
Hazardous waste	5,086,959	4,409,410	+15%	4,641,844
TOTAL WASTE PRODUCED	6,315,894	5,182,939	+22%	6,170,535

*The quantity of non-hazardous waste of 2017 is purified from the disposal by road of industrial wastewater made necessary by the temporary interruption of the discharge to the site of Bolognana, amounting to 2,453,940 kg.

The comparison shows an increase in the production of both hazardous and non-hazardous waste, to which the Melville and Godollo sites contributed in particular.

Amount of waste send to recovery at 31.12.2018

% of total non-hazardous waste	28%
% of total hazardous waste	78%

4.15.8. “ANTI-CORRUPTION” AREA

Kedrion, in line with its founding values, with the specific anti-corruption regulations and with the tenth principle of the Global Compact, according to which "companies are committed to fighting corruption in all its forms, including extortion and bribery", pursues its commitment to fighting corruption, in all its forms, direct and indirect.

Kedrion S.p.A. adopted a Code of Ethical Conduct (the “Code”) that contains ethical principles and values that inspire the responsible management of corporate activities, establishing rules of conduct and implementation rules. The Code has been shared with the subsidiaries that have implemented the principles of conduct contained in the Code.

The Code has been signed by all the Company's employees, collaborators and external suppliers and is made available to each new employee.

Subsidiaries have adopted policies and practices, in compliance with local regulations, aimed to preventing and prosecuting conduct that conflicts with the anti-corruption policy.

During 2018, no episodes of corruption were detected in all the companies of Kedrion group.

The following paragraphs describe the organisation and distinctive processes adopted in the anti-corruption area by the Group's main operating companies.

KEDRION S.P.A.

Kedrion S.p.A. combats corruption in its every form, in the widest context of the adopted Management and Control Organisation Model pursuant to Art. 6 of Legislative Decree 231/2001 (hereafter also “Model 231”) which it adopted, beginning in 2004, in the aim of preventing the risk of commission of offences provided for by the same Decree, also including offences of corruption in its every form in relations with public administration and between private parties and extended therefore also along the entire supply chain.

The organisational model adopted by Kedrion S.p.A. to prevent and counter active and passive corruption includes, the following elements:

- The company code of conducting activities of scientific drug information is certified by an accredited third party as compliant with the specific guidelines issued by Farmindustria;
- The Supervisory Body pursuant to Legislative Decree 231/2001, Art. 6 let. b, formed by nomination of the Board of Directors;
- Risk Mapping with regard to the offences provided for by Legislative Decree 231/2001, including offences of corruption in its every form;
- Adoption of a Code of Ethical Conduct, integral part of Model 231, subscribed by all employees, collaborators and suppliers of the Company;
- Information and training plan by the Supervisory Body in order to raise the awareness of the functions on the subject;
- Supervisory Board Information Report for the Company meeting (Board of Directors, Board of Statutory Auditors).

Kedrion S.p.A. keeps the risk mapping updated, i.e. the mapping of corporate areas that are hypothetically and theoretically exposed to "crime risk", including the risk of corruption.

The potential risks inherent in the offences envisaged by Legislative Decree 231/2001, which emerged from the risk mapping, are mainly those typical of the pharmaceutical sector; after having evaluated all the control measures implemented by the Company, the residual risk was acceptable.

In 2018, Kedrion updated its Model 231, also in view of the new provisions introduced to Legislative Decree 231/2001 by Law no. 179 of 2017 on "Provisions for the protection of the authors of reports of crimes or irregularities of which they have become aware in the context of a

public or private employment relationship" (the so-called "Whistleblowing"). With particular reference to the provisions contained in Article 6, paragraph 2-bis of Legislative Decree 231/2001, which provides for the need to adopt at least one reporting channel "capable of ensuring, by computer, the confidentiality of the identity of the reporter", Kedrion has implemented a web platform that allows reports to be made, thereby strengthening the reporting channels already implemented in the company, about violations (confirmed or suspected) of the provisions contained in Model 231, conduct and/or conduct that may constitute one of the relevant crimes under the Legislative Decree no. 231/2001 and finally extended the possible reports to other violations and/or non-compliance with the laws and/or the company procedures and policies in force.

KEDRION BIOPHARMA INC.

Kedrion Biopharma Inc. (KBI) mainly sells products to American clients, with some exceptions, and the fight against corruption on the national front has maximum priority in the KBI Compliance Programme, which nevertheless also remains attentive to international clients (FCPA - Foreign Corruption Practices Act).

The KBI Compliance Director is charged with maintaining the written guidelines, s/he has the task of carrying out training courses on topics related to the fight against corruption and implementing other elements of the Compliance Programme. The Compliance Director reports to the KBI Board of Directors and functionally, to the KBI General Director.

The risks related to the topic are relevant. The USA's legislative context is very active in carrying out anti-corruption investigations and penal actions for American clients, for which it provides numerous laws, such as the Anti-Kickback Statute, the False Claims Act, and the Foreign Corrupt Practice Act (FCPA). This legislation provides for severe federal punishments both civil and penal. Furthermore, the individual states have their own laws and are active in pursuing violations..

HUMAN BIOPLAZMA KFT.

HUMAN BioPlazma Kft., also including the KEDPLASMA Hungary operating unit, operates in Hungary in respect of the judicial and legislative framework applicable to its activities.

With regard to the governance and organisational structure of the Company, the chief executive officers (appointed by Kedrion S.p.A. as a single shareholder, as directors) are civilly and penally responsible for the legitimate activity of the Company, and in this sense also for investigations and suitable responses in relation to reports of suspected violations of the law, internal Company policies, resolutions and instructions of Kedrion S.p.A.

A Supervisory Board also exists to ensure that the chief executive officers carry out their tasks and duties in a legitimate manner. The Company's Memorandum of Association in force includes various thresholds and limitations for the chief executive officers in relation to some actions for which they must first obtain the written approval/consent of the single shareholder or the Supervisory Board.

The policies and processes adopted to combat any active or passive corruption are similar to those adopted by the other companies of the group; it is noted that compliance on the topic of sponsors is ensured by meeting the code of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the code of communication and pharmaceutical ethics of the Association of Hungarian Pharmaceutical Manufacturers (Magyarországi Gyógyszergyártók Országos Szövetsége (MAGYOSZ)).

KEDPLASMA GMBH

KEDPLASMA GmbH is divided into two organisational units: plasma and plasma derivatives. While the plasma unit sells products mostly within the Kedrion Group and therefore is only

exposed in a limited manner to third-party clients on the market, the plasma derivatives unit is exposed to third-party clients.

The Plasma Derivatives unit carries out consultation, training and active monitoring of Company activities relating to anti-corruption. This unit mainly sells to German clients, and the fight against corruption on the national front constitutes one of its priority.

The Company operates in Germany (with supply of plasma from other European countries like Poland, Austria and the Czech Republic, and of plasma derivatives directly from Kedrion S.p.A. in Italy) in respect of the legal and regulatory framework applicable to its activities.

As in the case of HUMAN BioPlazma, the chief executive officers (appointed by Kedrion S.p.A. as a single shareholder, as directors) are responsible and a Supervisory Board exists.

The policies and processes adopted to combat any active or passive corruption are similar to those adopted by the other companies of the group; it is noted just that compliance on the topic of sponsors is ensured by meeting the code of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the code of communication and pharmaceutical ethics of the FSA "Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V.", the AKG "Arzneimittel und Kooperation im Gesundheitswesen e.V." and other accredited bodies.

The risks related to the topic are linked to the fact that the German regulatory context is very active in the field of conducting anti-corruption investigations and penal actions.

4.15.9. "HUMAN RIGHTS" AREA

Since the beginning, the Kedrion Group is engaged in the creation of a working environment dominated by responsibility, trust and mutual respect, development of personality and diversity among individuals; Kedrion considers it fundamental that the relationships between colleagues, at every level of the organisation, are made with loyalty and correctness in mutual respect of the rights and freedom of people; it considers necessary that all employees and collaborators of the Company contribute to maintaining a climate of mutual respect of dignity, honour and reputation; it only approves behaviours coherent with the principle of respect for a person by whoever enacts them, towards whoever they are aimed and independently of the reasons; it considers it fundamental that managers and supervisors respond promptly and professionally to any doubt or problem raised by collaborators.

Kedrion Group prevents and opposes the employment of minors, forced labour, unjust disciplinary procedures, physical or mental coercion or abuse towards a person.

The Company prevents and counters all forms of discrimination of workers for nationality, race, religion, social class, gender, sexual orientation, political and trade union opinion, conditions of health, physical limitations, age, prior family responsibilities, marital status or for any other condition that may give rise to discrimination.

Conversely, the Company proposes to offer equal opportunities to all employees in career development, leave from work and retirement, respecting the fundamental principle of equality.

Compared to 2017, the main legislative change related to the principles of equal treatment, human rights and non-discrimination, which the European companies of the group have obviously adapted and structured, is that relating to the strengthening of the right to privacy and the processing of sensitive personal data (GDPR, with the introduction of the Data Protection Officer - DPO).

In 2018, no episodes of discrimination or violation of human rights were detected throughout the scope of consolidation.

The following paragraphs describe the organisation and distinctive processes adopted in the area of human rights by the Group's main operating companies.

KEDRION S.P.A.

The Company's Board of Directors has long implemented the Ethics Office function, which is responsible for defining, implementing, adapting and continuously improving the Company's Business Ethics Management System. The delegation of authority is extended to the implementation of the international voluntary standard SA8000 (Social Accountability 8000), i.e. the implementation of the Social Responsibility System on Ethics in relations with employees within Kedrion and in the supply chain in compliance with the SA8000 standard.

Kedrion S.p.A. prepared a specific Risk Analysis with respect to the principles of the SA8000 Social Responsibility Standard, which has not highlighted critical situations under the different aspects of compliance, ethics and legal, concerning the business-workers relationship and business-supply chain.

Principles and methods of conducting the Risk Analysis are described and regulated in the SA8000 Corporate Manual, as is the entire Social Responsibility Management System adopted by Kedrion S.p.A.. The SA8000 Manual, together with the Code of Ethical Conduct, is distributed to all employees upon hiring.

None of the reports submitted by the workers to the Ethics Officer constituted violations of human rights and workers' rights; specifically, none of these reports constitute violations of laws, applicable regulations, conduct and/or practices not in line with the provisions of the Code of Ethics and the SA8000 System adopted by the company.

Kedrion S.p.A., since 2005, recognizes, approves, supports and adopts the 10 Ethical Principles of the Global Compact concerning human rights, labour, the environment and the fight against corruption.

KEDRION BIOPHARMA INC.

Kedrion Biopharma Inc. (KBI) respects all USA laws on the fight against discrimination and has a control system to prevent and identify such conduct.

USA laws and those of the individual states are very severe towards cases of violation of equal treatment and protection of human rights, therefore, KBI is very attentive and avoids the risk of incurring sanctions and reputation damage.

HUMAN BIOPLAZMA KFT.

The Company, which also includes the KEDPLASMA Hungary business unit, operates in Hungary in respect of the judicial and legislative framework applicable to its activities.

In regard to the approach adopted by the Company on human rights and discrimination, particular attention is paid to this topic, among others, given that in Hungary the prohibition on discrimination and the principle of equal treatment are well governed in several laws, e.g. the Fundamental Law (Constitution), the Civil Code (Law N. V of 2013), Law N, CXXV of 2003 on equal treatment and promotion of equal opportunities (acknowledged in Hungarian legislation and thereby conciliated with the respective EU Directives, such as, for example 2000/78, 2000/43 and 2004/113; and Regulation 2016/679 - GDPR), the Code of Employment (Law N. I of 2012). Therefore, the Company is careful to be compliant with the requirements of the law for the activities it carries out.

With regard to the plasma collection activity carried out by the Company (KEDPLASMA Hungary Operating Unit), for the purposes of safety and quality assurance, it could happen that the company exclude some candidates/donors of plasma. To avoid cases of discrimination, the KEDPLASMA Hungary Business Unit, as a provider of health services, used the policy (rules and regulations) applicable to persons attending plasma collection centers, including donor candidates and employees, again in 2018. On the basis of this policy, a commitment is required

to carry out their duties in compliance with the requirements on equal treatment and the prohibition of discrimination against employees.

Constant and accurate compliance and monitoring of working relationships is carried out by the Company to oppose and prevent any form of discrimination, from recruitment to the end of the working relationship, conducted and controlled by the human resources department of the Company.

KEDPLASMA GMBH

The company KEDPLASMA GmbH – as regards human rights, non-discrimination and equal opportunities – is recognised in the Parent Company values listed above.

Specifically, the fundamental legislative point of reference in this context is the German federal law on equal treatment, Allgemeines Gleichbehandlungsgesetz (AGG), of 14 August 2006, which adopted the European Directives passed in the years 2000-2004: Guidelines 2000/78/EG on employment, anti-racism guidelines 2000/43/EG, guidelines 2002/73/EG and 2004/113/EG on equal treatment of men and women.

The AGG has the aim of preventing and eliminating discrimination due to race, ethnic origin, sex, religion or ideology, disability, age or sexual identity.

KEDPLASMA conducts constant and accurate compliance with this legislative requirement, from start to finish of the working relationship with employees and for the entire duration of the employment contract itself. In particular, under the coordination of the human resources department, KEDPLASMA puts in place employee recruitment policies, benefits planning policies and contractual conditions compliant with the legal obligations represented by the AGG. At the same time and with the same methods, extreme attention is paid to any occurrences of behaviour that are not compliant with the requirements in force.

4.15.10. METHODOLOGICAL NOTE

BOUNDARY AND REPORTING PROCESS

The DNF includes in its reporting boundary the Parent Company and the subsidiary companies consolidated with the line-by-line method (it should be noted that the American company that operates the plasma collection centers, KedPlasma LLC, is 100% controlled by KBI, therefore the data relating to KBI or the US region also include those of KedPlasma LLC). Any exceptions are indicated in the text; in the case in which some data are not available, the text highlights this in a clear and transparent way.

The working plan followed to prepare the DNF 2018 followed the phases and time-frames listed below, coherent with Legislative Decree 254/16 and aligned to the financial reporting process and the SOP (Standard Operating Procedure) on non-financial communications prepared and approved by the Kedrion Group:

1. Assignment of the task by the President and Chief Executive Officer of Kedrion S.p.A., to the Group Administration department (start of November 2018);
2. Identify the external consultant to support the activity (mid-November 2018);
3. Choose the type of DNF (consolidated), its location in the management report, its relationship with the GRI Standards and the chosen methodology (GRI in accordance-Core) (end of November 2018);
4. Contact the consultant and the Group Administration department with the data owners and the representatives of each department and legal entity of the Group concerned (before end of November 2018);
5. Training activity and information on the DNF (before mid-December 2018);

6. Development and approval, by the departments involved and the President and Chief Executive Officer of Kedrion S.p.A., of the Materiality Analysis (mid-January 2019);
7. Collection of data and their validation alongside the data owners and department representatives (before mid-February 2019);
8. Write the DNF draft and submit it to the data owners (end of February 2019);
9. Approval of the DNF draft by the data owners and submit the document to the Group Administration department (before mid-March 2019);
10. Send the DNF proposal to the company secretary with a view to its approval in the Board of Directors Meeting on 29 March (20 March 2019).

CORRELATION TABLE

Kedrion material topics	GRI Standard	Boundary		
		Internal	External	Limitations
Managerial development	404: Training and Education	✓		
Employer branding	GRI 102-8: General disclosure	✓		
	GRI 401: Employment	✓		
Company well-being	GRI 401: Employment	✓		
Injuries (Occupational health and safety)	403: Occupational Health and Safety	✓		
Relationship with local communities	413: Local Communities	✓		
	413: Local Communities	✓		
Scientific research activity	419: Socio-economic Compliance	✓		
Water consumption and water cycle	303: Water	✓		
Renewable and non-renewable energy consumption	302: Energy	✓		
Direct and indirect emissions	305: Emissions	✓		
Waste production	306: Effluents and Waste	✓		
Human rights	406: Non-discrimination	✓		
Anti-corruption	205: Anti-corruption	✓	✓	Reporting not extended to the external boundary (suppliers and other partners)

METHODOLOGIES FOR CALCULATING INJURIES AND EMISSIONS

Methodological Note

Health and safety indicators

The indicators used are the Total Injury Rate, TIR, and the Lost Work Days Rate, LWR.

$$TIR = \text{number of events} * x 200,000/\text{hours worked}^{**}$$

$$LWR = \text{number of days lost}^{***} x 200,000/\text{hours worked}$$

**Number of injuries (recordable injuries) that led to absence from work, restrictions to work or medical treatment, including events of biological risk (first aid cases and accidents on way to/from work are excluded).

**Hours effectively worked (where a measurement system is not present, these are estimated according to the work schedule).

***Given calendar days (the day of the event and the day of return to work are excluded).

Occupational diseases data is reported in the text communicating the only case that occurred in 2017.

The consumption of electricity from the grid, methane gas and gas oil, measured by reading on-site counters or telemetries, is transformed into GJ using conversion factors available online:

- Coefficient from therms to scm of natural gas 1 scm = 0.3734 therms (SNAM converter)
- Purchased electricity consumption: kWh x 0.0036 = GJ purchased electricity
- Gas oil and natural gas (fuel): conversion factors from Defra tables 2018 version
 - Consumption of natural gas: scm x 36.8877 / 1000 = GJ
 - Consumption of gas oil: tonne x 42.93 = GJ

To calculate the equivalent emissions of CO₂, the references are those reported below:

- Scope I (Defra 2018 version)
 - Natural gas: GJ x 55,55 = ton CO_{2e}
 - Gas oil: tonne x 3209.22 = kg CO_{2e}
 - GWP refrigerant gases:
 - R22: kg x 1810 = kg CO_{2e}
 - R404A: kg x 3922 = kg CO_{2e}
 - R407C: kg x 1774 = kg CO_{2e}
 - R410A: kg x 2088 = kg CO_{2e}
 - R507: kg x 3985 = kg CO_{2e}
 - R134A: kg x 1430 = kg CO_{2e}
 - R422D: kg x 2730 = Kg CO_{2e}
 - ISCEON: kg x 3805 = kg CO_{2e}
 - R449: kgx1397 = Kg CO_{2e}
- Scope II (Terna 2017 version)
 - Electricity:
 - kWh x 0.360 = kg CO_{2e} (Italy)
 - kWh x 0.421 = kg CO_{2e} (USA)
 - kWh x 0.493 = kg CO_{2e} (Germany)
 - kWh x 0.288 = kg CO_{2e} (Hungary)

GRI Standard	Disclosure	Paragraph	Omission
GRI 101: Foundation 2016			
General Disclosures			
Organisational profile			
	102-1 Name of the organization	§4.15.1	
	102-2 Activities, brands, products and services	§4.15.1	
	102-3 Location of headquarters	§4.15.1	
GRI 102: General Disclosures 2016	102-4 Location of operations	§4.15.1	
	102-5 Ownership and legal form	Operating Report	
	102-6 Markets served	Operating Report	
	102-7 Scale of the organization	Operating Report	
	102-8 Information on employees and other workers	§4.15.5	

102-9 Supply chain	§4.15.1
102-10 Significant changes to the organization and its supply chain	No
102-11 Precautionary Principle approach	§4.15.4
102-12 External activities	§4.15.1 e 4.15.6
102-13 Membership of associations	§4.15.1
102-14 Statement from senior decision-maker	§4.15
Strategy	
102-15 Key impacts, risks, and opportunities	§4.15.4
102-16 Values, principles, standards and norms of behavior	§4.15.4
102-18 Governance structure	Operating Report
Reporting practice	
102-40 List of stakeholder groups	§4.15.1
102-41 Collective bargaining agreements	§4.15.5
102-42 Identifying and selecting stakeholders	§4.15.1
102-43 Approach to stakeholder engagement	§4.15.1
102-44 Key topics and concerns raised	§4.15.3
102-45 Entities included in the consolidated financial statements	§4.15.2
102-46 Defining report content and topic Boundaries	§4.15.2
102-47 List of material topics	§4.15.3
102-48 Restatements of information	No
102-49 Changes in reporting	No
102-50 Reporting period	2018
102-51 Date of the most recent report	29/3/2018
102-52 Reporting cycle	Annual
102-53 Contact point for questions regarding the report	Finance Dpt
102-54 Claims of reporting in accordance with the GRI Standards	No
102-55 GRI content index	§4.15.10
102-56 External assurance	

Material Topics

GRI 200 Economic Standard Series

Anti-corruption

GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.8
	103-2 The management approach and its components	§4.15.8
	103-3 Evaluation of the management approach	§4.15.8

GRI 205: Anti-corruption 2016	205-3 Confirmed incidents of corruption and actions taken	Zero
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GRI 300 Environmental Standards Series

Energy

GRI 103:	103-1 Explanation of the material topic and its Boundary	§4.15.7
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Management Approach 2016	103-2 The management approach and its components	§4.15.7	
	103-3 Evaluation of the management approach	§4.15.7	
GRI 302: Energy 2016	302-1 Energy consumption within the organization	§4.15.7	
Water			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.7	
	103-2 The management approach and its components	§4.15.7	
	103-3 Evaluation of the management approach	§4.15.7	
GRI 303: Water 2016	303-1 Water withdrawal by source	§4.15.7	
Emissions			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.7	
	103-2 The management approach and its components	§4.15.7	
	103-3 Evaluation of the management approach	§4.15.7	
GRI 305: Emissions 2016	305-1 Direct (Scope 1) GHG emissions	§4.15.7	
Effluents and Waste			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.7	
	103-2 The management approach and its components	§4.15.7	
	103-3 Evaluation of the management approach	§4.15.7	
GRI 306: Effluents and Waste 2016	306-2: Waste by type and disposal method	§4.15.7	
GRI 400 Social Standard Series			
Employment			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.5	
	103-2 The management approach and its components	§4.15.5	
	103-3 Evaluation of the management approach	§4.15.5	
GRI 401: Employment 2016	401-1 New employee hires and employee turnover	§4.15.5	
	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees	§4.15.5	
Occupational Health and Safety			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.5	
	103-2 The management approach and its components	§4.15.5	
	103-3 Evaluation of the management approach	§4.15.5	
GRI 403: Occupational Health and Safety 2016	403-2 Types of injury and rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities	§4.15.5	<i>Some of the information required by the indicator is not currently available. Kedrion is committed to further structuring the data collection process in the coming years to cover GRI disclosure requirements.</i>
	403-3 Workers with high risk of diseases related to their occupation		
Training and Education			
GRI 103: Management	103-1 Explanation of the material topic and its Boundary	§4.15.5	
	103-2 The management approach and its components	§4.15.5	

Approach 2016	103-3 Evaluation of the management approach	§4.15.5	
GRI 404: Training and Education 2016	404-3 Percentage of employees receiving regular performance and career development reviews	§4.15.5	
Non-discrimination			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.9	
	103-2 The management approach and its components	§4.15.9	
	103-3 Evaluation of the management approach	§4.15.9	
GRI 406: Non-discrimination 2016	406-1 Incidents of discrimination and corrective actions taken	Zero	
Local Communities			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.6	
	103-2 The management approach and its components	§4.15.6	
	103-3 Evaluation of the management approach	§4.15.6	
GRI 413: Local Communities 2016	413-1 Operations with local community engagement, impact assessments, and development programs	§4.15.6	<i>Some of the information required by the indicator is not currently available. Kedrion is committed to further structuring the data collection process in the coming years to cover GRI disclosure requirements.</i>
Socio-economic compliance			
GRI 103: Management Approach 2016	103-1 Explanation of the material topic and its Boundary	§4.15.6	
	103-2 The management approach and its components	§4.15.6	
	103-3 Evaluation of the management approach	§4.15.6	
GRI 419: Socio economic compliance 2016	419-1 Non-compliance with laws and regulations in the social and economic area	§4.15.6	

Castelvecchio Pascoli, 29 March 2019

On behalf of the Board of Directors
The Chairman
Paolo Marcucci

5. FINANCIAL STATEMENTS

KEDRION Group

Registered office in LOC. AI CONTI - 55051 CASTELVECCHIO PASCOLI (LU)

Fully paid-up share capital Euro 55,186,279.

5.1. CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(In thousands of Euro)	NOTES	31.12.2018	31.12.2017
NON CURRENT ASSETS			
Property, plant and equipment	6.4.1	266,038	251,215
Investment property	6.4.2	2,327	2,386
Goodwill	6.4.3	230,554	219,318
Definite life intangible assets	6.4.4	83,331	62,034
Investments in associates	6.4.5	331	331
Investments in other companies	6.4.6	2,194	2,095
Other non-current financial assets	6.4.7	10,124	10,856
Deferred tax assets	6.4.8	12,341	6,089
Other non-current assets	6.4.9	1,262	655
TOTAL NON-CURRENT ASSETS		608,502	554,979
CURRENT ASSETS			
Inventories	6.4.10	344,118	280,180
Trade receivables	6.4.11	106,154	127,969
Contract asset	6.4.12	19,555	0
Current tax receivables	6.4.13	7,739	7,237
Other current assets	6.4.14	38,220	36,829
Other current financial assets	6.4.15	712	564
Cash and cash equivalents	6.4.16	116,325	104,522
TOTAL CURRENT ASSETS		632,823	557,301
Assets available for sale	6.4.17	1,554	0
TOTAL ASSETS		1,242,879	1,112,280

(In thousands of Euro)	NOTES	31.12.2018	31.12.2017
SHAREHOLDERS' EQUITY			
SHAREHOLDERS' EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE PARENT			
Share capital	6.4.18	55,186	55,186
Reserves	6.4.18	316,399	307,784
Net income attributable to Equity holders of the Parent	6.4.18	10,165	5,188
TOTAL SHAREHOLDERS' EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE PARENT		381,750	368,158
EQUITY ATTRIBUTABLE TO NON-CONTROLLING INTERESTS			
Capital and reserves attributable to non-controlling interests	6.4.18	277	(153)
Net Income attributable to non-controlling interests	6.4.18	1,476	1,003
TOTAL EQUITY ATTRIBUTABLE TO NON-CONTROLLING INTERESTS		1,753	850
TOTAL SHAREHOLDERS' EQUITY		383,503	369,008
NON CURRENT LIABILITIES			
Medium/long-term loan	6.4.19	490,126	511,932
Financial Liabilities	6.4.20	515	346
Provisions for risks and charges	6.4.21	922	959
Liabilities for employee benefits	6.4.22	9,028	6,738
Other non-current liabilities	6.4.23	5,085	7,834
TOTAL NON-CURRENT LIABILITIES		505,676	527,809
CURRENT LIABILITIES			
Financial liabilities	6.4.24	68,001	41,248
Current portion of medium/long-term debt	6.4.25	64,915	7,036
Provisions for risks and charges	6.4.26	1,450	598
Trade payables	6.4.27	170,959	122,522
Current tax payables	6.4.28	743	2,787
Other current liabilities	6.4.29	47,632	41,272
TOTALE CURRENT LIABILITIES		353,700	215,463
TOTAL LIABILITIES		859,376	743,272
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,242,879	1,112,280

KEDRION Group

Registered office in LOC. AI CONTI - 55051 CASTELVECCHIO PASCOLI (LU)

Fully paid-up share capital Euro 55,186,279.

5.2. STATEMENT OF PROFIT OR LOSS FOR THE YEAR

(in thousands of Euro)	NOTES	31.12.2018	31.12.2017
Revenues	6.5.1	687,939	602,501
Cost of sales	6.5.2	518,482	427,831
GROSS MARGIN		169,457	174,670
Other income	6.5.3	37,494	52,887
General and Administrative expenses	6.5.4	83,659	80,757
Sales and marketing expenses	6.5.5	46,314	51,785
Research and development costs	6.5.6	48,127	35,045
Other operating costs	6.5.7	8,286	8,325
OPERATING INCOME		20,565	51,645
Financial expenses	6.5.8	27,678	43,750
Financial income	6.5.9	15,387	1,953
INCOME BEFORE TAXES		8,274	9,848
Income taxes	6.5.10	(3,367)	3,657
NET INCOME/(LOSS) FOR THE PERIOD		11,641	6,191
Of which:			
Net Income attributable to Equity holders of the Parent		10,165	5,188
Net Income attributable to non-controlling interests		1,476	1,003

With respect to the non-recurring components of income, see Note 6.5.11 included in the explanatory notes to the consolidated financial statements.

KEDRION Group

Registered office in LOC. AI CONTI - 55051 CASTELVECCHIO PASCOLI (LU)

Fully paid-up share capital Euro 55,186,279.

5.3. STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(In thousands of Euro)	NOTES	31.12.2018	31.12.2017
NET INCOME FOR THE PERIOD		11,641	6,191
OTHER COMPREHENSIVE INCOME/(LOSS)			
Items of other comprehensive income that will subsequently be reclassified to profit or loss for the year net of taxes::			
Net Income/(losses) on cash flow hedges		71	554
Income taxes		(17)	(133)
Exchange differences on translation of foreign operations	6.4.18	8,251	(26,050)
Income taxes		0	0
Total items of other comprehensive income that will subsequently be reclassified to profit or loss for the year net of taxes		8,305	(25,629)
Items of other comprehensive income that will not subsequently be reclassified to profit or loss for the year:			
Net actuarial gains (losses) from defined benefit plans	6.4.22	104	9
Income taxes		(30)	(2)
Total items of other comprehensive income that will not subsequently be reclassified to profit or loss for the year (net of taxes)		74	7
TOTAL ITEMS OF OTHER COMPREHENSIVE INCOME (NET OF TAXES)		8,379	(25,622)
TOTAL COMPREHENSIVE INCOME/(LOSS) (NET OF TAXES)		20,020	(19,431)
Attributable to:			
Equity holders of the Parent		18,436	(20,118)
Non-controlling interests	6.4.18	1,584	687

KEDRION Group

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Fully paid-up share capital Euro 55,186,279.

5.4. STATEMENT OF CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY (NOTE 6.4.18)

(in thousands of Euro)	Share capital	Legal reserve	Share premium reserve	Other reserves	Cash flow hedge reserve	Foreign currency translation reserve	TFR reserve (IAS 19)	Income for the period	Total Shareholders' Equity attributable to Equity holders of the Parent	Total Equity attributable to non-controlling interests	Total Shareholders' Equity
	6.4.17	6.4.17	6.4.17	6.4.17	6.4.17	6.4.17	6.4.21	6.4.21	6.4.21	6.4.21	6.4.21
BALANCES AS AT 01.01.2017	55,186	7,072	18,807	283,376	-1,072	18,122	-737	10,722	391,476	2,517	393,993
Allocation of profit for the year	0	416	0	7,106	0	0	0	-7,522	0	0	0
Distribution of dividends	0	0	0	0	0	0	0	-3,200	(3,200)	(2,354)	(5,554)
Exchange differences	0	0	0	0	0	(25,734)	0	0	(25,734)	(316)	(26,050)
Other components of total profit for the year	0	0	0	0	421	0	7	5,188	5,616	1,003	6,619
BALANCES AS AT 31.12.2017	55,186	7,488	18,807	290,482	-651	(7,612)	(730)	5,188	368,158	850	369,008
(in thousands of Euro)	Share capital	Legal reserve	Share premium reserve	Other reserves	Cash flow hedge reserve	Foreign currency translation reserve	TFR reserve (IAS 19)	Income for the period	Total Shareholders' Equity attributable to Equity holders of the Parent	Total Equity attributable to non-controlling interests	Total Shareholders' Equity
BALANCES AS AT 01.01.2018	55,186	7,488	18,807	290,482	(651)	(7,612)	(730)	5,188	368,158	850	369,008
Allocation of profit for the year	0	255	0	84	0	0	0	(339)	0	0	0
Distribution of dividends	0	0	0	0	0	0	0	(4,849)	(4,849)	(939)	(5,788)
Other variations	0	0	0	5	0	0	0	0	5	0	5
Kedron Brasil capital increase	0	0	0	0	0	0	0	0	0	258	258
Exchange differences	0	0	0	0	0	8,143	0	0	8,143	108	8,251
Other components of total profit for the year	0	0	0	0	54	0	74	10,165	10,293	1,476	11,769
BALANCES AS AT 31.12.2018	55,186	7,743	18,807	290,571	(597)	531	(656)	10,165	381,750	1,753	383,503

KEDRION Group

Registered office in LOC. AI CONTI - 55051 CASTELVECCHIO PASCOLI (LU)

Fully paid-up share capital Euro 55,186,279.

5.5. CONSOLIDATED STATEMENT OF CASH FLOW

(In thousands of Euro)

NOTES 31.12.2018 31.12.2017

NET INCOME/(LOSS) (BEFORE TAXES) FOR THE PERIOD **8,274** **9,848**

Adjustments to reconcile net profit with cash flow generated / (absorbed) by operating activities:

Amortization and depreciation		26,295	25,895
Financial Charge	6.5.8	27,678	43,750
Financial Income	6.5.9	(15,387)	(1,953)
Provisions for employee benefits	6.4.22	2,534	1,714
Payables for employee benefits	6.4.22	(192)	(183)
Net change in provisions for risks and charges	6.4.21 6.4.26	815	(2,582)
Net change in other non-current assets and liabilities	6.4.23 6.4.9	(2,461)	1,632

Net changes in operating assets and liabilities:

Trade receivables	6.4.11	1,933	6,271
Inventories	6.4.10	(60,279)	226
Trade payables	6.4.27	48,164	(40,977)
Other current assets and liabilities		5,594	(657)

Other cash flow from operating activities

Income taxes paid		(6,659)	(6,160)
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NET CASH FLOW GENERATED BY OPERATING ACTIVITIES (A) **36,309** **35,536**

Investments in tangible assets	6.4.1	(22,397)	(65,111)
Disposal of tangible assets	6.4.1	248	184
Purchase of plasma collection centre		(29,104)	(15,009)
Goodwill		214	0
Investments in associates/others		0	(331)
Investments in intangible assets	6.4.4	(14,302)	(11,172)
Disposal of intangible assets	6.4.4	115	89

NET CASH FLOW ABSORBED BY INVESTMENT ACTIVITIES (B) **(65,226)** **(91,350)**

(In thousands of Euro)	NOTES 31.12.2018 31.12.2017		
Distribution of dividends	6.4.18	(7,511)	(8,724)
Capital increase		258	0
Bond repayment		0	342,448
New bond issue		0	(91,080)
New medium/long-term loans	6.4.19	58,371	173,343
Repayment of medium/long-term loans	6.4.19	(27,910)	(285,477)
Interest collected	6.5.9	526	529
Interest paid		(20,260)	(20,258)
Change in non-current financial assets	6.4.7 6.4.19	901	(3,912)
Net change in short-term financial assets and liabilities		36,103	(13,104)
NET CASH FLOW GENERATED / (ABSORBED) BY FINANCING ACTIVITIES (C)		40,478	93,765
Net cash flow generated by operating activities (A)		36,309	35,536
Net cash flow absorbed by investment activities (B)		(65,226)	(91,350)
Net cash flow generated / (absorbed) by financing activities (C)		40,478	93,765
TOTAL NET CASH FLOW D=(A+B+C)		11,561	37,951
Cash and cash equivalents at the beginning of the period (E)		104,522	66,508
Net effect of conversion of foreign currencies on cash and cash equivalents (F)		240	62
CAH AND CASH EQUIVALENTS AT THE END OF THE PERIOD H=(D+E+F+G)		116,323	104,521
CASH AND CASH EQUIVALENTS AT THE BEGINNING OF THE PERIOD:			
Cash and Cash equivalents:		104,522	66,510
Current account overdrafts and cash equivalents payable on demand		0	(2)
CASH AND CASH EQUIVALENTS AT THE BEGINNING OF THE PERIOD		104,522	66,508
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD:			
Cash and cash equivalents	6.4.16	116,325	104,522
Current account overdrafts and cash equivalents payable on demand	6.4.24	(2)	0
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD:		116,323	104,522

Castelvecchio Pascoli, 29 March 2019

On behalf of the Board of Directors
The Chairman
Paolo Marcucci

6. EXPLANATORY NOTES

6.1. INTRODUCTION

Kedron S.p.A. is a joint-stock company incorporated and domiciled in Italy, and together with its subsidiaries (“Kedron Group”) carries out activity of production and distribution of biological drugs derived from the process of industrial plasma fractionation. In addition, it also markets synthetic pharmaceutical products and implements operations relative to the collection and sale of plasma in foreign markets as well as other activities, such as the transfer of technology relating to the production of plasma derivatives. Further information on the activities performed by the Group can be found in the Report on Operations.

In addition to Kedron S.p.A., the consolidated financial statements of Kedron as at 31 December 2018, prepared by the directors of the parent company, include the following companies:

- The US subsidiary Kedron Biopharma Inc. (formerly Kedron Melville), 100% owned by Kedron;
- The indirect US subsidiary KEDPlasma LLC. (formerly ABS), 100% owned by Kedron BioPharma Inc.
- The Austrian subsidiary Kedron International GmbH, 100% owned by Kedron;
- The Hungarian subsidiary Human BioPlazma KFT, 100% owned by Kedron;
- The indirect Hungarian subsidiary KEDPlasma Kft, 100% owned by Human BioPlazma KFT;
- the Swiss subsidiary Kedron Swiss Sarl, 100% owned by Kedron S.p.A.;
- The German subsidiary KEDPLASMA GmbH, 100% owned by kedron S.p.A.;
- The Mexican subsidiary Kedron Mexicana SA de CV, 60% owned by Kedron S.p.A. The remaining 40% is owned by a third party;
- The Portuguese subsidiary KEDRION PORTUGAL - DISTRIBUIÇÃO DE PRODUTOS FARMACÊUTICOS UNIPessoal, LDA 100% owned by Kedron;
- The Brazilian subsidiary Kedron Brasil Distribuidora de Produtos Hospitalares Ltda (hereinafter referred to as Kedron Brasil), 51% owned by Kedron. The remaining 40% is owned by a third party;
- The Indian subsidiary Kedron Biopharma India Private Limited, 60% owned by Kedron, 20% owned by Human BioPlazma Kft and the remaining 20% by Kedron Biopharma Inc.;
- The subsidiary Kedron Betaphar SA, 60% owned by Kedron;
- The subsidiary Kedron de Colombia Sas, 100% owned by Kedron.

The parent company Kedron S.p.A. is the issuer of two bonds listed on the Irish Stock Exchange. The first of the two loans issued in 2014 for an initial amount of Euro 300,000 thousand and its outstanding capital is equal to Euro 58,204 thousand. The loan has a nominal interest rate of 4.625% and expires in April 2019.

On July 12, 2017, the Parent Company issued a second senior, unsecured, non-convertible 3% coupon bond of Euro 350 million, with an issue price set at 99.43 (below the par) and 5 years maturity. In the context of this new issue, a total of Euro 91,080 thousand of the bonds issued in 2014 were repurchased.

Because of these listed loans, Kedron has become a Public Interest Entity according to the definition set in art. 16 of Legislative Decree 39/2010.

The 69.38% of the share capital of Kedron S.p.A is held by Sestant Internazionale S.p.A., 25.06% by FSI Investimenti S.p.A. and for 5.56% from Sestant S.p.A., which jointly control the Company based on statutory arrangements that provide a qualified majority in the Board of Directors for the Reserved Matter adoption. The Board of Directors acknowledges that the Company is not subject

to management and coordination by the joint controlling companies Sestant Internazionale S.p.A., FSI Investimenti S.p.A. and Sestant S.p.A. in accordance with the provisions of Articles 2497 sexies and 2497 septies of the Civil Code. The Company's bodies have full and unconditional autonomy from the management point of view, as the preparation of the strategies it is carried out by the Management without any interference by the shareholders.

The presentation format for the consolidated balance sheet classifies items in an increasing order of liquidity, where:

- Current activities include activities which:
 - They are supposed to be realized, or held for sale or consumption, in the normal course of the operating cycle;
 - They are held for the purpose of negotiation;
 - They are supposed to be realized within twelve months from the closing date of the financial year; or
 - They consist of cash or cash equivalents unless it is forbidden to trade them or use them to repay a liability for at least twelve months from the closing date of the financial year;
- Non-current assets are all other assets that do not fall within the definition above. They mainly include intangible assets with a finite and indefinite life, tangible assets and equity investments;
- Current liabilities include liabilities that:
 - It is expected to become extinct in their normal operating cycle;
 - They are held mainly for the purpose of trading;
 - They must be settled within twelve months from the closing date of the financial year; or
 - the entity does not have an unconditional right to defer settlement of the liability for at least twelve months from the reporting date;
- Non-current liabilities include all other liabilities that do not fall within the definition above.

The presentation format for the consolidated Statement of profit or loss for the year as at 31st December 2018 and 2017 is illustrated by function, the format considered more representative than the presentation by nature of expense. The adopted format complies with internal reporting and business management methods. The consolidated statement of cash flow was prepared according to the indirect method and in the format compliant with IAS 7, classifying cash flows under operating, investment and financing activities.

The cash flow related to financial charges and financial income paid and collected is put in financing activities and not in operating activities.

Directors at the meeting of the Board of Directors on 29th March 2019 approved the financial statements for the year ended 31st December 2018.

6.2. PERIOD'S SIGNIFICANT EVENTS

6.2.1. MELVILLE PLANT'S REFITTING

With regard to the plasma-derived products segment, the most important (expected) situation that had an effect on the performance of the year was represented by the completion of the project that saw the total shutdown of the US plant in Melville from April 2016 until the first half of 2018 (the so-called "refitting") for (i) the complete restructuring of the existing fractionation line with the aim of complete integration and harmonization of this plant with the others of the Kedrion Group, as well as the implementation of some recommendations received from the US Food & Drug

Administration (FDA) and (ii) the realization of a fractionation and purification line of the anti-D immunoglobulin (RhoGAM) , aimed at internalising the production of this specialty.

The project, which involved investments for the Group of Euro 3.9 million in 2018 (in addition to approximately Euro 83.6 million already invested in the years 2016-2017), was completed from an industrial point of view with the operational restart of the fractionation in the second half of the year, with approximately 80,000 liters fractionated. In August 2018, the fractionation plant was inspected by the FDA, which led to its final approval by the American authorities in February 2019. The new line dedicated to the RhoGAM product was also inspected by the FDA in November 2018 and the operational start-up of this line, initially for filling and packaging activities, is expected in the first half of 2019.

The partial activity of the Melville plant resulted in a significant impact on the income statement for the year due to the non-absorption of costs of the plant (which only from the moment of the restart found partial correspondence in production), and the write-down of intermediate and finished product inventory realized before the plant shutdown for a total of Euro 76.0 million, as well as the reduction in margins on sales due to the use of an outsourcing production contract with Grifols for the US market.

6.2.2. CASTELVECCHIO PASCOLI NEW PLANT FOR PURIFICATION OF IMMUNOGLOBULIN 10% (KIG10)

The project to build a 10% immunoglobulin purification plant (Klg10) using the chromatographic method at Castelvecchio Pascoli (LU) also continued during the year. In December 2018 the IND (Investigational New Drug) application for the development of KIG10 was submitted to the FDA and approved the following month, the date from which Kedrion is authorized to start clinical trials. Currently, production for clinical studies is carried out in the Godollo plant and then, once these studies have been completed, in the Castelvecchio plant (purification phase while fractionation will be carried out in the Melville plant).

The restructuring of the Melville plant delayed the completion of the preparatory activities for obtaining the necessary authorizations and registration of the product itself, resulting in an increase in start-up costs. The project costs for the year, which have not yet been balanced in production and related revenues, amount to Euro 8.4 million. Moreover, following the 2018 innovation agreement between the Ministry for Economic Development (Mise), the Region of Tuscany and Kedrion S.p.A, for which part of the investment programme for this project is financed by Mise and the Region of Tuscany, grant of Euro 1.8 million was recorded in other non-recurring income.

6.2.3. NEW PRODUCT: KEDRAB

Sales of KEDRAB, a concentrated anti-rabies hyperimmune immunoglobulin developed in partnership with Kamada, an Israeli pharmaceutical company, began in early 2018. Kedrion is the exclusive distributor of this product in the US market and the turnover of the first year of activity was equal to Euro 12.9 million.

6.2.4. SALES AND PURCHASES / STARTING UP OF PROPERTY COLLECTION CENTERS

The Group is continuing its investment activity aimed at increasing the number of collection centers as planned in the strategic plan guidelines.

This growth takes place through the establishment of new collection centers, the purchase of plasma collection centers from third parties and is partly financed by the sale of collection centers. Specifically, in September 2018, three plasma collection centers were sold and three centers were purchased at the same time with Grifols Group. In addition, in December 2018 the sale of

three other plasma collection centers to Grifols Group was formalised. This sale contributed significantly to the result for the period, recording an amount equal to approximately Euro 28 million among other income.

In addition, five centers were acquired/launched in the United States and one in Hungary, for a total of 27 centers owned at the end of the year.

The details of the acquisitions in 2018 are described in paragraph 6.2.5 below and the details of the disposals of collection centers for the same period in paragraph 6.2.6.

6.2.5. BUSINESS CONSOLIDATION IN 2018

In 2018, the subsidiary KEDPLASMA LLC, on the basis of a purchase and sale agreement, acquired from Biomat USA Inc. the business units relating to 3 plasma collection centers in the United States, and at the same time sold another 3 centers owned. The allocation of the price paid, equal to USD 10.8 million (EUR 9.5 million), was completed by the end of September on the basis of an expert's report entrusted to a third-party company.

(In thousands of Dollars)	Fair value recognized in acquisitions			Total
	Lincoln	Augusta	Youngstown	
ACQUIRED NET ASSETS				
Property, plant and equipment	285	168	662	1,115
Intangible assets with finite useful lives	2,630	2,393	2,851	7,874
- Of which Donor list	1,434	1,389	1,694	4,517
- Of which Licenses	904	584	804	2,292
- Of which Trade Names and Trademarks	292	420	353	1,065
TOTAL NET ASSETS AT FAIR VALUE	0	0	0	0
GOODWILL ARISING ON AQUISITIONS	2,915	2,561	3,513	8,989
ACQUISITION CHARGE	1,954	1,904	1,998	5,856
- In compensation with disposals	4,869	4,465	5,511	14,845

In addition, also in 2018, the subsidiary KEDPLASMA LLC acquired from Immunotek Biocenters LLC the business units relating to 5 plasma collection centers in the United States, mainly comprising the related plants and equipment, the personnel involved, the existing contractual relationships and relations with donors. The allocation of the price paid, equal to USD 35.1 million (EUR 30.7 million), was completed by the end of the year on the basis of an expert's report entrusted to a third-party company.

(In thousands of Dollars)	Fair value recognized in acquisitions					
	Myrtle Beach	Sarasota	Longview	Bradenton	Irving	Total
ACQUIRED NET ASSETS						
Property, plant and equipment	445	437	444	525	494	2,345
Intangible assets with finite useful lives	1,738	1,960	4,089	2,312	3,656	13,755
- Of which Donor list	451	569	1,944	827	1,426	5,217
- Of which Licenses	953	1,051	1,620	1,112	1,744	6,480
- Of which Trade Names and Trademarks	334	340	525	373	486	2,058
NET WORKING CAPITAL	1,089	711	999	910	1,334	5,043
TOTAL NET ASSETS AT FAIR VALUE	3,272	3,108	5,532	3,747	5,484	21,143
GOODWILL ARISING ON ACQUISITIONS	3,817	3,602	1,466	3,164	1,851	13,900
PURCHASE CONSIDERATION TRANSFERRED	7,089	6,710	6,998	6,911	7,335	35,043
- Of which cash	7,089	6,710	6,998	6,911	7,335	35,043

Acquisitions made in 2018 were consolidated as from the date of acquisition of control.

6.2.6. DISPOSALS OF PROPERTY COLLECTION CENTERS

The following table shows the effects of the disposals of the centers in 2018.

(In thousands of Dollars)	Net value of disposals						
	Gastonia	Rockhill	Winston Salem	Ocala	Kissimmee	Greenville	Total
NET ASSETS SOLD							
Property, plant and equipment	363	274	192	472	394	371	2,066
Intangible assets with finite useful lives	0	0	0	1,561	937	1,330	3,828
- Of which Donor list	0	0	0	493	159	261	913
- Of which Licenses	0	0	0	844	522	790	2,156
- Of which Trade Names and Trademarks	0	0	0	224	256	279	759
NET WORKING CAPITAL	107	190	114	142	151	150	853
TOTAL NET ASSETS AT FAIR VALUE	470	464	306	2,175	1,482	1,851	6,747
GOODWILL	1,471	1,327	1,942	1,795	1,523	1,758	9,816
PROCEEDS ON DISPOSALS	7,731	7,688	9,918	8,529	8,054	8,244	50,164
Gain from the sale of the centers	5,790	5,897	7,670	4,559	5,049	4,635	33,601

6.2.7. FOREIGN EXCHANGE

The exchange rate trend (in particular of the US Dollar, which went from 1.1993 as at 31 December 2017 to 1.1450 as at 31 December 2018) generated a positive impact on the income statement due to realised and unrealised exchange rate differences of Euro 9.3 million (last year the effect on the result was negative for Euro 17.0 million), as well as an increase in the shareholders' equity of the Group and of third parties of Euro 8.3 million due to the change in the translation reserve

6.3. ACCOUNTING STANDARDS AND MEASUREMENT CRITERIA

6.3.1. CONTENTS AND FORM OF THE CONSOLIDATED FINANCIAL STATEMENTS

The consolidated financial statements of Kedrion S.p.A. as at 31st December 2018 have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and adopted by the European Union, and in accordance with the regulations issued to implement the art. 9 of Legislative Decree n. 38/2005. IFRS also includes all valid International Accounting Standards ("IAS") and all interpretations of the International Financial Reporting Standards Interpretations Committee ("IFRS IC"), including those previously issued by the Standing Interpretations Committee ("SIC").

The accounting standards adopted in drawing up the consolidated financial statements as at 31 December 2018 are consistent with those used to draw up the annual consolidated financial statements as at 31st December 2017, except for the new principles, amendments and interpretations in force as of 1st January 2018 that have been adopted.

The consolidated financial statements have been drawn up according to the historical cost principle, except for derivative financial instruments, which are entered at fair value. They have also been drawn up on the assumption that the business is a going concern and, if allowed, on the accrual accounting principle.

The functional currency of the consolidated financial statements is the Euro, and all figures are rounded up to the nearest thousand Euro unless indicated otherwise.

6.3.2. CONSOLIDATION AREA

The consolidated financial statements include the financial statements of Kedrion S.p.A. and those of its subsidiaries as at 31 December 2018. Control is obtained when the Group is exposed to or has the right to variable returns resulting from its involvement with the investee and, at the same time, is able to influence said returns by exercising its power over said entity.

Specifically, Kedrion S.p.A controls an investee if, and only if, the company has:

- power over the investee (i.e. it has valid rights that give it the ability to direct the relevant activities of the investee);
- Exposure or rights to variable returns from its involvement with the investee;
- The ability to use its power over the investee to affect the amount of its returns.

Generally, it is assumed that holding a majority of voting rights entails control. To support this assumption and when the Group holds less than the majority of voting rights (or similar rights), the Group considers all of the relevant facts and circumstances to establish whether it controls the investee, including:

- Contractual agreements with other holder of voting rights;
- Rights resulting from contractual agreements;
- Voting rights and potential voting rights of the Group.

The Group reconsiders whether it has control over an investee if the facts and the circumstances indicate that there have been changes in one or more of the three elements that define control. Consolidation of a subsidiary starts when the Group obtains control of the same and ceases when the Group loses control of the same. The assets, liabilities, revenues and costs of the subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date on which the Group obtains control until the date on which the Group no longer has control over the Company.

The profit (loss) for the year and all of the other components of comprehensive income are attributed to the shareholders of the parent and to the non-controlling interests, even if this implies that the non-controlling interests have a negative balance. When necessary, the appropriate adjustments are made to the financial statements of subsidiaries, in order to guarantee compliance with the Group's accounting policies. All intragroup assets and liabilities, shareholders' equity, revenues, costs and cash flows relating to transactions between group entities are fully eliminated at the time of consolidation.

Changes in the share of investment in a subsidiary that do not result in a loss of control are recorded under shareholders' equity.

If the Group loses control of a subsidiary, it must eliminate the relative assets (including goodwill), liabilities, non-controlling interests and other equity components, while any profit or loss is recognised in the statement of profit or loss. Any equity investment maintained must be recognised at its fair value.

The table below summarises with regard to the subsidiary companies, the information as at 31st December 2018 concerning their name, registered office and the percentage of share capital held directly and indirectly by the Group.

Subsidiary companies (consolidate with the line-by-line method)						
Name	Registered Office	Currency	Share capital units of currency	% control		Notes
				Direct	Indirect	
Kedrion International GmbH	Vienna – Austria	Euro	70,000	100%		
HUMAN BioPlazma Kft.	Gödöllő – Hungary	Hungarian Forint	4,000,000,000	100%		
Kedrion Mexicana S.A. de C.V.	Mexico City – Mexico	Peso	2,061,320	60%		
Kedrion Biopharma Inc.	New Jersey – United States	US Dollar	1	100%		
KEDRION BRASIL DISTRIBUIDORA DE PRODUTOS HOSPITALARES LTDA	Goiania – Brazil	Brazilian Real	700,000	51%		
Kedrion Betaphar Biyofarmasötik İlaç Sanayi ve Ticaret Anonim Şirketi	Ankara - Turkey	Turkish Lira	500,000	60%		
KEDRION DE COLOMBIA S.A.S.	Bogotá - Colombia	Colombian peso	30,000,000	100%		
KEDRION PORTUGAL - DISTRIBUIÇÃO DE PRODUTOS FARMACÊUTICOS UNIPESSOAL, LDA	Alges - Portugal	Euro	50,000	100%		
Kedrion Swiss Sarl	Zug – Switzerland	Swiss Franc	20,000	100%		
KEDPLASMA GmbH	Grafelfing – Germany	Euro	25,000	100%		
Kedrion Biopharma India Private Limited	Gurgaon - India	Indian rupee	13,900,000	60%	40%	1
KEDPLASMA LLC	Delaware – United States	Us Dollar	1,382,522		100%	2
KEDPlasma Kft.	Gödöllő – Hungary	Hungarian Forint	12,000,000		100%	3

1. Through Biopharma Inc and through Human BioPlazma KFT
2. Through Kedrion Biopharma INC.
3. Through Human BioPlazma KFT.

6.3.3. CONSOLIDATION CRITERIA

The consolidated financial statements are prepared on the basis of draft financial statements drawn up by each of the consolidated companies and approved by their respective Boards of Directors or similar competent bodies. These draft financial statements of the subsidiaries are prepared with reference to the same financial year and by adopting the same accounting standards as the parent company. Subsidiaries are consolidated on a line-by-line basis as from the date of their acquisition, i.e. the date on which the Group acquires control, and cease to be consolidated on the date on which control is transferred outside the Group.

Specifically, for the consolidated companies, the following consolidation criteria were applied:

- The carrying amount of the investments included in the consolidation area was de-recognised against the subsidiaries' shareholders' equity according to the line-by-line method and where the direct or indirect investment is less than 100%, the share of the result and of shareholders'

equity attributable to non-controlling interests is attributed and stated in a separate item of the consolidated Statement of profit or loss for the year and in the consolidated Statement of financial position;

- Any difference between the acquisition cost and the carrying amount of shareholders' equity of the investees at the time of acquisition of the investment, if positive, is allocated to the specific assets of the companies acquired on the basis of their current values at the acquisition date and, for the remaining portion, where conditions are met, to the item Goodwill. In this case, these amounts are not amortised but subject to impairment testing at least once a year and in any case whenever it is deemed necessary in the event of impairment. If derecognition of the investment gives rise to a negative difference, this is entered in the statement of profit and loss;
- Payables and receivables, costs and revenues, gains and losses ensuing from transactions performed between Group companies are derecognised with consideration for the related tax effects;
- The effects arising from extraordinary transactions involving Group companies (mergers, contributions, etc.) in the case of jointly-controlled business combinations are derecognised.

6.3.4. TRANSLATION INTO EURO OF FINANCIAL STATEMENTS DRAWN UP IN FOREIGN CURRENCY

The consolidated financial statements are presented in Euro, the Company's functional currency. Each company in the Group defines its own functional currency which is used to measure the individual items in its individual financial statements.

The financial statements of foreign companies expressed in currencies other than the Euro are translated into Euro according to the following procedures:

- The items of the profit and loss statement are translated at the year-average exchange rates, while the balance sheet items are translated at the rates in force at year-end with the exclusion of shareholders' equity (included in the result for the year);
- The shareholders' equity items, including the result for the year, are translated at historical exchange rates.

The translation difference arising from this process is entered under consolidated shareholders' equity under the item "Exchange differences on translation of foreign operations", which is classified within the item Other Reserves. At the time of disposal of a foreign company, the exchange differences accumulated in this reserve, and relating to the company sold, are booked within the statement of profit and loss.

The exchange rates used to determine the value in Euro of the financial statements expressed in foreign currencies of the subsidiaries (value for 1 Euro) are set forth in the table below:

Currency (for 1 Euro)	Average exchange rates for the year ended 31 December		Year-end exchange rate as at 31 December	
	2018	2017	2018	2017
US dollar	1.18	1.13	1.15	1.20
Hungarian Forint	318.89	309.19	320.98	310.33
Swiss Franc	1.16	1.11	1.13	1.17
Mexican Peso	22.71	21.33	22.49	23.66
Brazilian Real	4.31	3.61	4.44	3.97
Indian Rupee	80.73	73.53	79.73	76.61
Turkish lira	5.71	4.12	6.06	4.55
Colombian Peso	3,486.74	3,336.17	3,721.81	3,580.19

TRANSACTION AND BALANCES

Transactions are initially recorded by the Group's entities at their respective functional currency applying currency exchange interest spot rate as of transaction date. Foreign currency monetary assets and liabilities are exchanged in functional currency applying currency exchange interest rate at reporting date. Foreign currency translation realised gains and losses and those arising on translation of monetary items are recognized in the Consolidated Statement of profit or loss. Tax charges related to differences arising on translation of monetary items are recognized in the Consolidated Statement of profit or loss too. Non-monetary items measured in terms of historical cost in a foreign currency are translated using the exchange interest rates as at the date of initial transaction. Non-monetary items measured at fair value in a foreign currency are translated using the exchange interest rate as at fair value settlement date. The gain or loss arising on translation of non-monetary items measured at fair value is treated in line with the recognition of the gain or loss on the change in fair value of the item (i.e translation differences on items whose fair value gain or loss is recognized in OCI or profit or loss are also recognized in OCI or profit or loss, respectively.)

6.3.5. CHANGES IN INTERNATIONAL ACCOUNTING STANDARDS

The Group adopts IFRS 15 and IFRS 9 for the first time. The impact and nature of the changes following the adoption of these new accounting standards are described below. Several other amendments and interpretations apply for the first time in 2018, but do not have any impact on the Group's financial statements, therefore it was not necessary to restate the opening balances at 1 January 2018. The Group has not adopted in advance any other standards, interpretations or amendments published but not yet in force.

IFRS 15 REVENUES FROM CUSTOMER CONTRACTS

IFRS 15 replaces IAS 11 Long-term Contracts, IAS 18 Revenues and related interpretations and it is applied, with limited exceptions, to all revenues from customer contracts. IFRS 15 establishes a five-step model to account customer contracts revenues and requires revenue to be recognised in an amount that reflects the consideration to which the entity expects to be entitled in exchange for transferring control of the goods or services to a customer.

IFRS 15 requires entities to evaluate all material facts and circumstances when they apply each step of the model to customer contracts. The standard also specifies the methods of accounting for incremental costs for obtaining a contract and for the costs directly related to the execution of a contract. The Group has adopted the new standard with a modified approach, i.e. by not applying the standard retrospectively to comparative data.

The effects of the adoption of IFRS 15, which are reclassifications, are as follows:

Impact on income statement (increase/(decrease) of economic result):		
	Adjustments	31.12.18
Revenue from contracts with customers		(2,575)
Revenues	(a),(b),(c),(d)	(2,575)
Cost of sales	(a),(b),(c),(d)	(1,523)
Gross margin		(4,098)
Net operating profit		4,098
Profit for the year		0

Impact on equity (increase/(decrease)):		
	Adjustments	31.12.18
		Euro 0
Assets		
Trade receivables	(d)	(19,555)
Contract Assets	(d), (e)	18,943
Total Current Assets		(612)
Total Assets		(612)
Shareholders' equity		0
Liabilities		
Other liabilities (current)	(e)	(612)
Total current liabilities		(612)
Total liabilities and equity		(612)

The adoption of IFRS 15 didn't have a material impact on the other components of the comprehensive income statement for the year or on the cash flow statement.

The nature of the effects is described below:

- a) Reclassification of product distribution costs from operating costs to reduce revenues for Euro 3,948 thousand at 31 December 2018;
- b) Reclassification of the change in inventories relating to assets deriving from contracts from cost of goods sold to revenues of Euro 1,523 thousand at 31 December 2018;

- c) Reclassification of payback costs to the Italian Medicines Agency (Agenzia Italiana per il Farmaco) from operating costs to a revenue reduction of Euro 150 thousand at 31 December 2018;
- d) Reclassification from trade receivables to assets deriving from contracts for Euro 19,555 thousand;
- e) Reclassification from other payables of contractual liabilities to customers for Euro 612 thousand.

IFRS 9 FINANCIAL INSTRUMENTS

In July 2015, IASB issued the final version of IFRS 9 Financial Instruments replacing IAS 39 Financial Instruments: Recognition and Measurement and all previous versions of IFRS 9. IFRS 9 brings together all three aspects of the project on accounting for financial instruments: classification and measurement, impairment and hedge accounting. IFRS 9 is effective for financial years beginning on or after 1 January 2018; early application is permitted. With the exception of hedge accounting, retrospective application of the standard is required, but comparative information is not required. With regard to hedge accounting, the standard is generally applied prospectively, with a few limited exceptions.

The Group has been adopting the new standard since 1 January 2018 without restating the comparative information. During 2017, the Company completed its analysis of the main new features introduced by IFRS 9, assessing the possible impact of applying all three aspects of IFRS 9. The Group did not see a significant impact on its statement of financial position and shareholders' equity, and the amounts allocated for impairment losses were not significantly different from those obtained from the procedures previously applied for the reasons described below. Furthermore, there were no changes in the classification of the Group's financial instruments.

- Classification and measurement

The application of the classification and valuation requirements provided for by IFRS 9 has not a significant impact on financial statements and shareholders' equity, since the financial instruments held by the Group that can generate a difference in the application of the new standard are only receivables, financial liabilities and derivative instruments, while the Group does not hold debt and equity instruments. The Group continues to measure at fair value all financial assets previously recognised at fair value.

Loans and trade receivables are held for the purpose of being paid at contractual maturities and generate cash flows represented solely by the collection of principal and interest. Given the characteristics of the contractual cash flows of these instruments, the Group respect the compliance with the criteria for measurement at amortised cost in accordance with IFRS 9.

- Impairment

IFRS 9 requires the Group to record expected credit losses on all its obligations, loans and trade receivables, either on an annual basis or on a residual maturity basis. The Group applies the simplified approach and records the expected losses on all trade receivables on the basis of their residual duration, defining a matrix for the allocation based on the historical experience of the individual Group companies in relation to losses on receivables, adjusted to take account of specific forecast factors relating to creditors and the economic environment. In fact, in 2018, the Group analysed the historical insolvency rate of its customer portfolio and integrated this historical information with that already used in the current valuation procedure. The Group already carried out a specific risk analysis by credit category based on country risk, residual duration and the recovery procedures used. The Group, therefore, already incorporated into the calculation of the

provision for doubtful accounts considerations on the current macroeconomic situation and forecasts on future recoverability conditions. This analysis showed that the forecast insolvency rate, i.e. the loss rate (which synthetically represents the probability of default (PD) for the amount of expected losses (LGD)) calculated in consideration of forward looking elements, is similar to the percentages of write-downs already used, since the valuation in the past was not limited to incurred losses only, but incorporated elements of valuation on expected losses for each individual receivable. Therefore, the provisions of IFRS 9 have no significant overall impact on the Group's shareholders' equity.

- Hedge accounting
The Group decided not to apply IFRS 9 with regard to hedge accounting, continuing to apply the provisions of IAS 39.

IFRIC INTERPRETATION 22 FOREIGN CURRENCY TRANSACTIONS AND ADVANCE CONSIDERATION

The Interpretation clarifies that, in determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which an entity initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, then the entity must determine the date of the transactions for each payment or receipt of advance consideration. This Interpretation does not have any impact on the Group's consolidated financial statements.

AMENDMENTS TO IAS 40 TRANSFER OF INVESTMENT PROPERTY

The amendments clarify when an entity should transfer property, including property under construction or development into, or out of investment property. The amendments state that a change in use occurs when the property meets, or ceases to meet, the definition of investment property and there is evidence of the change in use. A mere change in management's intentions for the use of a property does not provide evidence of a change in use. These amendments do not have any impact on the Group's consolidated financial statements.

AMENDMENTS TO IFRS 2 CLASSIFICATION AND MEASUREMENT OF SHARE-BASED PAYMENT TRANSACTIONS

The IASB issued amendments to IFRS 2 Share-based Payment that address three main areas: the effects of vesting conditions on the measurement of a cash-settled share-based payment transaction; the classification of a share-based payment transaction with net settlement features for withholding tax obligations; and accounting where a modification to the terms and conditions of a share-based payment transaction changes its classification from cash settled to equity settled. On adoption, entities are required to apply the amendments without restating prior periods, but retrospective application is permitted if elected for all three amendments and other criteria are met. The Group's accounting policy for cash-settled share based payments is consistent with the approach clarified in the amendments. In addition, the Group has no share-based payment transaction with net settlement features for withholding tax obligations and had not made any modifications to the terms and conditions of its share-based payment transaction. Therefore, these amendments do not have any impact on the Group's consolidated financial statements.

AMENDMENTS TO IFRS 4 APPLYING IFRS 9 FINANCIAL INSTRUMENTS IFRS 4 INSURANCE CONTRACTS

The amendments address concerns arising from implementing the new financial instruments standard, IFRS 9, before implementing IFRS 17 Insurance Contracts, which replaces IFRS 4. The amendments introduce two options for entities issuing insurance contracts: a temporary exemption from applying IFRS 9 and an overlay approach. These amendments are not relevant to the Group.

AMENDMENTS TO IAS 28 INVESTMENTS IN ASSOCIATES AND JOINT VENTURES – CLARIFICATION THAT MEASURING INVESTEEES AT FAIR VALUE THROUGH PROFIT OR LOSS IS AN INVESTMENT BY INVESTMENT CHOICE

The amendments clarify that an entity that is a venture capital organization, or other qualifying entity, may elect, at initial recognition on an investment-by-investment basis, to measure its investments in associates and joint ventures at fair value through profit or loss. If an entity that is not itself an investment entity, has an interest in an associate or joint venture that is an investment entity, then it may, when applying the equity method, elect to retain the fair value measurement applied by that investment entity associate or joint venture to the investment entity associate's or joint venture's interests in subsidiaries. This election is made separately for each investment entity associate or joint venture, at the later of the date on which: (a) the investment entity associate or joint venture is initially recognized; (b) the associate or joint venture becomes an investment entity; and (c) the investment entity associate or joint venture first becomes a parent. These amendments do not have any impact on the Group's consolidated financial statements.

AMENDMENTS TO IFRS 1 FIRST-TIME ADOPTION OF INTERNATIONAL FINANCIAL REPORTING STANDARDS – DELETION OF SHORT-TERM EXEMPTIONS FOR FIRST-TIME ADOPTERS

Short-term exemptions in paragraphs E3–E7 of IFRS 1 were deleted because they have now served their intended purpose. These amendments do not have any impact on the Group's consolidated financial statements.

The Group has not adopted in advance any principle, interpretation or improvement issued but not yet in force.

6.3.6. STANDARDS ISSUED BUT NOT YET EFFECTIVE

The standards which, at the date of drafting of the Company's financial statements, were already issued but not yet effective are shown below. The list refers to the standards and interpretations that the Company reasonably expects to be applicable in the future. The Company intends to adopt these standards when they become applicable.

IFRS 16: LEASES

IFRS 16 was published in January 2016 and replaces IAS 17 Leases, IFRIC 4 Determining Whether an Arrangement Contains a Lease, SIC-15 Operating Leases - Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. IFRS 16 defines the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases in the financial statements based on a single model similar to the one used to account for finance leases in accordance with IAS 17. The standard sets out two exemptions for recognition by lessees – leases relating to assets with “low value” (for example, personal computers) and short-term leases (for example, leases maturing within 12 months or less). Upon lease commencement, the lessee shall recognise a liability against the

lease payments (i.e. a lease liability) and assets that represent the right-of-use of the underlying asset for the duration of the lease (i.e. the right-of-use of the asset). Lessees must separately record interest expense on the lease liability and the amortisation of the right-of-use of the asset. Lessees must also remeasure the lease liability on the occurrence of specific events (for example: change in the conditions of the lease contract, change in future lease payments resulting from a change in an index or a rate used to determine those payments). The lessee generally recognises the remeasurement amount of the lease liability as an adjustment to the right-of-use of the asset. The principle does not, however, provide for significant changes for lessors.

IFRS 16 is effective for annual periods beginning on or after 1 January 2019 and requires lessors and lessees to provide more comprehensive information than that required by IAS 17.

The Group completed its preliminary assessment of the potential impacts of applying the new standard at the transition date (January 1, 2019). This process was divided into several phases, including the complete mapping of the contracts potentially suitable to contain a lease and the analysis of the same in order to understand the main clauses relevant for the purposes of IFRS 16, as well as the determination of the discount rate to be applied in the calculation of the new liability resulting from these contracts.

The process of implementing the new company information system, which is responsible for the accounting management of the standard and the alignment of administrative processes and controls to monitor the critical areas on which the standard insists, is nearing completion. This process is expected to be completed in early 2019.

The Group applies the standard retrospectively and it chosen the "modified" method, recognising the cumulative effect of the application of the standard in shareholders' equity at 1 January 2019, in accordance with the provisions of paragraphs IFRS 16:C7-C13. In particular, the Group will record, with regard to the lease contracts previously classified as operating:

- a financial liability, equal to the present value of the remaining future payments at the date of transition of each contract;
- a right of use equal to the value of the financial liability at the transition date, net of any accrued income and prepaid expenses relating to the lease and recognised in the balance sheet at the balance sheet date of these financial statements.

The main impacts on the consolidated financial statements of the Group are very significant because of the large number of contracts with rights of use in place within the Group and it can be summarised as follows:

- financial position: higher non-current assets due to the recording of the "right of use of the leased asset" for approximately Euro 71,425 thousand, as a balancing entry to higher financial payables;
- income statement: presenting costs by function, no significant impact of reclassification among the various cost items is expected, except for financial charges, amounting to approximately Euro 3,151 thousand for the year 2019.
- classification of cash flows from leasing contracts in the cash flow statement;
- alternative performance indicators: the different nature, qualification and classification of the expenses described in the previous point will consequently have an impact on EBITDA, net invested capital, net financial debt, as well as on other economic and financial indicators.

Significant effects on existing financial covenants on loans are also expected, as the latter are monitored on the basis of alternative performance indicators. Negotiations are therefore underway with banks to neutralise the effects of the new standard with respect to the amounts used for the calculation.

The expected impacts of the adoption of IFRS 16 are mainly related to the lease contracts of the American, German and Hungarian plasma collection centers.

The estimation of the tax impacts is still ongoing.

In adopting IFRS 16, the Group intends to make use of the exemption granted in relation to short-term leases (i.e. contracts expiring within 12 months or less) and for lease contracts for which the underlying asset is a low-value asset (i.e. the assets underlying the lease contract do not exceed Euro 5,000 when new). For these contracts, the introduction of IFRS 16 will not result in the recognition of the financial liability of the lease and the related right of use, but the lease payments will be recorded in the income statement on a straight-line basis for the duration of the respective contracts.

In addition, with reference to the transition rules, the Group intends to make use of the following practical expedients:

- Classification of contracts expiring within 12 months from the date of transition as short term leases. For these contracts, lease payments will be recognized in the income statement on a straight-line basis;
- Exclusion of initial direct costs from the measurement of the right of use at January 1, 2019;
- Use of information at the transition date to determine the lease term, in particular for the exercise of extension and early termination options.

The transition to IFRS 16 introduces some elements of judgement that involve the definition of certain accounting policies and the use of assumptions and estimates in relation to the lease term and the definition of the incremental borrowing rate. The main ones are summarised below:

- Lease term: the identification of the lease term is a very important issue since the form, legislation and commercial practices of real estate lease contracts vary significantly from one jurisdiction to another. The Group, for the lease contracts of collection centers that provide for one or more renewal options at the end of the non-cancellable period, has chosen not to consider the renewable period within the duration of the contract, evaluating the reasonable certainty of the possibility of exercising the option and taking into consideration the residual time frame of each contract (on average equal to 15 years).
- For the other property lease contracts that provide for a renewal option at the end of the non-erasable period, it has chosen to consider the renewable period within the duration of the contract, including the renewals specified in the contract.
- Definition of the discount rate: since most of the lease contracts signed by the Group do not include an implicit interest rate, the Group calculated an Incremental Borrowing Rate-IBR rate. In order to determine the IBR to be used for discounting future lease payments, the Group determined the IBR as the rate of a risk-free instrument plus the Group's credit spread. The weighted average IBR applied during the transition is 3.6%.

In order to help understand the impacts of first-time adoption of the standard, the following table provides a reconciliation between future obligations relating to lease contracts, as disclosed in note 6.6.5 of these consolidated financial statements at 31 December 2018, and the expected impact of the adoption of IFRS 16 at 1 January 2019.

(In millions of Euro)

Lease obligations reconciliation

Operating lease as at 31 December 2018	104,149
Short term lease	(1,362)
Low value lease	(419)
Not discounted financial liabilities for lease at 01.01.2019	102,368
Discounting effect	(30,944)
Discounted financial liabilities for lease at 01.01.2019	71,425

AMENDMENTS TO IFRS 10 AND IAS 28: SALE OR CONTRIBUTION OF ASSETS BETWEEN AN INVESTOR AND ITS ASSOCIATE OR JOINT VENTURE

The amendments address the conflict between IFRS 10 and IAS 28 in dealing with the loss of control of a subsidiary that is sold or contributed to an associate or joint venture. The amendments clarify that the gain or loss resulting from the sale or contribution of assets that constitute a business, as defined in IFRS 3, between an investor and its associate or joint venture, is recognized in full. Any gain or loss resulting from the sale or contribution of assets that do not constitute a business, however, is recognized only to the extent of unrelated investors' interests in the associate or joint venture. The IASB has deferred the effective date of these amendments indefinitely, but an entity that early adopts the amendments must apply them prospectively. The Group will apply these amendments when they become effective.

IFRIC INTERPRETATION 23: UNCERTAINTIES ON TAX TREATMENT OF TAXES

The Interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of IAS 12 and does not apply to taxes or levies outside the scope of IAS 12, nor does it specifically include requirements relating to interest and penalties associated with uncertain tax treatments. The Interpretation specifically addresses the following:

- Whether an entity considers uncertain tax treatments separately
- The assumptions an entity makes about the examination of tax treatments by taxation authorities
- How an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates
- How an entity considers changes in facts and circumstances

An entity has to determine whether to consider each uncertain tax treatment separately or together with one or more other uncertain tax treatments. The approach that better predicts the resolution of the uncertainty should be followed. The interpretation is effective for annual reporting periods beginning on or after 1 January 2019, but certain transition reliefs are available. The Group will apply the interpretation from its effective date. Since the Group operates in a complex multinational tax environment, applying the Interpretation may affect its consolidated financial statements. In addition, the Group may need to establish processes and procedures to obtain information that is necessary to apply the Interpretation on a timely basis.

AMENDMENTS TO IAS 28: LONG-TERM INTEREST IN ASSOCIATES AND JOINT VENTURE

The amendments clarify that an entity applies IFRS 9 to long-term interests in an associate or joint venture to which the equity method is not applied but that, in substance, form part of the net investment in the associate or joint venture (long-term interests). This clarification is relevant because it implies that the expected credit loss model in IFRS 9 applies to such long-term interests.

The amendments also clarified that, in applying IFRS 9, an entity does not take account of any losses of the associate or joint venture, or any impairment losses on the net investment,

recognized as adjustments to the net investment in the associate or joint venture that arise from applying IAS 28 Investments in Associates and Joint Ventures.

The amendments should be applied retrospectively and are effective from 1 January 2019, with early application permitted. Since the Group does not have such long-term interests in its associate and joint venture, the amendments will not have an impact on its consolidated financial statements.

AMENDMENTS TO IFRS 9: PREPAYMENT FEATURES WITH NEGATIVE COMPENSATION

Under IFRS 9, a debt instrument can be measured at amortized cost or at fair value through other comprehensive income, provided that the contractual cash flows are 'solely payments of principal and interest on the principal amount outstanding' (the SPPI criterion) and the instrument is held within the appropriate business model for that classification. The amendments to IFRS 9 clarify that a financial asset passes the SPPI criterion regardless of the event or circumstance that causes the early termination of the contract and irrespective of which party pays or receives reasonable compensation for the early termination of the contract.

The amendments should be applied retrospectively and are effective from 1 January 2019, with earlier application permitted. These amendments have no impact on the consolidated financial statements of the Group.

ANNUAL CYCLE OF IMPROVEMENTS 2015-2017

These improvements include:

- IFRS 3 Business Combination: The amendment clarifies that an entity re-evaluates the interest held in a joint operation when it obtains control of the business;
- IFRS 11 Joint Arrangements: The amendment clarifies that an entity does not re-evaluate the interest held in a joint operation when it obtains joint control of the business;
- IAS 12 Income taxes. The amendment clarifies that an entity must account for all income taxes arising from the payment of dividends in the same way;
- IAS 23 Borrowing costs: The amendment clarifies that an entity must account for loans originally incurred to develop an asset, as part of other loans when the asset is ready for use or for sale. The amendment is in force for the financial years starting on 1 January 2019 or later. Early application is allowed. The Group will apply the interpretation on the date of entry into force.

IFRS 17 INSURANCE CONTRACTS

In May 2017, the IASB issued IFRS 17 Insurance Contracts (IFRS 17), a comprehensive new accounting standard for insurance contracts covering recognition and measurement, presentation and disclosure. Once effective, IFRS 17 will replace IFRS 4 Insurance Contracts (IFRS 4) that was issued in 2005. IFRS 17 applies to all types of insurance contracts (i.e., life, non-life, direct insurance and re-insurance), regardless of the type of entities that issue them, as well as to certain guarantees and financial instruments with discretionary participation features.

A few scope exceptions will apply. The overall objective of IFRS 17 is to provide an accounting model for insurance contracts that is more useful and consistent for insurers. In contrast to the requirements in IFRS 4, which are largely based on grandfathering previous local accounting policies, IFRS 17 provides a comprehensive model for insurance contracts, covering all relevant accounting aspects. The core of IFRS 17 is the general model, supplemented by:

- A specific adaptation for contracts with direct participation features (the variable fee approach)
- A simplified approach (the premium allocation approach) mainly for short-duration contracts

IFRS 17 is effective for reporting periods beginning on or after 1 January 2021, with comparative figures required. Early application is permitted, provided the entity also applies IFRS 9 and IFRS 15 on or before the date it first applies IFRS 17. This standard is not applicable to the Group.

AMENDMENTS TO IAS 19: PLAN AMENDMENT, CURTAILMENT OR SETTLEMENT

The amendments to IAS 19 address the accounting when a plan amendment, curtailment or settlement occurs during a reporting period. The amendments specify that when a plan amendment, curtailment or settlement occurs during the annual reporting period, an entity is required to:

- Determine current service cost for the remainder of the period after the plan amendment, curtailment or settlement, using the actuarial assumptions used to remeasure the net defined benefit liability (asset) reflecting the benefits offered under the plan and the plan assets after that event
- Determine net interest for the remainder of the period after the plan amendment, curtailment or settlement using: the net defined benefit liability (asset) reflecting the benefits offered under the plan and the plan assets after that event; and the discount rate used to remeasure that net defined benefit liability (asset).

The amendments also clarify that an entity first determines any past service cost, or a gain or loss on settlement, without considering the effect of the asset ceiling. This amount is recognized in profit or loss.

An entity then determines the effect of the asset ceiling after the plan amendment, curtailment or settlement.

Any change in that effect, excluding amounts included in the net interest, is recognized in other comprehensive income.

The amendments apply to plan amendments, curtailments, or settlements occurring on or after the beginning of the first annual reporting period that begins on or after 1 January 2019, with early application permitted.

These amendments will apply only to any future plan amendments, curtailments, or settlements of the Group.

6.3.7. DISCRETIONARY ASSESSMENTS AND SIGNIFICANT ACCOUNTING ESTIMATES

Preparation of the Group financial statements requires that directors make discretionary assessments, estimates and assumptions affecting the value of revenues, costs, assets and liabilities and the disclosures on potential assets and liabilities as at the reporting date. During the year, the most significant discretionary assessments concerned the verification of any impairment loss on goodwill and the judgment applied in defining the accounting effects related to the refinery project of Melville plant, as better indicated below. Additional items that require the formulation of estimates include deferred tax assets and liabilities, employee benefits and other items detailed below.

In the future, if these estimates and assumptions - which are based on the best assessment available at the time and are subject to regular review - should differ from the final results, they will be amended accordingly in the period in which the circumstances change. The effect of the change will be carried to the statement of profit and loss.

IMPAIRMENT OF GOODWILL

Goodwill is subject to impairment testing at least once a year; impairment testing involves an estimate of the fair value of the cash flow generating unit to which goodwill is attributed, based on the discounted cash flow model (DCF), and most of estimates and assumptions refer to the

estimate of cash flows, the growth rates to be applied beyond the explicit forecast period and the determination of the discount rate.

As at 31 December 2018 and 2017, the carrying amount of goodwill is equal to Euro 230.621 thousand and Euro 219.318 thousand. Further details are provided in paragraph 6.4.3.

ACCOUNTING ESTIMATES CONNECTED WITH THE MELVILLE FACTORY REFITTING PROJECT

The refitting project for the Melville production plant involved recourse to the judgement of the directors, in particular with reference to (i) the allocation of the costs incurred for the refitting during 2018 to fixed assets or to the income statement; (ii) the determination of the availability for use of the investments and the definition of their useful life; and (iii) the identification of the costs charged to the income statement by the subsidiary during the year and presented in the consolidated financial statements as non-recurring.

Property plant and equipment and intangible assets with a finite useful life

As part of the plant's refitting project, the Group constantly monitored the costs related to it through internal reporting, also prepared for reporting purposes to the Board of Directors, which compares the project budget data with the final figures and divides these capitalized amounts ("Capex") and costs charged to the income statement for the period ("Opex"). All the costs that do not meet the capitalization requirements set forth in the accounting standards and described in note 6.3.8 have been considered as Opex.

Since the refitting project represents a significant change in the plant, the Group also verified the recoverability of the carrying amount of the costs capitalized in years prior to the refitting of the plant by (i) a detailed analysis of the existing assets, which led to zero the value of the replaced or no longer usable assets due to the refitting project and (ii) impairment test on the CGU, as described in the following note 6.4.3.

In the month of August, after the 30 days provided for by the US Food & Drug Administration (FDA) regulatory procedure, the so-called CB30, during which the US authority could have rejected the request to restart production, the fixed costs were allocated to the correct asset classes and depreciation began.

Inventories

Inventories of raw materials, semi-finished and finished products are generally subject to expiration, so management considers the expiration date associated with each lot to be a fundamental element in assessing their recoverability. It should be noted that the expiry dates of raw materials are no longer relevant once they are put into production. In such cases, reference is made to the expiry date attributed in the production process to semi-finished and finished products.

Inventories with upcoming expiry dates are entirely written down to take consideration of their difficult recoverability.

As regards the finished and semi-finished product inventories of the Melville plant which were transformed before the start of the refitting project, the Group has prudently taken the decision not to distribute these products and it has therefore proceeded to write down or destroy them.

Non-recurring costs

Costs related to Melville plant and charged to the income statement during the plant's standstill period, write-downs of inventories recognized in the year according to the procedure indicated above, are considered by the management as non-recurring as related to the closure of the plant for the construction of the refitting phase described in the introduction and therefore to an

operation whose occurrence is exceptional and clearly not frequent in the normal course of business. These costs were quantified based on the results of the cost accounting of the establishment cost centers and were included in the non-recurring costs in the period detailed in note 6.5.11.

DEFERRED TAX ASSETS AND LIABILITIES

Deferred tax assets are recognised for all temporary differences and all tax losses carried forward, to the extent to which it is likely that future taxable income will exist from which such losses can be recovered. A considerable discretionary assessment is required of directors to determine the amount of deferred tax assets to be recognised. They have to estimate the future likelihood of events and the total future taxable earnings, along with a planning strategy for future taxes. Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current income tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority. The carrying amount of prepaid tax assets as at 31st December 2018 is equal to Euro 12,341 thousand. Further details are provided in paragraph 6.4.8. The same considerations described above are also applied to tax consolidation receivables due from the shareholder Sestant S.p.A. for possible transfer of tax losses by the Parent Company.

EMPLOYEE BENEFITS - EMPLOYEE SEVERANCE INDEMNITY

The actuarial valuation requires the development of assumptions about discount rates, future salary increases, turnover and mortality rates. Due to the long-term nature of these plans, these estimates are subject to a significant degree of uncertainty. All assumptions are reviewed annually.

Actuarial assessment calls for the drafting of assumptions regarding discount rates, future pay increases, staff turnover and mortality rates. Given the long-term nature of such plans, these assessments are subject to a considerable degree of uncertainty. All assumptions are viewed on an annual basis.

Net payables to employees for severance indemnity as at 31st December 2018 and 2017 amounted to 9,028 thousand Euro and 6,738 thousand Euro. Further details are provided in paragraph 0.

OTHER ACCOUNTING ESTIMATES

Estimates are also used to recognize provisions for credit risks, inventory obsolescence and product rebates, amortization of tangible and intangible assets with a finite life, the valuation of receivables for services accrued, invoices to be received for services provided and income taxes for the year.

They also concern development costs that are capitalized on the basis of the accounting principle referred to in note 6.3.8. To determine the values to be capitalized, the directors must elaborate assumptions regarding the expected future cash flows from fixed assets, the discount rates to be applied and the periods of manifestation of expected benefits. At December 31, 2018 and 2017, capitalized development costs were Euro 148 thousand and Euro 196 thousand respectively.

Finally, in the next paragraph we give an indication of the estimates applied in determining the fair value of financial instruments, the determination of which did not however have any particular effect on the 2018 financial statements.

FAIR VALUE MEASUREMENT

The Group measures financial instruments, such as derivatives, and non-financial assets at fair value at each reporting date.

The fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

A fair value measurement assumes that the sale of the asset or transfer of the liability takes place:

- a) in the principal market for the asset or liability; or
- b) in the absence of a principal market, in the most advantageous market for the asset or liability.

The principal market or most advantageous market must be accessible by the Group.

The fair value of an asset or liability is measured adopting the assumptions that market operators would use in determining the price of the asset or liability, assuming that they are acting to best satisfy their economic interest.

Fair value measurement of a non-financial asset considers the market operator's capacity to generate economic benefits through the highest and best use or selling it to another market operator that will ensure its highest and best use.

The Group uses measurement techniques suitable to the circumstances, for which there is sufficient data available to measure the fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or posted in the financial statements are categorised based on the fair value hierarchy, as described below:

- Level 1 - (unadjusted) quoted prices in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 – Inputs other than quoted market prices included within Level 1, that are observable for the asset or liability, either directly or indirectly;
- Level 3 – measurement techniques for which the input data of the asset or liability is unobservable.

The fair value measurement is classified fully in the same level of the fair value hierarchy as the lower hierarchy level used for measurement.

For assets and liabilities recognised in the financial statements on a recurring basis, the Group determines whether transfers occurred between hierarchy levels, reviewing the categorisation (based on the input of the lowest level, which is significant for the fair value measurement as a whole) at each reporting date.

Group management determines the criteria and procedures for both recurring and non-recurring fair value measurement.

External experts are involved in measuring significant assets, such as property investments, and significant liabilities, where necessary.

At each reporting date, Group management analyses the changes in the values of assets and liabilities for which revaluation or recalculation is required, based on the Group's accounting standards.

For these analyses, the main inputs applied in the most recent measurement are verified, comparing the information used in the measurement to contracts and other significant documents. Group management, also with the support of the external experts, where necessary, conducts a comparison between each change in the fair value of each asset or liability and significant external sources, to determine whether the change is reasonable.

The results of the measurements are periodically presented to the Group's Board of Statutory Auditors and independent Auditors. This presentation includes a discussion of the main assumptions used in the measurements.

For the purposes of fair value disclosure, the Group determines the classes of assets and liabilities based on the nature, characteristics and risks of the asset or liability and the level of fair value hierarchy as illustrated above.

6.3.8. VALUATION CRITERIA

PROPERTY, PLANT AND EQUIPMENT

Tangible assets are recognised at their historical cost, including accessory costs directly attributable and necessary to operational start-up of the asset for the use for which it was purchased. This cost item includes costs to replace machine and system parts at the time they are incurred, and provided they comply with recognition criteria.

Maintenance and repairs expenses, that are not expected to enhance and/or prolong the residual life of the assets, are recorded in the period they are incurred; otherwise, they are capitalised.

Tangible assets are recorded net of related depreciation and any impairment loss calculated as described below. Depreciation is calculated on a straight-line basis over the expected useful life of the asset to the company; the latter is reviewed on an annual basis and any changes, where necessary, are applied prospectively.

If significant parts of such tangible assets have different useful lives, the relevant components are recorded separately. Land, unbuilt or annexed to buildings, is recorded separately and is not subject to depreciation as it is considered to have an unlimited useful life.

The carrying amount of tangible assets is subject to impairment testing to identify any loss of value if events or changing circumstances indicate that the carrying amount cannot be recovered. If there is any indication of this type - and in cases where the carrying amount exceeds the recoverable value - the assets are written-down to reflect their recoverable value. The recoverable value of tangible assets is the higher of the net sale price (fair value) and the value in use.

The value in use is calculated by discounting expected future cash flows at a pre-tax rate that reflects the current market estimate as a ratio between the time value of money and the risks specified for that asset. For an asset that does not generate largely independent cash flows, the value in use is determined in relation to the cash flow generating unit to which the asset pertains. Impairment is recognised in the statement of profit or loss under depreciation expense and write-downs. Such impairment losses are reversed if the reasons generating impairment cease to exist. At the time of sale or when there are no grounds to expect future economic benefits from use of an asset, it is eliminated from the balance sheet and any loss or gain (calculated as the difference between the disposal value and the carrying amount) is recognised in the statement of profit or loss in the year in which it is eliminated.

INVESTMENT PROPERTY

Assets held for earnings rather than production purposes are classified under a specific item, "Investment property", in accordance with IAS 40, and recorded at their cost less depreciation, depletion and amortization.

Assets falling into this category include land and/or buildings (or parts of buildings) held by the owner or by the lessee as part of a finance or operating lease agreement for the purpose of leasing to third parties in order to benefit from related lease instalments, or in order to benefit from the increase in value of the asset, unless such property:

- Is used in production, for provision of goods and services or for administrative purposes;
- Is held for sale as part of normal business operations.

This type of property is classified separately from other real estate assets held.

FINANCE AND OPERATING LEASING

Finance lease contracts, which essentially transfer all ownership risks and benefits of the leased asset to the Group, are capitalised as at the leasing date at the fair value of the leased asset or, if less, at the current lease instalment value. Instalments are distributed on a pro quota basis between capital and interest so as to permit application of a constant interest rate on the balance

outstanding on the debt. Financial expenses are recognised directly in the statement of profit or loss.

Capitalised leased assets are amortised on the basis of the estimated useful life of the asset. If there is no reasonable certainty that the Group will become owner of the asset upon termination of the contract, amortisation is applied to the shorter of the asset's estimated useful life and the duration of the lease contract.

Leases for which the lessor substantially retains all risks and rewards associated with ownership of the assets are classed as operating leases, and the related costs are recognised in the statement of profit or loss on a straight-line basis for the duration of the contract.

BUSINESS COMBINATIONS AND GOODWILL

Business combinations are accounted for by the acquisition method. This requires recognition - at fair value - of identifiable assets (including any definite life and indefinite life intangible assets not previously recognised) and identifiable liabilities (including potential liabilities and excluding future restructuring) of the acquired company.

Goodwill acquired in a business combination is initially measured at cost, represented by the difference between the cost of the business combination and the relevant net fair value portion of the identifiable asset, liability or potential liability (of the acquired company). If the amount is lower than the fair value of the net assets of the subsidiary acquired, the difference is booked to the statement of profit or loss.

After the initial recognition, goodwill is valued at cost net of accumulated impairment. For the purpose of impairment testing, goodwill acquired under a business combination is allocated, from the date of acquisition, to each cash generating unit which is expected to benefit from the synergies of the combination, regardless of whether other assets or liabilities of the acquired entity are assigned to said units.

Goodwill is tested for impairment at least once per year (at 31 December) and more frequently if there is evidence that the carrying amount has suffered impairment.

Impairment of goodwill is determined by measuring the recoverable value of the cash generating unit (or group of cash generating units) to which the goodwill is attributable. If the recoverable value of the cash generating unit is lower than the carrying amount of the cash generating unit to which the goodwill has been allocated, impairment is recorded. Any decrease in the value of goodwill cannot be written back in future years.

If goodwill has been allocated to a cash generating unit and the entity disposes of part of the assets of said unit, the goodwill associated to the asset disposed of is included in the asset's carrying amount, when the disposal results in a profit or loss. Goodwill associated with asset disposed of is calculated on the basis of the values relating to the asset disposed of and of the part of the cash generating unit retained.

Investments in associates

The Group consolidates its investments in associates by using the equity method. An associate is a company over which the Group exercises significant control.

By using the equity method, an investment in an associate is initially recorded at cost and the carrying amount is increased or reduced to recognise the investor's share of the profits and losses of the investee realised after the acquisition date. Goodwill relating to the associate is included in the carrying amount of the investment and is not subject to amortisation, nor to an individual impairment check.

The statement of profit or loss reflects the Group's share of the associate's result for the year. If an associate records adjustments by direct recognition in shareholders' equity, the Group records its respective share and includes the amount, where applicable, in the statement of changes in

shareholders' equity. Any unrealised gains or losses from transactions between the Group and the associate are eliminated in proportion to the investment in the associate.

The statement of profit or loss reflects the Group's share of the associate's result for the year. The Group's share represents the result of the associate attributable to shareholders; therefore, this refers to the result after taxes and amounts due to other shareholders of the associate.

The associate's financial statements are drafted at the same date as those of the Group. Where necessary, the associate's financial statements are adjusted to bring them into line with the Group's accounting standards.

Following the application of the equity method, the Group assesses whether or not it is necessary to recognise impairment of its investment in the associate. At each reporting date, the Group checks whether there is objective evidence that its investment in the associate has suffered impairment. In this case, the Group calculates the amount of the loss as the difference between the recoverable value of the associate and the carrying amount of the latter in its financial statements, recording said difference in the profit (loss) for the year, under the item "Group's share of the associate's result".

Upon loss of a significant influence over the associate, the Group evaluates and records the residual investment at fair value. The difference between the carrying amount of the investment at the date of the loss of significant influence and the fair value of the residual investment and of fees received is recorded in the statement of profit or loss..

Investments in other companies and available-for-sale financial assets

Investments in other companies, booked as non-current financial assets, which are not available-for-sale, are measured at cost less impairment since the fair value cannot be calculated reliably.

Definite life intangible assets

Definite life intangible assets are recorded under assets at their purchase cost when it is likely that use of the asset will generate future economic benefits and when the cost of the asset can be reliably calculated. Intangible assets acquired through business combinations are recognised at the fair value defined at the acquisition date, if the fair value can be reliably calculated. Intangible assets with a definite useful life are amortised on a straight-line basis over their estimated useful life. The useful life is reviewed on an annual basis and any changes, where necessary, are applied prospectively.

Development costs

Research costs are recognised in the statement of profit or loss at the time they are incurred.

Development costs incurred for a specific project are only capitalised when the Group can demonstrate the technical probability of completing the intangible asset so that it becomes available for use or for sale, its intention to complete the asset for use or for sale, how it will generate future economic benefits, availability of technical, financial and other resources needed to complete development and its capacity to reliably assess the cost attributable to the asset during development.

While under development, the asset is tested for impairment on an annual basis. After initial recognition, development costs are assessed at cost less any amortisation or accrued impairment. Amortisation of the asset begins when development has been completed and the asset is ready for use. It is amortised according to the period in which it is expected that the related project will generate revenues for the Group. While the asset is still not in use, it will be subject to annual impairment testing.

Trademarks and Rights

This item relates to licence rights for marketing authorisations for specialist medicines and to trademarks for registration of pharmaceutical products. The purchase cost of trademarks and rights are amortised over the useful life of the acquired asset, normally 5 years for rights and 10 years for trademarks.

Other Intangible assets

This item refers to:

- The purchase of application software amortised over 5 years;
- Sales contracts entered into with customers and the list of hyperimmune plasma donors registered with the purchase method in the business combination of the US subsidiary KEDPLASMA LLC, amortized over a period of time of 15 years;

Impairment test

Intangible assets with an indefinite useful life and those still non available are tested for impairment at least once per year - on 31st December - both individually and at cash generating unit level, as more appropriate, and when there is evidence of impairment.

The other intangible assets are subject to verification, in order to detect any loss in value, if events or changes in the situation indicate that the carrying amount cannot be recovered. If there is an indication of this type and, in the event that the book value exceeds the recoverable value, the assets are written down to reflect their recoverable value. The recoverable amount of the intangible assets is represented by the greater of the net sale price ("fair value") and the value in use.

The value in use is calculated by discounting the expected future cash flows, using a pre-tax discount rate that reflects the current market estimate for the cost of money compared to time and the specific risks of the asset. For an asset that does not generate widely independent financial flows, the value in use is determined in relation to the cash-generating unit to which this asset belongs. Impairment losses are recorded in the income statement under amortization, depreciation and write-downs based on the destination to which the asset refers. These losses in value are restored if the reasons that generated them no longer exist.

Impairment of non-financial assets

At each reporting date, the company assesses the existence of indicators of impairment of assets. In this case, or where an annual impairment test is required, the company estimates the recoverable value. The recoverable value is the higher of the fair value of the asset or cash generating unit, net of sale costs, and its value in use. The recoverable value is determined for each individual asset, except when said asset generates cash flows that are not sufficiently independent from those generated by other assets or asset groups. If the carrying amount of an asset is higher than its recoverable value, said asset has been impaired and is consequently written down to its recoverable value.

In determining the value in use, the company discounts estimated future cash flows to the present value by using a pre-tax discount rate which reflects the market valuations of the present value of money and the specific risks of the asset. In calculating the fair value net of sale costs, account is taken of recent market transactions. If it is not possible to identify said transactions, an appropriate valuation model is used. These calculations are corroborated by the proper valuation multipliers, prices of listed shares for investees whose shares are traded on the market, and other available fair value indicators or using the discounted cash flow (DCF) method.

The Company bases its impairment test on detailed budgets and provisional calculations, drafted separately for each cash generating unit of the company to which individual assets are allocated. These budgets and provisional calculations generally cover a period of three or more years.

Impairment of operating assets, including the impairment of inventories, is recorded in the statement of profit or loss under cost categories consistent with the use of the asset that recorded impairment. Fixed assets revalued previously are an exception, where the revaluation was accounted for in the consolidated statement of comprehensive income and classified as a revaluation reserve. In these cases, the impairment is, in turn, recorded in the consolidated statement of comprehensive income up to the amount of the previous revaluation.

For assets other than goodwill - and at each reporting date - the company assesses the elimination (or reduction) of indicators of impairment that were previously recorded and, if these indicators exist, estimates the recoverable value. The value of an asset previously written down can only be written back if there are changes in the assumptions on which the calculation of the recoverable value was based, after the recognition of the latest impairment. The write-back cannot exceed the carrying amount which would have been determined, net of amortisation, if no impairment had been recorded in previous years. This write-back is booked to the statement of profit or loss except in the case that the fixed asset is accounted for at the revalued amount; in this case, the write-back is treated as a revaluation increase.

Other non-current financial assets and other non-current assets

These assets are valued according to the cost method, amortised by the effective discount rate method net of any impairment.

The amortised cost is calculated by taking into consideration all purchase discounts or bonuses, and includes commissions as an integral part of the effective interest rate and transaction costs.

Inventories

Inventories are assessed at the lower between the purchase and/or production cost, determined by the weighted average cost method, and the net realisable value. The estimated net realisable value includes the estimated sale price less costs estimated for completion and estimated sale costs. Raw materials and consumables are entered at purchase cost, inclusive of accessory charges. Work in progress, semi-finished and finished products are entered on the basis of directly attributable production costs and a portion of the indirect production costs incurred in the year and reasonably attributable to the products.

The value of inventories is adjusted, where necessary, through entry of a special provision for write-down that takes the factors of obsolescence into account.

Trade receivables

Trade receivables are normally recognised at fair value - in general corresponding to their nominal sum - and later measured at the amortised cost, written down in the event of impairment.

The Group records an expected credit loss (ECL) write-down using the simplified method. ECLs are based on the difference between the contractual cash flows due under the contract and all the cash flows the Group expects to receive, discounted at an approximation of the original effective interest rate.

The Group determines impairment losses on trade receivables by considering the amount of receivables of doubtful collectability, analysing the specific conditions of the Group's customers, any guarantees given in favour of Group companies, appropriately assessing outstanding disputes and the possibilities of recovering past due receivables, as well as determining the expected insolvency rate, analysing the average rate of loss on receivables recorded in recent years.

Receivables in a currency other than the operating currency are recognised at the exchange rate valid on the date of the transaction, and then translated to the year-end exchange rate. Any translation gain or loss is recognised in the statement of profit or loss.

For nationwide receivables from public authorities characterised by an average repayment period of more than 12 months, an analytical time-discounting process was applied based on assumptions and estimates.

Other current assets and other financial assets

These are initially recognised at fair value and thereafter according to the amortised cost method. A financial asset (or, where applicable, part of a financial asset or part of a group of similar financial assets) is eliminated from the financial statements when:

- The right to receive cash flows from the asset has ended;
- The Group retains the right to receive cash flows from the asset, but is contractually obliged to transfer these sums in full and without delay to a third party;
- The Group has transferred the right to receive cash flows from the asset and (a) has transferred substantially all asset ownership risks and rewards or (b) has not transferred substantially all asset risks and rewards but has transferred control of the asset.

Where the Group has transferred the right to receive cash flows from an asset but has not substantially transferred or retained all risks and rewards, or has not lost control of the asset, the asset is recorded in the Group financial statements to the extent of the Group's residual involvement in the asset. Residual involvement in the form of a guarantee on the transferred asset is assessed at the lower between the initial recognition value and the maximum payment the Group could be held to make.

In cases in which residual involvement is in the form of a put or call option on the transferred asset (including options settled in cash or similar), the extent of Group involvement corresponds to the amount of the transferred asset that the Group could buy back. Nevertheless, if a put option is issued on an asset measured at fair value (including options settled in cash or similar), the extent of the Group's residual involvement is limited to the lower between the fair value of the transferred asset and the option exercise price.

Cash and cash equivalents

Cash, cash equivalents and short-term deposits include cash on hand and demand or short-term deposits, the latter with an original maturity date of no more than three months.

Loans

All loans are initially recognized at the fair value of the sum received, net of accessory loan allocation charges. After initial recognition, loans are assessed at amortized cost using the effective interest rate method.

Any gain or loss is recognized in the statement of profit or loss when the liability has been settled, other than by the amortization process.

Payables due to bondholders were recognized at the fair value of the payment, net of accessory bond issue charges. After initial recognition, loans are assessed at amortized cost using the effective interest rate method.

A financial liability is removed when the obligation underlying the is extinguished or fulfilled.

In cases where an existing financial liability is replaced by another one of the same lender, under substantially different conditions, or when the conditions of an existing liability are substantially changed, such exchange or modification is treated as an accounting cancellation of the original

liability and the recognition of a new liability, with budgetization in the income statement of any differences between the book values.

Provisions for risks and charges

Provisions for risks and charges are made when the Group has to meet a current commitment (legal or implicit) deriving from a past event, when an outlay of resources is likely to meet that commitment and it is possible to perform a reliable estimate of the amount.

When the Group considers that a provision for risks and charges will be repaid in full or in part, e.g. in the case of risks covered by insurance policies, the indemnity is recorded separately in the balance sheet if, and only if, it is a near certainty. In this case, the cost of any provision is recognised in the statement of profit or loss net of amortisation recorded for the indemnity.

If time-discounting of the value of money is significant, the provisions are discounted at a pre-tax rate that reflects, where possible, the specific liability risks. When time discounting is applied, the increase in the provision due to the passing of time is recognised as a financial charge.

Liabilities for employee benefits

Post-employment benefits due to employees are divided, on the basis of the economic nature, into defined contribution or defined benefit plans. In defined contribution plans, the company's legal or implicit obligation is limited to the amount of contributions to be paid: consequently the actuarial risk and investment risk are borne by the employee. In defined benefit plans, the company's obligation consists of granting and ensuring the agreed benefits to employees: consequently the actuarial risk and investment risk are borne by the company. Italian legislation (Art. 2120 of the Italian Civil Code) states that, as at the date on which each employee terminates his employment contract with the company, he/she shall receive an indemnity known as an Employee Severance Indemnity, which is considered a defined benefit plan according to IAS 19. Calculation of this indemnity is based on certain items that make up the annual salary of the employee for each year of service (revalued as appropriate) and on the length of service. According to Italian civil law, this indemnity is reflected in the financial statements through a calculation method based on the indemnity matured for each employee as at the reporting date, and as if all employees had terminated their employment contract on that date. IASB's IFRIC considered the matter of the Italian employee severance indemnity and concluded that, in application of IAS 19, it has to be calculated according to the Projected Unit Credit Method (PUCM), in which the total payable for accrued benefits must reflect the expected date of resignation and must be time-discounted.

Effective as of 2007, the Group acknowledged the effects of the amendments introduced by the "2007 Financial Law" and subsequent decrees and regulations, relating to the allocation of amounts of Employee Severance Indemnity accrued from 1 January 2007. In particular, for the purposes of application of IAS 19, the new legislation changes, as of 1 January 2007, the nature of Employee Severance Indemnity from "defined benefit plan" to "defined contribution plan", with particular reference to companies with more than 50 employees.

Starting from 2012, actuarial gains and losses are booked to the Statement of profit or loss and other comprehensive income.

In addition to the TFR mentioned above, there is a defined benefit plan relating to the Hungarian HBP subsidiary that will be paid to employees (i) in part on the achievement of certain work-related thresholds at the company; (ii) partly on the retirement date.

The net commitment of the Group from defined benefit plans is calculated separately for each plan, estimating the amount of the future benefit accrued by the employee in exchange for services rendered in the current and previous financial years. This benefit is then discounted back to calculate the current value.

Actuarial assessment of these payables is assigned to an independent actuary. The Group has no other defined benefit or defined contribution pension plans.

Financial Instruments

Financial instruments are initially recognised at fair value and thereafter measured according to the following classification:

- Financial assets at amortised cost (debt instruments);
- Financial assets at fair value recorded in the comprehensive income statement with reclassification of accumulated profits and losses (debt instruments);
- Financial assets at fair value recorded in the comprehensive income statement without reversal of profits and losses accumulated at the time of their elimination (equity instruments);
- Financial assets at fair value recorded in the income statement.

For financial assets, this treatment is divided into the following categories:

- Financial assets measured at fair value with changes recognised in the statement of profit or loss;
- Investments held to maturity;
- Loans and receivables;
- Available-for-sale financial assets.

With regard to financial liabilities, provision is made for just two categories:

- Financial liabilities measured at fair value with changes recognised in the statement of profit or loss;
- Liabilities recorded at the amortised cost.

The fair value calculation methods for such financial instruments, for accounting or reporting purposes, are summarised below according to the main financial instrument categories to which they are applied:

- Derivatives: suitable pricing models have been adopted on the basis of market interest rate values and exchange ratios;
- Receivables, payables and unlisted financial assets: for financial assets with maturity beyond one year, the discount cash flow method has been applied, i.e. time discounting of expected cash flows based on the current interest rates and credit ratings;
- Listed financial Instruments: the market value as at the date of reference is used.

Derivatives

The Group uses derivatives as currency forward contracts to hedge, respectively, its currency exchange risks and interest rate swaps, with the intention of hedging financial risks relating to changes in interest rates on existing medium/long-term debt.

In compliance with IAS 39, which the Group chosen to continue to apply, hedge accounting rules may only be applied to hedging derivatives if:

- a) at the time of hedging, formal designation and documentation on the hedge exists;
- b) it is envisaged that the hedge will be highly effective;
- c) its effectiveness may be reliably measured; and
- d) the hedge itself is highly effective in accounting periods other than those to which it is designated.

All derivatives are measured at fair value. When derivatives have characteristics for which hedge accounting is appropriate, the following accounting treatment is applied:

- Fair value hedge - if a financial derivative is designated as a hedge against exposure to changes in the current value of an asset or liability in the balance sheet that could affect the statement

of profit or loss, gains or losses deriving from subsequent assessments of the current value of the hedge are recognised in the statement of profit or loss, as are gains or losses on the item hedged.

- Cash flow hedge - if a financial derivative is designated as a hedge against changes in the cash flows of an asset or liability in the balance sheet, or a transaction seen as highly likely and which could affect the statement of profit or loss, the effective portion of gains or losses on the financial instrument is recognised under shareholders' equity. Any accrued gains or losses are written-off from shareholders' equity and recognised in the statement of profit or loss in the period in which the hedge is applied. Hedge-related gains or losses, or on that part of the hedge which has become ineffective, are recognised in the statement of profit or loss when ineffectiveness is confirmed.

If the conditions for the application of hedge accounting are not met, any effects deriving from the fair value measurement of the derivative are recognised directly to the statement of profit or loss.

Non-Current assets held for sale

Non-current assets held for sale rather than production purposes are classified under a specific item, " Non-Current assets held for sales ", in accordance with IFRS 5 and recorded at the lower between Net Book Value and fair value less selling and distribution costs.

Revenues

Revenues from contracts with customers are recognised when control of the goods and services is transferred to the customer for an amount that reflects the consideration that the Group expects to receive in exchange for these goods or services. The Group has concluded that it generally acts as the principal in the agreements that generate revenues, as it usually controls the goods and services before they are transferred to the customer.

Note 6.3.7 illustrates the significant discretionary evaluations, estimates and assumptions relating to revenues deriving from contracts with customers.

Sales of goods

Revenues from the sale of finished products and goods are recognized when the asset is transferred to the customer.

The Group considers if there are other promises in the contract that represent obligations to do on which a part of the amount of the transaction must be allocated. In determining the price of the sale transaction, the Group considers the effects deriving from the possible presence of a variable price, significant financing components, non-monetary fees and payments to be paid to the customer.

Variable consideration

If the amount defined in the contract includes a variable amount, the Group estimates the amount of the consideration to which it will be entitled in exchange for the transfer of the goods to the customer.

The variable consideration is estimated at the time the contract is stipulated and it is not possible to record it until it is highly probable that, when the uncertainty associated with the variable consideration will be subsequently resolved, there will be no significant downward adjustment to the accounted amount of cumulative revenue. Volume discounts and other contractual discounts give rise to variable fees.

The Group can grant discounts to some customers where the quantity of products purchased during the period reaches certain turnover thresholds. To estimate the variable consideration related to the expected discounts, the Group applies the expected value method.

Amounts to be paid to the customer

Contracts with customers may include the payment of fees to customers. The Group records the consideration to be paid to the customer as a reduction in the transaction price and, consequently, in revenue, unless the payment to the customer is made in exchange for a separate good or service transferred by the customer to the Group. If the amount to be paid to the customer includes a variable amount, this is estimated by the Group.

Revenues from services

The Group provides plasma processing services on behalf of third parties. The Group recognizes the revenues deriving from these services over time, using an input-based method to assess the progress of the service.

The Group considers if there are other promises in the contract that represent obligations to do on which a part of the consideration for the transaction must be allocated. In determining the price of the sale transaction, the Group considers the effects deriving from the possible presence of a variable price, significant financing components, non-monetary fees and payments to be paid to the customer.

Revenues are recognised to the extent to which it is likely that the economic benefits will be enjoyed by the Group and that the relative amount can be reliably determined, regardless of the date of collection. Revenues are measured at the fair value of the amount received or to be received, taking into account the payment terms defined in the contract and excluding tax and duties. In all sale contracts in which it is the primary debtor, the Group has entered into the same and is implementing the same on its own behalf, has discretionary power over pricing policies and is also exposed to inventory and credit risk.

Variable consideration

If the amount promised in the contract includes a variable amount, the Group estimates the amount of the consideration to which it will be entitled in exchange for the provision of services to the customer.

The variable consideration is estimated at the time the contract is stipulated and it is not possible to record it until it is highly probable that, when the uncertainty associated with the variable consideration will be subsequently resolved, there will be no significant downward adjustment to the accounted amount of cumulative revenue. Discounts and other contractual penalties give rise to variable fees.

The Group can grant discounts or penalties to customers based on the terms of service contracts. To estimate the variable consideration related to the expected discounts, the Group applies the expected value method.

Contractual balances

Contract assets

Contract activity represents the right of the entity to obtain the agreed amount in exchange of the transfer of control of the goods or services to the customer.

If the Group meets its obligation by transferring goods or services to the customer before the customer pays the consideration or before payment is due, the entity must recognise an asset resulting from the contract, excluding amounts presented as receivables.

Trade receivables

A credit represents the Group's unconditional right to receive the consideration (i.e., it only needs to run out of time for the consideration to be paid).

Contract liabilities

The contract liability is an obligation to transfer to the customer goods or services for which the Group has already received the consideration (or for which a portion of the consideration is due). If the customer pays the consideration before the Group has transferred control of the goods or services, the liability arising from the contract is recognised when the payment is made or (if earlier) when it is due. Liabilities arising from contracts are recognised as revenues when the Group meets its obligations under the contract.

Costs for obtaining a contract

The Group may pay commissions to third-party sales contracts. For these costs the Group applies the practical expedient that allows to immediately pay the costs for obtaining contracts, since the depreciation period of the activity that the Group would otherwise have used would have been less than a year.

Similarly, in the comparative year, revenues are recognized in accordance with IAS 18 to the extent that it is probable that the economic benefits will be achieved by the Group and the relative amount can be reliably determined, regardless of the date of collection. Revenues are measured at the fair value of the consideration received or to be received, in accordance with the terms of payment contractually defined and excluding taxes and duties. The Group, concluded that it is operating on its own account in all the sales contracts as it is the primary debtor, has the discretion on the pricing policy and is also exposed to the risk of stock and credit.

The revenue is recognized when the company has transferred to the buyer all the significant risks and benefits connected to the asset ownership, generally on the date of delivery of the goods. The revenue is valued at the fair value of the amount received or to be received, net of returns and rebates, trade discounts and volume reductions.

The recognition of revenues for the provision of services is based on the stage of completion of servicing activities as at the reporting date, measured as a percentage with reference to different variables depending on the services provided and contracts stipulated with the customer. The provision of services not yet completed as at the reporting date is booked as 'long term contracts' under trade receivables. Any revenues invoiced as at the reporting date in excess of the amount accrued according to the stage of completion of the service is suspended under advances from customers and classified under trade payables. When the result of services cannot be reliably measured, the revenues are recognised to the extent to which it is considered that costs incurred can be recovered.

In the case of nationwide revenues from public authorities that are characterised by an average collection period of more than 12 months, an analytical time-discounting process was applied based on assumptions and estimates so as to determine the implicit financial component.

Interest income

For all financial instruments measured at amortised cost and interest bearing financial assets classified as available for sale, interest income is recognised using the effective interest rate, which is the rate that accurately discounts future revenues, estimated for the expected life of the financial instrument or for a shorter period, when necessary, with respect to the net carrying

amount of the financial assets. Interest income is under financial income in the statement of profit or loss for the year.

Rental income

Rent resulting from investment property is recognised on a straight line basis for the duration of the rental agreements in place on the date of the financial statements and is classified under revenues, given their operational nature.

Government grants

Government grants are recognised when there is a reasonable certainty that they will be received and all related conditions are satisfied. Where government grants are related to a cost component (operating grants) they are recognised as revenues across the relevant financial years in proportion to the costs they are expected to offset. Where the grant is related to an asset (capital grants), the asset and the grant are recorded separately under assets and liabilities at par value and the release to the statement of profit or loss takes place progressively on a straight-line basis over the estimated useful life of the related asset.

Dividends

Dividend income is recorded when shareholders become entitled to receive payment, which occurs when the Shareholders' Meeting approves distribution.

Income taxes

Current taxes

These taxes reflect a realistic estimate of the tax burden, calculated by applying the regulations in force in countries in which the Kedrion Group operates. The current tax payable is recorded in the balance sheet, net of any prepaid taxes.

As regards the Parent Company, it should be noted that, from 2016, as a consolidating company together with the consolidating partner Sestant S.p.A., it exercised the option for the "national tax consolidation" as a consolidating company, as per the Articles 117-129 of Presidential Decree December 22, 1986 n. 917 (so-called TUIR), which makes it possible to determine the IRES tax on a taxable base corresponding to the algebraic sum of the positive and negative taxable income of the individual participating companies, after making some adjustments provided for by current legislation.

The economic relations, as well as the reciprocal responsibilities and obligations between the consolidating and consolidated, are defined in the "Group Regulations governing the application of the provisions on" National Consolidation "".

Consequently, the debt or credit for IRES current taxes of the Parent Company is classified as "Other payables" or "Other receivables". Furthermore, any accrued tax losses are transferred to the shareholder Sestant with the recognition of a consolidated tax income recognized in the income statement

Deferred taxes

Deferred taxes are calculated on the timing differences existing as at the reporting date between the taxable values taken as reference for the assets and liabilities, and the values recorded in the financial statements.

Deferred tax liabilities are recognised on all taxable timing differences, except in the following cases:

- when the deferred tax liabilities derive from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and which, at the time of the

transaction, has no effect either on the profit for the year calculated for accounting purposes or on the profit or loss calculated for tax purposes;

- with regard to taxable timing differences relating to investments in subsidiaries, associates and joint ventures, where the reversal of timing differences can be monitored and it is likely that this will not happen in the foreseeable future.

Deferred tax assets are recognised for all deductible timing differences - and for all tax assets and liabilities carried forward - to the extent that it is likely that future tax gains will exist and on which the deductible timing differences and tax assets and liabilities carried forward can be applied, with the exception of cases where:

- the deferred tax asset associated with deductible timing differences derives from the initial recognition of an asset or liability in a transaction that is not a business combination and which, at the time of the transaction, has no effect either on the profit for the year calculated for accounting purposes or on the profit or loss calculated for tax purposes;
- with regard to taxable timing differences associated with investments in subsidiaries and associates, deferred tax assets are recognised only to the extent to which it is likely that the deductible timing differences can be reversed in the near future and that there are sufficient tax profits on which the timing differences can be applied.

The amount of deferred tax assets to be recorded in the financial statements is reviewed at each year-end and reduced by the extent to which it is no longer likely that future tax gains will be available to allow the utilisation of all or part of the relevant tax credit. Deferred tax assets not recognised are reviewed annually at year-end and recognised at the extent to which it is likely that tax gains are sufficient to allow recovery of the deferred tax assets.

Deferred tax assets and liabilities are measured on the basis of tax rates expected to apply in the financial year in which such assets are realised or in which such liabilities are extinguished, taking into account the current tax rates and those issued or substantially in issue at the reporting date. Deferred tax assets and liabilities are offset where a legal right exists to offset the current tax assets against current tax liabilities, and the deferred taxes relate to the same taxpayer and the same tax authority.

Income taxes on items recorded directly under shareholders' equity are recognised directly in shareholders' equity rather than in the statement of profit or loss.

Value added tax

Revenues, costs and assets are recognised net of value added tax (VAT) except where this tax is applied on the purchase of non-deductible goods or services; in this case, it is recorded as part of the purchase cost of the asset or part of the cost item recorded in the statement of profit or loss.

The net total of indirect taxes on purchases and sales that can be recovered from or paid to the tax authority is included in the financial statements under other current assets or liabilities as appropriate at the balance sheet date. The value added tax (VAT) connected to Public Entities's billing is subject to the split payment scheme, according to which the public body is obliged to pay the supplier only the fee agreed upon while the VAT due must be credited by the public body in an appropriate current account bound to be acquired by the tax authorities.

6.4. COMMENTS ON THE MAIN ITEMS IN THE CONSOLIDATED STATEMENT OF FINANCIAL POSITION

6.4.1. PROPERTY, PLANT AND EQUIPMENT

The historical cost, accumulated depreciation and the net carrying amount of the item Property, plant and equipment as at 31 December 2018, 1 January 2018 and 1 January 2017 are provided in the table below:

(In thousands of Euro)	Land and buildings	Plant and equipment	Industrial and commercial equipment	Other assets	Assets Under Construction and advances	Total
COST						
Balance as at 1 January 2017	87,293	180,669	18,097	21,578	84,252	391,889
Reclassifications	1,712	1,981	1,903	(1,997)	(2,773)	826
Increases	1,841	4,986	822	1,818	59,332	68,799
Translation differences	(1,311)	(1,721)	(258)	(419)	(6,808)	(10,517)
Decreases	0	(804)	(152)	(44)	(10)	(1,010)
Balance as at 1 January 2018	89,535	185,111	20,412	20,936	133,993	449,987
Reclassifications	20,319	64,451	1,963	1,854	(85,463)	(3,124)
Increases	2,480	11,654	1,985	1,984	11,343	29,446
Translation differences	(261)	(193)	114	87	4,911	4,658
Decreases	(629)	(365)	(1,573)	(1,322)	0	(3,889)
Assets held for sale	(822)	(958)	(1,022)	(511)	0	(3,313)
Balance as at 31 December 2018	110,622	259,700	21,879	23,028	64,784	480,013
DEPRECIATION AND IMPAIRMENT						
Balance as at 1 January 2017	31,767	119,565	14,525	16,020	0	181,877
Depreciation of the year	3,486	12,854	1,144	1,716	0	19,200
Write-downs	0	0	0	0	0	0
Disposals	0	(642)	(120)	(64)	0	(826)
Translation differences	(228)	(930)	(123)	(199)	0	(1,480)
Reclassifications	310	580	248	(1,137)	0	1
Balance as at 1 January 2018	35,335	131,427	15,674	16,336	0	198,772
Depreciation of the year	3,855	11,989	1,175	1,752	0	18,771
Write-downs	0	0	0	0	0	0
Disposals	(190)	(350)	(535)	(770)	0	(1,845)
Translation differences	11	19	50	46	0	126
Reclassifications	42	143	0	0	(187)	(2)
Assets held for sale	(368)	(697)	(394)	(388)	0	(1,847)
Balance as at 31 December 2018	38,685	142,530	15,970	16,977	(187)	213,975
Carrying amounts as at 01.01.2018	54,200	53,684	4,738	4,600	133,993	251,215
Carrying amounts as at 31.12.2018	71,937	117,170	5,909	6,051	64,971	266,038

Of which under finance lease:

(In thousands of Euro)	31.12.2018			31.12.2017		
	Historical cost	Accumulated depreciation	Net value	Historical cost	Accumulated depreciation	Net value
Buildings	3,219	757	2,462	3,303	571	2,733
Plant and equipment	99,886	75,500	24,385	97,370	70,470	26,901
Fittings	1,596	1,578	18	1,596	1,563	33
Other assets	9,255	8,265	990	9,255	7,782	1,472
TOTAL	113,956	86,101	27,855	111,525	80,386	31,139

During the year ended on 31 December 2018, Kedrion Group realized net investments for Euro 79,902 thousand. Among this, Euro 4,818 thousand are financed through financial lease that didn't affect current financial cash.

Increases from acquisitions mainly concern:

- **Melville plant (NY, USA)** for a total amount of Euro 4.9 million primarily relating to the completion of Melville fractionation plant refitting project and new fractionation and purification line for the production of the proprietary medicinal product RhoGAM.
- **Bolognana Plant (LU, Italy)** for a total of Euro 6.7 million, relating mainly to renovation and improvements to existing buildings and plants.
- **Sant'Antimo Plant (NA, Italy)** for a total of Euro 5.5 million, relating to renovation and improvements to existing buildings and plants.
- **Godollo Plant (Ungheria)** for a total of Euro 1.8 million, relating mainly to renovation and improvements to existing plants.
- **Plasma collection centers in Germany, Hungary and the United States** for a total amount of Euro 47.0 million, of which Euro 44.8 million for the completion of the purchase of 8 new US centers and for the downpayments for the purchase of 11 more US centers, Euro 0.7 million for the opening of a new U.S. center and a Hungarian center, and the rest for interventions and improvements in other centers.
- **Castelvecchio Pascoli (LU, Italy)** for a total amount of Euro 8.2 million, mainly relating to the KIg10 project (Euro 7.1 million) for the construction of a department to produce new-generation immunoglobulins, while the remainder refers to interventions and improvements to the warehouse and adjacent buildings.
- **Other investments** for a total amount of Euro 5.7 million, mainly relating to IT hardware and software investments, including the implementation of SAP in the company that manages plasma collection in the United States and a new Group information system to improve data collection and management.

Over the past years the Kedrion Group has benefited from government grants on tangible assets pursuant to Italian Laws 488/92 and 388/00, totaling Euro 6,703 thousand and Euro 3,356

thousand respectively. These grants were provided on the basis of investments incurred and capitalized for Euro 12,184 with regard to Italian Law 488/92 and for Euro 12,805 thousand with regard to Italian Law 388/00. In 2010 a “Programme Agreements” contract was signed with the Italian Medicines Agency, on the basis of which 10% of investments made in the Bolognana production plant over the 2007-2009 three-year period were financed, for a maximum of Euro 24,900 thousand. Total investments were equal to Euro 26,535 thousand and the grant contributed amounted to Euro 2,490 thousand. Tangible assets were recorded at their purchase price and the value of the grant was discounted under other current and non-current liabilities (for the portion exceeding 12 months). The portion relevant to the year was subsequently carried to the statement of profit or loss on a straight-line basis throughout the expected useful life of the asset concerned. As at 31 December 2018, deferred income was recorded for this benefit for a total of Euro 502 thousand.

The Hungarian subsidiary Human Bioplazma has benefited in previous years from a grant for tangible assets totalling around Euro 897 thousand, the residual amount as at 31 December 2018 recognised under deferred income was Euro 598 thousand.

Tangible assets were recorded at their purchase price and the value of the Tax receivable was discounted under other current and non-current liabilities (for the portion exceeding 12 months). The portion relevant to the year is carried to the statement of profit or loss on a straight-line basis throughout the expected useful life of the assets concerned. As at 31st December 2018, deferred income of Euro 371 thousand was recorded for this tax receivable.

There are no restrictions on the ownership of property, plant and equipment used to guarantee liabilities and contractual commitments in place for the purchase of these types of assets.

6.4.2. PROPERTY INVESTMENT

The historical cost, accumulated depreciation and the net carrying amount of the item Investment property as at 31 December 2018 and as at 31 December 2017 are provided in the table below:

(In thousands of Euro)	Land and buildings
COST	
Balance as at 1 January 2017	2,627
Reclassifications	0
Increases	0
Translation differences	0
Decreases	0
Balance as at 1 January 2018	2,627
Reclassifications	0
Increases	9
Translation differences	0
Decreases	(13)
Balance as at 31 December 2018	2,623
Depreciation and impairment	
Balance as at 1 January 2017	182
Depreciation of the year	59
Write-downs	0
Disposals	0
Translation differences	0
Reclassifications	0
Balance as at 1 January 2018	241
Depreciation of the year	60
Write-downs	0
Disposals	(5)
Translation differences	0
Reclassifications	0
Balance as at 31 December 2018	296
Carrying amounts as at 01.01.2018	2,386
Carrying amounts as at 31.12.2018	2,327

During the year, a rural building was sold to Monsagrati, and a capital gain of Euro 11 thousand was realised from the sale.

The land classified under investment property, with specification of its fair value, is located in the following places:

- Castelvechio Pascoli (LU) - historical cost Euro 73 thousand; fair value Euro 51 thousand.
- San Pietro in Campo (LU) - historical cost Euro 104 thousand; fair value Euro 453 thousand.
- Monsagrati (LU) - historical cost 1,363 thousand Euro; fair value Euro 1,733 thousand.

The buildings classified under investment property instead refer to:

- a residential apartment located in Monsagrati (LU) - residual value Euro 13 thousand; fair value Euro 35 thousand.
- a new industrial building located in S. Antimo (NA), with a residual value of Euro 827 thousand gross of accessory purchase charges, and fair value of Euro 968 thousand.

The fair value of investment property is determined by using valuation models and observable market parameters, therefore under the fair value hierarchy according to IFRS 13, they are investment property at fair value of Level 2.

6.4.3. GOODWILL

Goodwill entered in the balance sheet is subject to annual impairment testing. Listed below are the carrying amounts - as at the reporting dates - of the item Goodwill entered in the consolidated financial statements as well as their allocation to specific cash generating units (CGU), and the changes during the period:

(In thousands of Euro)	Balance at 31.12.2017	Reclassifica tions	Increases for Business Combinatio n	Translation differences	Assets held for sale	Decreases	Balance at 31.12.2018
Plasma derivatives CGU goodwill - Kedrion Biopharma	34,511	(34,511)	0	0	0	0	0
Plasma derivatives CGU goodwill - Kedrion	149,417	(149,417)	0	0	0	0	0
Plasma derivatives CGU goodwill - Human BioPlazma	2,807	(2,807)	0	0	0	0	0
Plasma derivatives CGU goodwill	0	186,735	0	1,543	0	0	188,278
Plasma CGU goodwill	31,634	0	17,255	1,293	0	(8,573)	41,609
CGU Goodwill - Others	949	0	0	0	(67)	(215)	667
TOTAL	219,318	0	17,255	2,836	(67)	(8,788)	230,554

The differences relative to CGU "plasma" is due to the following:

- Increase deriving from the purchase of eight new centers for Euro 17,255 thousand (19.7 million US Dollars);
- Decrease due to the sale of six plasma collection centers for Euro 8,573 thousand (USD 9.8 million);
- Translate differences per Euro 1,293 thousand.

The variation for the plasma-derived CGU is due to the following movements:

- Reclassification by consolidation of the previous three plasma-derived CGUs for Euro 186,735 thousand, better described below;
- Translation difference of Euro 1,543 thousand.

Until December 31, 2017, the Kedrion Group consisted of two segments (Plasma and Plasma derivates) and five Cash Generating Units, of which three referred to Plasma derivates business:

- Plasma derivatives CGU - Kedrion Biopharma
- Plasma derivatives CGU - Kedrion
- Plasma derivatives CGU - Human BioPlazma
- Plasma CGU

- Other CGU

In 2018, the definition of the CGUs into which the Plasma derivatives segment were divided was revised for the reasons indicated below and, consequently, the related goodwill was reallocated.

CGU PLASMA DERIVATES GOODWILL

As indicated above, until 31 December 2017, 3 CGUs had been identified in the Plasmaderivates segment, corresponding to the Group's legal entities that own the various plants for fractionation and/or purification, according to an approach adopted up to that time consistent with the internal reporting provided to top management and with the presentation of the Group's results to the market and financial communications, reflecting the existence of independent cash generation centers, and the Group's growth history through acquisitions.

Over the years, in order to fully exploit the existing synergies, the Group has gradually integrated the overall management of the Plasmaderivates segment, with a process that was substantially completed during the year 2018 with the finalisation of the refitting of the Melville plant. At present, the production allocation of the Group's plasma-derived products has therefore become unrelated to its geographical location, but rather aimed at optimising efficiency and the ability of the Group to respond to market demand.

The consequence of this integration strategy was a change in the allocation of resources within the Group and a new way of managing the production and marketing of plasma-derived products. In this context, business reporting is already structured in the two sectors Plasma and Plasma derivatives and this is reported in the annual consolidated financial statements of the Group.

The completion of this integration process has made the reality of the business no longer consistent with the 3 CGUs that had been identified within the Plasmaderivati segment until 31 December 2017. Therefore, starting from the 2018 financial statements, the three CGUs previously identified have been merged into a single "Plasmaderivati" CGU, and all the goodwill that previously belonged to the three separate CGUs has been reallocated to the latter, in line with the provisions of IAS 36 in paragraph 87.

The impairment test of the goodwill allocated to the Plasmaderivates segment was carried out both with the three-CGU configuration, in continuity with what was done in previous years, and with reference to the new single Plasmaderivates CGU. In both cases there was no need to write down the goodwill.

The impairment test was carried out using the Discounted Cash Flow (DCF) method net of taxes. The expected cash flows, used in the calculation of the DCF, were determined on the basis of a 4-year business plan that consider the various reference scenarios, and on the basis of the development expectations of the various markets. Profitability (EBIT) is expected to grow because of the completion of the restructuring and development projects: Melville and Castelvechio Pascoli plants. In terms of balance sheet, an increase in commercial working capital was expected as a result of the growth resulting from these projects and the investments for their completion.

In order to determine the CGU value in use, cash flows projections over the next 4 years were discounted and then was added a terminal value. The terminal value represents the current value, at the last year of the projection of all subsequent cash flows calculated as perpetual income and was determined using long period growth rate ("g" rate) equal to 0%.

The discount rates applied to prospective cash flows (WACC) are summarized in the following table:

CGU	WACC
CGU plasma derivates goodwill	9.97%

A sensitivity analysis was also performed on the key assumptions the recoverable amount is based on, such as growth rate changes equal to +/- 0.5% and WACC changes equal to +/- 0.5%. Directors believe that reasonable change in the key assumptions will not generate an excess of the carrying amount compared to the recoverable amount.

CGU GOODWILL – PLASMA

Goodwill relating to Haemopharm (merge with Kedrion BioPharma Inc. on 1st November 2016) and KEDPlasma LLC, for a total of Euro 41,609 thousand, was allocated to the Plasma USA CGU, and - given that their core business is the collection and marketing of plasma - was subjected to a impairment test comparing the carrying amount with the recoverable value calculated on the basis of the CGU value in use.

The value in use calculation is based on discounted cash flow (DCF) model. Cash flows projections are derived from Kedrion Group consolidated business plan for the next five years (2019-2022). In order to determine the CGU value in use, cash flows projections over the next 4 years were discounted and added to the terminal value. The terminal value represents the current value, at the last year of the projection of all subsequent cash flows calculated as perpetual income and was determined using long period growth rate ("g" rate) equal to 0%.

The discount rates applied to prospective cash flows (WACC) are summarized in the following table:

CGU	WACC
CGU plasma goodwill	7.95%

The calculation of the value in use on the basis of these parameters did not involve any impairment of goodwill. A sensitivity analysis was also performed on the results applied to the recoverable amount (such as changes of both long term growth rate and WACC equal to +/- 0.5%). The Directors believe that any reasonable change in the key assumptions will not generate an excess of the carrying amount compared to the recoverable amount.

GOODWILL – OTHERS CGU

Kedrion Group decided to represent in CGU – Others, all goodwill related to minor activities for Euro 667 thousand.

In 2007, the purchase of a business unit was completed, consisting of a hydroelectric control unit including accessories, for the generation of electricity. This acquisition involved the recording of goodwill for Euro 215 thousand, in 2018 this business unit was sold to third parties and consequently this goodwill was eliminated.

In 2005, the Group established a marketing company, Kedrion International GmbH, with registered office in Vienna (Austria), jointly with a third party from outside the group. The Group's share of the investment was 30% of the share capital. During the course of 2006, the Group increased its investment in the company by acquiring a further 70%, thus achieving total control. In the transaction the Group recognized goodwill of Euro 459 thousand to the vendor.

Subsequently, on 31 December 2010, a contract was signed for the purchase of 95% of the shares of Kedrion Portugal Unipessoal Lda and a purchase option for the remaining 5%. This acquisition involved the recording of goodwill for Euro 165 thousand.

On 18 November 2013 Kedrion S.p.A. acquired 51% of Kedrion Brasil Distribuidora de Produtos Hospitalares Ltda-Me from a local partner – FBM Farma Industria Farmaceutica LTDA.

This acquisition involved the recording of goodwill for Euro 43 thousand.

The goodwill related to KedPlasma GmbH, equal to Euro 67 thousand, referred to plasma collecting and distribution in German market, has been reclassified under assets held for sale.

6.4.4. DEFINITE LIFE INTANGIBLE ASSETS

The historical cost, accumulated amortisation and the net carrying amount of the item Definite life intangible assets as at 31st December 2018 and as at 31st December 2017 are provided in the table below:

(In thousands of Euro)	Development costs	Trademarks and Rights	Assets under construction	Others	Total
COST					
Balance as at 1 January 2017	12,160	49,776	11,515	48,461	121,912
Reclassifications	227	4,078	(4,545)	1,654	1,414
Increases	0	752	11,413	2,928	15,093
Translation differences	(10)	(4,268)	(1,180)	(3,819)	(9,277)
Decreases	0	(165)	(87)	(2)	(254)
Balance as at 1 January 2018	12,377	50,173	17,116	49,222	128,888
Reclassifications	0	5,491	(10,856)	2,241	-3,124
Increases	0	6,141	13,422	13,629	33,192
Translation differences	(214)	1,553	581	1,336	3,256
Decreases	(1,736)	(2,870)	0	(987)	(5,593)
Assets held for sale	0	0	0	(227)	(227)
Balance as at 31 December 2018	10,427	60,488	20,263	65,214	156,392
AMMORTISATION AND IMPAIRMENT					
Balance as at 1 January 2017	12,132	24,064	0	27,386	63,582
Amortisation for the year	59	2,619	0	3,957	6,635
Write-downs	0	0	0	0	0
Disposals	0	(165)	0	0	(165)
Translation differences	(10)	(1,316)	0	(1,872)	(3,198)
Reclassifications	0	0	0	0	0
Balance as at 1 January 2018	12,181	25,202	0	29,471	66,854
Amortisation for the year	48	2,731	0	4,685	7,464
Write-downs	0	0	0	0	0
Disposals	(1,736)	(223)	0	(176)	(2,135)
Translation differences	(214)	575	0	722	1,083
Reclassifications	0	0	0	0	0
Assets held for sale	0	0	0	(205)	(205)
Balance as at 31 December 2018	10,279	28,285	0	34,497	73,061
Carrying amounts as at 31.12.2017	196	24,971	17,116	19,751	62,034
Carrying amounts as at 31.12.2018	148	32,203	20,263	30,717	83,331

As at 31 December 2018, Trademarks and Rights totaled Euro 24,971 thousand and was made up of the following items specific to the commodity sector:

(In thousands of Euro)	31.12.2018	31.12.2017
Rights	18.119	12.186
Trademarks	14.084	12.785
RIGHTS AND TREADKMARKS	32.203	24.971

Rights refers to patent rights on the proprietary medicinal product RhoGAM which was acquired during 2012 and measured at fair value at the time of PPA, while considering a 5% royalty on expected turnover for a period of 15 years, and licences for Marketing Authorisations of other proprietary medicinal products.

Trademarks primarily regard the “RhoGAM” trademark, with a residual value of Euro 8,053 thousand.

The item assets under construction is mainly composed of:

- Costs incurred for obtaining AIC for new medicinal products for Euro 5.0 million;
- Advances paid for the acquisition of new centers for Euro 14.4 million;
- For the remaining part, mainly from software.

The management carried out the necessary verifications of recoverability without identifying any indicators of impairment relating to this item.

The item Other intangibles mainly includes the customer lists relating to the acquisition of RhoGAM for Euro 10,719 thousand, application software programs for Euro 9,744 thousand and the list of hyperimmune plasma donors of the subsidiary KEDPLASMA LLC for Euro 10,256 thousand.

6.4.5. INVESTMENTS IN ASSOCIATED COMPANIES

The details of the investments in associates at December 31, 2018 and December 31, 2017 are shown below.

(In thousands of Euro)	31.12.2018	31.12.2017
Participations in the associated company Kirov Plasma	331	331
INVESTMENTS IN ASSOCIATED COMPANIES	331	331

On 23 March 2017 a new company was set up in Russia, JSC Kirov Plasma. Kedrion S.p.A. it has the role of technological partner and holds 25% of the joint venture. The Italian-Russian partnership was born with the aim of completing the construction of a production plant in Kirov. In the 2018 financial year the company is in the start-up phase, for this reason it is not considered significant to present the data of this company.

6.4.6. INVESTMENTS IN OTHER COMPANIES

A breakdown of investments in other companies as at 31 December 2018 and as at 31 December 2017 is provided below.

(In thousands of Euro)	31.12.2018	31.12.2017
Other investments	2,194	2,095
Investments in other companies	2,194	2,095

Other equity investments of Euro 2,183 thousand are represented by the 4.3% stake held by the subsidiary Kedrion Biopharma in the US research company Entegriion Inc. in partnership with which a project considered strategic for the Group is currently being developed, on behalf of the US Department of Defence (DoD), for the creation of a blood derivative product that can be used in emergency situations in the military context.

Investments in other companies, booked as non-current financial assets which are not available-for-sale, are measured at cost less impairment since the fair value cannot be calculated reliably. There were no impairment losses as at 31 December 2018.

6.4.7. OTHER NON-CURRENT FINANCIAL ASSETS

(In thousands of Euro)	31.12.2018	31.12.2017
Guarantee deposits	1,089	1,090
Start up financing	8,244	8,617
Financial deferrals	791	1,149
Other non-current financial assets	10,124	10,856

Guarantee deposits are mainly associated with lease agreements for plasma collection centers and offices. Start up financing of 8.244 was granted by the US subsidiary KedPlasma LLC. to Immunotek to finance the opening of new US plasma collection centers, and will be repaid through a reduction in the purchase price of plasma collected.

The financial deferrals refer to prepaid bank charges relating to credit lines available to the Group, whose usability is exhausted in the next financial years.

6.4.8. DEFERRED TAX ASSETS

The table below shows the composition of deferred tax assets and liabilities as at 31 December 2018 and as at 31 December 2017.

(in thousands of Euro)	31.12.2018	31.12.2017
Deferred tax assets	13,268	7,949
Deferred tax liabilities	(927)	(1,860)
Total net deferred tax assets (liabilities)	12,341	6,089

The table below provides a breakdown of deferred tax assets as at 31 December 2018 and 31 December 2017:

(in thousands of Euro)	Taxable amount 2017	Total deferred tax assets	Increase	Decrease	Taxable amount 2018	Total deferred tax assets 2018
Trademarks and goodwill amortisation	142	40	0	89	53	15
Unpaid directors' fees	16	4	453	15	454	109
Unpaid membership fees	12	3	124	12	124	30
Unpaid interest expense	984	236	0	978	6	1
Unpaid tax	0	0	0	0	0	0
Currency adjustment	599	144	760	599	760	182
Risk provisions	634	177	1,470	398	1,706	450
Intercompany profit eliminated	12,434	3,469	0	2,130	10,304	2,885
TFR (employee severance indemnity) Reserve (IAS 19)	334	80	0	125	209	50
Hedging Derivatives	856	205		70	786	189
Deferred taxes in Kedrion Biopharma	0	0	22,456	0	22,456	5,345
Others relevant values	459	120	2,094	0	2,553	664
TOTAL	16,472	4,478	27,357	4,416	39,413	9,919
Tax credit of the subsidiary HUMAN BioPlazma	3,471	3,471	0	122	3,349	3,349
TOTAL DEFERRED TAX ASSET	19,943	7,949				13,268

The table below provides a breakdown of deferred tax liabilities as at 31 December 2018 and 31 December 2017:

(in thousands of Euro)	Taxable amount 2017	Total deferred tax liabilities	Increase	Decrease	Taxable amount 2018	Total deferred tax liabilities 2018
Deferred taxes in the subsidiary Kedrion Biopharma	3,076	1,230		3,076	0	0
Deferred taxes in the subsidiary Human Bioplazma	1,059	201		295	764	145
Other	1,786	429	1,472	0	3,258	782
Total deferred tax liabilities	5,921	1,860	1,472	3,371	4,022	927
Net impact on Shareholders' Equity	14,022	6,089				12,341

Deferred taxes include, inter alia, the tax credit, with a residual value of Euro 3,349 thousand as at 31 December 2018, accrued on investments made by the Hungarian subsidiary Human Bioplazma, which may be used to reduce 80% of tax due over a period of 10 years.

There are no deferred taxes on undivided profits of subsidiaries or other temporary differences that may originate.

The Group has assessed the recoverability of the net deferred tax assets recorded.

6.4.9. OTHER NON-CURRENT ASSETS

The table below provides a breakdown of other non-current assets as at 31 December 2018 and as at 31 December 2017:

(in thousands of Euro)	31.12.2018	31.12.2017
Prepaid expenses	1,199	356
Tax credit	5	258
Other non-current assets	58	41
OTHER NON-CURRENT ASSETS	1,262	655

The item Prepaid expenses includes the non-current portion of prepaid expenses relating primarily to the rights of renewal of Marketing Authorisations.

6.4.10. INVENTORIES

The table below provides a breakdown of inventories as at 31 December 2018 and as at 31 December 2017:

(in thousands of Euro)	31.12.2018	31.12.2017
Raw materials and consumables	114,002	74,910
Work in progress	136,171	107,887
Finished products and goods for resale	93,945	97,383
INVENTORIES	344,118	280,180

The increase in inventories is mainly due to the restart of the Melville plant. The value of inventories is stated net of a provision for doubtful accounts of Euro 3,995 thousand, of which Euro 3,338 thousand relating to inventories at Melville plant and Euro 657 thousand relating to inventories of the Parent company.

6.4.11. TRADE RECEIVABLES

The table below provides a breakdown of trade receivables as at 31 December 2018 and as at 31 December 2017:

(in thousands of Euro)	31.12.2018	31.12.2017
Receivables due from customers	106,154	112,659
Receivables accrued on services	0	15,310
TRADE RECEIVABLES	106,154	127,969

For the terms and conditions relating to receivables from related parties, reference should be made to Paragraph 6.6.2.

Trade receivables are non-interest bearing and normally have a contractual maturity of between 45 and 120 days. In 2018, receivables from customers decreased by Euro 21,815 thousand. This decrease is mainly due to an improvement in collection times and to the reclassification of receivables for services accrued in the contract assets following the application of IFRS 15.

The adjustment of receivables due from foreign customers at the precise exchange rate on December 31, 2018 led to the recognition of an unrealized exchange rate loss of Euro 746 thousand.

With regard to non-performing receivables for which recovery is doubtful, a specific bad debt provision has been set up, totalizing Euro 5,414 thousand; this is deemed consistent with the doubtful loan positions known at year-end. Year's utilization relates to the stipulation of settlement agreements with some customers on long-term positions.

The table below provides a breakdown of changes in the bad debt provision for the year ended 31 December 2018:

(in thousands of Euro)	For trade receivables	For default interest	Total
Balance as at 01.01.2018	4,336	405	4,741
Utilisation in the year	(966)	(213)	(1,179)
Allocations for the year	1,852	0	1,852
Balance as at 31.12.2018	5,222	192	5,414

The Group determines impairment losses on trade receivables considering the amount of receivables of doubtful collectability, analysing the specific conditions of the Group's customers, any guarantees given in favour of Group companies, suitably assessing outstanding disputes and the possibilities of recovering past due receivables, as well as determining the expected insolvency rate after analysing the average loss rate on receivables recorded in recent years.

The provision for default interest relates to receivables for default interest which, in accordance with regulations in force, the Group invoices to national public authorities.

6.4.12. CONTRACT ASSETS

The movements in contract assets at 31 December 2018 and 31 December 2017 are shown below.

(in thousands of Euro)	31.12.2018	31.12.2017
Contract assets	19,555	0
CONTRACT ASSETS	19,555	0

According to IFRS 15, receivables for work in progress are represented as "contract assets" separately from trade receivables.

Contract assets are initially recognised for revenues deriving from toll services as the receipt of the consideration is subject to the positive completion of the service. Upon completion of the latter and acceptance by the customer, the amounts recognised as contractual assets are reclassified under trade receivables.

6.4.13. CURRENT TAX RECEIVABLES

The table below provides a breakdown of current tax receivables as at 31st December 2018 and as at 31st December 2017:

(in thousands of Euro)	31.12.2018	31.12.2017
Foreing taxes	4,077	2,589
IRES	3,662	4,648
Current tax receivables	7,739	7,237

Receivables concern the surplus of payments on account made by Kedrion S.p.A and by foreign subsidiary Kedrion Biopharma Inc.

6.4.14. OTHER CURRENT ASSETS

The table below provides a breakdown of other current assets as at 31 December 2018 and as at 31 December 2017:

(in thousands of Euro)	31.12.2018	31.12.2017
Receivables from employees	278	466
Social security receivables	93	388
Other receivables	9,645	7,939
Advances on other receivables	(560)	(511)
Sundry	93	106
VAT and other tax receivables	24,085	24,457
Insurance	626	798
Fees for renewal of marketing authorisations	80	52
Costs pertaining to subsequent years	3,880	3,134
Other current assets	38,220	36,829

These other current assets are considered recoverable and, as a result, were not subject to value adjustments.

The item "Other receivables" includes credits of Parent Company for Euro 6,409 to the shareholder Sestant S.p.A. following the adhesion to the national fiscal consolidation for the 2016-2018 three-year period. On that occasion, the Group regulations governing the application of the provisions concerning national consolidation was delivered.

The credit toward the Ministry of Economic Development and the Region of Tuscany, for some financed research projects, amount to Euro 2,030 thousand.

Other receivables also include receivables accrued from the Italian Medicines Agency (AIFA) for Euro 1,153 thousand for the recognized contribution on some research projects and on investments made during the three-year period 2007-2009 on the Bolognana plant and for some refunds due to the excess fees paid.

The increase in VAT credits is mainly related to Kedrion S.p.A. either as a result of the investments made either the effects of billing to the public administration through the so-called "split payment" and to VAT credits of the Hungarian subsidiary; the other tax receivables relate to the credit accrued by Kedrion on the research and development activities carried out in 2018 equal to Euro 4,629 thousand.

Costs related to future periods relate primarily to down payments of the next period.

6.4.15. OTHER CURRENT FINANCIAL ASSETS

(in thousands of Euro)	31.12.2018	31.12.2017
Financial Deferrals	358	358
Other financial assets	354	206
Other current financial assets	712	564

The item Other financial assets shows the interest accrued by the subsidiary KEDPLASMA LLC on the loan granted to Immunotek Biocentres LLC for the new plasma collection centers' opening for Euro 344 thousand and short-term guarantee deposits for Euro 10 thousand.

6.4.16. CASH AND CASH EQUIVALENTS

The table below provides a breakdown of the item as at 31 December 2018 and 2017:

(in thousands of Euro)	31.12.2018	31.12.2017
Bank and postal deposits	115,195	104,402
Cash at bank and on hand	1,130	120
Cash and cash equivalents	116,325	104,522

6.4.17. OTHER CURRENT ASSET HELD FOR SALE

On March 12, 2019, an agreement was reached for the sale to Haema AG. The four plasma centers belonging to KEDPLASMA GmbH with simultaneous payment of an advance of Euro 10 million. This agreement, which provides for a total amount of Euro 20.5 million, will be finalized by July 3, 2019 with the delivery of the four centers and the collection of the balance. Assets held for sale at 31 December 2018 amount to Euro 1,554 thousand, as summarized in the following table:

(in thousands of Euro)	Tangible assets	Intangible assets	Goodwill	Total assets held for sale
Historical cost	3,313	227	67	3,607
Accumulated depreciation	(1,848)	(205)	0	(2,053)
NET BOOK VALUES	1,465	22	67	1,554

6.4.18. CAPITAL AND RESERVES

The share capital of Kedrion S.p.A. amounts to 55,186,279 thousand Euro; it is fully paid-up and is composed of 55,186,279 shares each with a par value of 1 Euro. Following the reverse merger of Kedrion Group S.p.A. and the share capital increase subscribed by Sestant S.p.A., Sestant Internazionale S.p.A. holds 69.38% of the shares, FSI Investimenti S.p.A. holds 25.06% and Sestant S.p.A. holds 5.56%.

Changes in consolidated shareholders' equity during the year ended 31 December 2018 therefore refer to:

- the distribution of dividends to shareholders for Euro 4,849 thousand;
- the carrying forward of the remaining comprehensive income as at 31 December 2017;
- the change in the translation reserve for Euro 48,143 thousand;

- the reserve for hedging financial instruments entered as a result of the stipulation of some "interest rate swap" contracts to hedge the interest rate risk on existing loans for Euro 54 thousand;
- the IAS 19 reserve for Euro 74 thousand.

The item "Other reserves" is composed as follows:

- the reserve of payments for future capital increases of Euro 68,883 thousand, made in 2009 by the shareholders via waiver of their financial receivable including interest accrued up to the effective date of the reverse merger;
- the capital account reserve created in 2012 by the shareholders Sestant and Investitori Associati IV via waiver of a financial receivable of Euro 5,000 thousand;
- the consolidation reserve deriving from the contribution of Kedrion shares to the Kedrion Group;
- the merger surplus deriving from the reverse merger of Kedrion Group S.p.A in Kedrion S.p.A occurred in 2014 for Euro 23,8 thousand.

Minority interests in shareholders' equity, equal to Euro 1,753 thousand as at 31 December 2018, relate to the minority interest of 40% held by Medici Pharma S.A.P.I. de C.V. in Kedrion Mexicana, equal to Euro 1,692 thousand, 49% held by FBM Farma Industria Farmaceutica LTDA in Kedrion Brasil, equal to Euro (9) thousand and 40% held by Betaphar İlaç San. ve Tic. A.Ş. for 25% and Mahmut Arslan for the remaining 15% in Kedrion Betaphar, equal to 51 thousand euro.

Dividends paid and proposed

(in thousands of Euro)	31.12.2018	31.12.2017
Paid in the year	6,449	3,849
Proposed for approval by the Shareholders' Meeting (*)	5,083	4,849

(*) Not recognized as a liability at December 31.

Dividends paid during 2018 are different from those submitted for shareholders meeting because of non-paid share of 2016 dividends at 31 December 2017.

Below information is provided relating to subsidiaries with significant non-controlling interests:

Non-controlling interests held by minority shareholders

Company Name	Registered office	2018	2017
Kedrion Mexicana	Mexico	40%	40%
Kedrion Brasil	Brazil	49%	49%
Kedrion Betaphar	Turkey	40%	40%

The financial information of these subsidiaries is shown below. This information is based on the financial statement balances before intercompany netting.

Statement of profit or loss (in thousands of Euro)	Kedrion Mexicana		Kedrion Brasil		Kedrion Betaphar	
	2018	2017	2018	2017	2018	2017
Revenues	28,474	25,072	771	153	2,611	1,204
Cost of sales	(22,103)	(18,614)	(659)	(122)	(1,920)	(900)
GROSS MARGIN	6,371	6,458	112	31	691	304
Other income	0	1	35	114	50	124
General and administrative expenses	(707)	(608)	(214)	(282)	(256)	(274)
Sales and marketing expenses	(677)	(744)	0	0	(47)	(14)
Research and development costs	0	0	0	0	0	0
Other operating costs	(282)	(251)	0	0	0	0
OPERATING INCOME	4,705	4,856	(67)	(137)	438	140
Financial expenses	(1,021)	(1,209)	(62)	(97)	(700)	(209)
Financial income	1,491	418	61	14	438	52
INCOME BEFORE TAXES	5,175	4,065	(68)	(220)	176	(17)
Income Taxes	(1,577)	(1,269)	0	0	0	0
NET INCOME/(LOSS) FOR THE PERIOD	3,598	2,796	(68)	(220)	176	(17)
Total comprehensive income/(loss) net of taxes	3,598	2,796	(68)	(220)	176	(17)
Attributable to non-controlling interests	1,439	1,118	(33)	(108)	70	(6)
Dividends paid to non-controlling interests	939	2,354	0	0	0	0

Statement of financial position	Kedrion Mexicana		Kedrion Brasil		Kedrion Betaphar	
	2018	2017	2018	2017	2018	2017
(In thousands of Euro)						
Property, plant and equipment and other non-current financial assets	178	139	43	12	227	447
Inventories	8,165	5,584	183	1	272	10
Trade receivables and other assets	7,668	6,747	181	87	399	105
Cash and cash equivalents	1,140	3,446	391	20	1,796	464
Financial liabilities	0	0	(3)	(237)	(783)	(782)
Trade payables and other payables	(12,900)	(13,210)	(623)	(17)	(1,780)	(293)
Loans and financing and liabilities for deferred taxes (non-current taxes)	0	0	(157)	(287)	0	0
Shareholders' equity	4,251	2,706	15	(422)	130	(48)
Attributable to:						
Equity holders of the Parent	2,559	1,631	7	(217)	79	(29)
Non-controlling interests	1,693	1,075	8	(205)	51	(19)

6.4.19. MEDIUM/LONG-TERM DEBT

The item Medium/long-term debt includes the non-current portion (over 12 months) of bank loans, financial payables due to bondholders and payables to other lenders for loans provided for research and to leasing companies for the purchase of tangible assets.

The table below provides a breakdown of this item as at 31 December 2018, with a specification of the total loan and of the current portion (classified in the consolidated statement of financial position under the item "current portion of medium/long-term debt"):

MEDIUM/LONG-TERM DEBT	2018		2017	
	31.12.2018	Of which current portion	31.12.2017	Of which current portion
(In thousands of Euro)				
Loan BPER (Kedrion S.p.A.)	0	0	282	282
Revolving Credit Facility Mediobanca, Banca IMI and Natixis (Kedrion S.p.A.)	138,304	0	100,000	0
Loan FBM Industria Farmaceutica (Kedrion Brasil Ltda)	66	0	189	189
Kedrion Betaphar Loan	80	0	80	0
Total medium/long-term debt	138,450	0	100,551	471
Less current portion	0		(471)	
Non-current portion of medium/long-term debt	138,450		100,080	

Payables to leasing companies	13,910	6,761	17,313	6,565
Less current portion	(6,761)		(6,565)	
Net payables to leasing companies	7,149		10,748	
Old bond (Kedrion S.p.A.)	58,154	58,154	57,999	0
Less current portion	(58,154)		0	
New bond (Kedrion S.p.A.)	344,527	0	343,105	
Net payables to bondholders	344,527		401,104	
Total current portion		64,915		7,036
Medium/long term debt	490,126		511,932	

As at 31 December 2018, medium/long-term debt - broken down by year of maturity and after the amortised cost effect - was as follows:

Medium/Long Term Loan as at 31.12.2018					
(In thousands of Euro)	Payables to bondholders	Ministry for Education, Universities and Research (MIUR)	Payables for leased assets	Financial liabilities	Total medium/long-term debt
Within 12 months	58,204	0	6,761	0	64,965
Within 24 months	0	0	3,685	146	3,831
Within 36 months	0	0	2,136	0	2,136
Within 48 months	350,000	0	1,094	138,304	489,398
Within 60 months	0	0	234	0	234
Over 60 months	0	0	0	0	0
TOTAL LOANS	408,204	0	13,910	138,450	560,564
Less current portion	58,204	0	6,761	0	64,965
Total medium/long-term debt	350,000	0	7,149	138,450	495,599

The table below provides information on the loans granted to the Group:

Description	Maturity	Interest rate 31.12.2018	Balance outstanding as at 31 Dec. 2018	Due within 12 months	Due within 5 years	Due beyond 5 years
Betaphar Loan	08.02.2020	Does not accrue interests	80	0	80	0
FBM Industria Farmaceutica	11.04.2020	Selic + 2.00%	66	0	66	0
Revolving Credit Facility	22.04.2022	Euribor+1.75%	138,304	0	138,304	0
Bonds	24.04.2019	4.625%	58,204	58,204	0	0
Bonds	12.07.2022	3%	350,000	0	350,000	0

With respect to the credit facilities indicated above and those repaid in 2018, interest expense accrued for an approximate total of Euro 15,043 thousand.

Debt structure remained stable compared to the structure reshaped in 2017 when, taking advantage of the favourable conditions on the capital markets, the Group completed a series of operations aimed at refinancing a large part of its medium/long-term debt.

In July 2017, Kedrion S.p.A. issued a new Euro 350 million bond with a 5-year maturity, placed with leading international investors and listed on the Irish Stock Exchange. The bond was issued below par at a price of 99.43 with a coupon of 3%, for a yield of 3.125%. The proceeds from this new issue were partially used to repurchase, through a tender offer, Euro 91 million of the remaining 149 million of the bond with a coupon of 4.625% issued in 2014, the remaining amount of which is Euro 58,204 million to be repaid on 24 April 2019.

In the context of this refinancing, Kedrion also extended by three years from April 2019 to April 2022 the maturities of two of the revolving credit facilities, of Euro 158 and 30 million respectively. In December 2017, the Parent Company also subscribed to a new Euro 60 million revolving credit facility maturing in December 2021.

Bank loan agreements and Company's bond issues require compliance with financial covenants. With regard to the former, the financial covenants include the obligation for the Company to comply with certain levels of financial indices. The main ones relate the Group's net debt to consolidated profitability (Leverage Ratio) and consolidated profitability with financial charges (Interest Cover Ratio).

The bond issues include the obligation for the Company to comply with certain debt limits of the Group companies that do not guarantee the issue (so-called Priority Indebtedness) and to take on additional debt if not in compliance with the Fixed Charge Cover Ratio.

The value of these Covenants is monitored by the company at each calculation date and at December 31, 2018 these ratios are respected.

Payables to leasing companies include contracts stipulated in the financial year ended in December 31, 2018 for a total of 4,036 thousand Euro to finance the investments made. The interest rates applied on these loans are in line with those of the market. For commitments on financial risks, see note 6.6.4.

The table below shows the changes required by IAS 7 with changes in liabilities related to financing activities, including both changes related to cash flows and non-monetary changes:

(In thousands of Euro)	Value at 01.01.2018	Cash Flow	Interest rate change effect	Fair value variation	Capex	Other non- monetary movements	Value at 31.12.2018
Bond Old	57,998	0	0	0	0	156	58,154
Bond New	343,105	0	0	0	0	1,421	344,526
Other medium-long term loan	117,864	30,461	0	0	4,036	0	152,361
Financial short term asset and liabilities	40,684	36,103	(9,685)	(140)	0	324	67,287
Non current financial asset and liabilities	(10,510)	901	0	0	0	0	9,609
TOTAL LIABILITY FROM FINANCING ACTIVITY	549,141	67,465	(9,685)	(140)	4,036	1,902	612,719

6.4.20. FINANCIAL LIABILITIES

The item includes the non-current portion of liabilities deriving from the fair value measurement of the hedging financial instruments recorded after the stipulation of some Interest Rate Swap contracts to hedge the interest rate risk on the Parent Company's loans for Euro 515 thousand.

6.4.21. PROVISIONS FOR RISKS AND CHARGES

The table below provides a breakdown of this item and its changes as at 31st December 2018:

(In thousands of Euro)	Value at 31.12.2017	Provisions	Utilisation	Value at 31.12.2018
Contractual risks for services	959	0	37	922
PROVISIONS FOR RISKS AND CHARGES	959	0	37	922

6.4.22. LIABILITIES FOR EMPLOYEE BENEFITS

As at 31 December 2018, Liabilities for employee benefits amount to Euro 9,028 thousand and are made up of the employee severance indemnity due to employees of Kedrion S.p.A., as provided by Art. 2120 of the Italian Civil Code for Euro 3,604 and other employees' benefits for the remaining amount.

For the purposes of recording in the financial statements, the employee severance indemnity pursuant to Art. 2120 of the Italian Civil Code falls under the category of defined benefit pension plans insofar as it is considered a defined benefit obligation and, as such, has been accounted for in accordance with IAS 19 which requires the valuation of the related liabilities using actuarial techniques. The main assumptions adopted are summarized in the following tables:

Summary of the Technical Economic Bases – financial assumptions	31.12.2018	31.12.2017
Annual discount rate	1.57%	1.30%
Annual inflation rate	1.50%	1.50%
Annual rate of Employee severance indemnity increase	2.625%	2.625%

Summary of the Technical Demographic Bases

Demographic assumptions

Death	RG48 mortality tables published by Ragioneria Generale dello Stato (Italian State General Accounting Department)
Disability	INPS (Italian National Social Security Institute) tables broken down by age and gender
Retirement	100% on reaching AGO requirements

Table showing the annual turnover frequency and TFR (employee severance indemnity) advances

	31.12.2018	31.12.2017
Frequency of advances	2.00%	2.00%
Turnover Frequency	2.00%	2.00%

It should be noted that - for the actuarial calculation - a discount rate determined in relation to a basket of corporate AAA-rated bonds was used (iBoxx Corporate AA 10+ index), in accordance with the guidelines advised by the Association of Actuaries on 31st December 2018 and the reference accounting standard.

The table below shows the changes in the employee severance indemnity for the years as at 31 December 2018 and as at 31 December 2017:

(In thousands of Euro)	31.12.2018	31.12.2017
Present value of the obligation at the start of the period	3,848	3,986
Financial charge	52	54
Benefits paid	(192)	(184)
Actuarial loss (gain) recorded	(104)	(9)
PRESENT VALUE OF THE OBLIGATION AT THE END OF THE PERIOD	3,604	3,847

The other liabilities for employee benefits amount to Euro 5,424 thousand and mainly consist for Euro 976 thousand, of a defined benefit plan relating to the Hungarian subsidiary HBP and Euro 4,253 thousand from the present value of the liability recorded in relation to the system incentive 2016-2018.

The average number of employees, expressed in terms of full-time equivalent staff, is reported in the following table:

Staff - FTE	31.12.2018	31.12.2017
Total FTE (emp.+ emp. leasing + temp.+outsourcing)	2,556	2,317
- Of which employee leasing Kedrion S.p.A.	0	0
- Of which temporary workers Kedplasma LLC	0	0
- Of which temporary workers Kedrion Biopharma	23	31
- Of which outsourcing Kedrion Mexicana e Kedrion India	8	8

6.4.23. OTHER NON-CURRENT LIABILITIES

The table below provides a breakdown of this item for the years ended 31 December 2018 and 31 December 2017:

(In thousands of Euro)	31.12.2018	31.12.2017
Grant on investments	731	874
Hungary grant	3,336	4,013
Tax payables	999	1,517
Other liabilities	19	1,430
OTHER NON-CURRENT LIABILITIES	5,085	7,834

The liabilities for the grant on investments include:

- the benefit set forth in Italian Law 488/92, the tax credit pursuant to Italian Law 388/00 received in the past as capital account payments, and the credit accrued on investments made in the first half of 2015 and represent the non-current portions of these grants pertaining to subsequent years that are entered in the statement of profit or loss on a straight-line basis throughout the useful life of the asset concerned;
- The residual amount of the capital grant due on the basis of the program agreements signed with the Italian Medicines Agency represents the portion relating to future years which will be charged to the statement of profit or loss based on the useful life of the investments financed. The portion booked to the statement of profit or loss in the year amounts to Euro 48 thousand.

The non-current portion of the capital grant due on the basis of an agreement stipulated by the Hungarian subsidiary Human Bioplazma with the government to finance the investments made in the production plant amounts to Euro 3,336 thousand, including a tax credit accrued on investments made by the Hungarian subsidiary Human Bioplazma, which may be used to reduce 80% of tax due over a period of 10 years.

The item "Tax payables" relates to the assessment with adhesion that defined the minutes of findings issued on October 3, 2016 against Kedrion S.p.A, in which the reporters had highlighted, relative to the year 2013:

- The suitability of the documentation provided with regard to the regulation of document charges regarding transfer prices;
- A higher taxable amount in the transactions for the purchase of plasma, both collected and brokered, in respect of the German subsidiary KEDPLASMA GmbH and for the plasma separation operations carried out by the Hungarian subsidiary HUMAN BioPlazma Kft. For approximately EUR 2.5 million in total and a corresponding higher tax for Euro 0.8 million.

The definition was extended to subsequent years (2014 and 2015) with a total cost of approximately Euro 1.9 million.

6.4.24. FINANCIAL LIABILITIES

The following table shows the details of the item in question for the years ended December 31, 2018 and December 31, 2017:

(In thousands of Euro)	31.12.2018	31.12.2017
Due to banks for advances on bills and invoices	25,145	1,279
Due to other lenders	4,902	1,227
Hedging derivatives	362	507
Non-Hedging derivatives	139	556
Payables to bondholders for interest	6,799	6,799
Current account overdrafts and cash equivalents payable on demand	413	238
Revolving credit facility	30,000	30,000
Other financial payables	241	642
FINANCIAL LIABILITIES	68,001	41,248

Financial liabilities, equal to Euro 68,001 thousand, are composed of current account liabilities and short-term debt, as specified in the table above.

Payables to other lenders are represented by payables to leasing and factoring companies.

Derivative hedging instruments regard the fair value measurement of liabilities deriving from Interest Rate Swap contracts stipulated to cover the interest rate of the Revolving Credit Facility loan for Euro 158 million for Euro 202 thousand and for the Revolving Credit Facility of Euro 30 million. Euro for Euro 160 thousand.

Payables to bondholders refer to the interest accrued on bonds issued at the annual rate of 4.625% and those accrued on the new bond issued at the annual rate of 3% for a total of Euro 6,799 thousand.

The item overdraft and payable liquid assets on demand shows the accrued interest as at 31 December and the negative balance of some currency accounts.

The Revolving Credit Facility is a credit line granted by Cassa di Risparmio di Pistoia and Luccchia for a total of Euro 30 million, which as at 31 December was entirely used.

The use of credit lines granted by the banks to the Parent Company as at 31 December 2018 is equal to 34.91% of the total credit line against 8.3% of 31 December 2017.

6.4.25. CURRENT PORTION OF MEDIUM/LONG-TERM DEBT

The table below provides a breakdown of the current portion of medium/long term debt as at 31 December 2018 and as at 31 December 2017:

(In thousands of Euro)	31.12.2018	31.12.2017
Old bonds	58,154	0
Medium/long-term debt	0	471
Payables to leasing companies	6,761	6,565
CURRENT PORTION OF MEDIUM/LONG-TERM DEBT	64,915	7,036

The residual current portion of medium/long-term loans is the bond maturing on 24 April 2019. For further details, see note 6.4.19.

6.4.26. CURRENT PROVISIONS FOR RISKS AND CHARGES

(In thousands of Euro)	Amount as at 31.12.2017	Reclassification s / Provisions	Utilisation	Value as at 31.12.2018
Legal disputes	598	1,215	363	1,450
TOTAL	598	1,215	363	1,450

The utilization of the item is related to the definition of the limit overrun of hospital expenses charged to pharmaceutical companies for the years ranging from 2013 to 2015, to the definition of the dispute with a private individual and to the definition through verification with the accession of the minutes statement issued on 3 October 2016 as already explained in note 0.

The provision refers to an ongoing transaction with Biotest for certain contractual breaches raised by the German company relating to the supply of intermediate products at the Godollo plant for Euro 650 thousand, to the tax dispute between the subsidiary Kedrion Biopharma Inc. and the State of California for Euro 414 thousand and to the provision to cover the breach of the roof of hospital expenses borne by the pharmaceutical companies for the year 2018 for Euro 150 thousand.

6.4.27. TRADE PAYABLES

The table below provides a breakdown of trade payables as at 31 December 2018 and as at 31 December 2017:

(In thousands of Euro)	31.12.2018	31.12.2017
Italian suppliers	36,494	33,178
Foreign suppliers	120,920	77,743
Invoices to be received	18,505	12,322
Advances to suppliers	(4,677)	(368)
Credit notes to be received	(283)	(353)
TRADE PAYABLES	170,959	122,522

Trade payables are non-interest bearing and are, in general, settled within 60-90 days. The value includes payables relating to normal business activities of the group companies, particularly the purchase of raw materials, components and outsourced processing and services

The increase in this item is mainly due to the peak in purchases of plasma at the end of the year and to the increase in investments due to the maintenance activities of the plants during the year-end shutdown.

6.4.28. CURRENT TAX PAYABLES

The balance of Euro 743 thousand as at 31 December 2018 represents mainly the payable for current income taxes of foreign companies, in particular of Kedrion International for Euro 385 thousand and Kedrion Mexicana for Euro 247 thousand, of which the following is a breakdown which breaks down as follows:

(In thousands of Euro)	31.12.2018	31.12.2017
IRES	0	0
IRAP	41	0
Other current taxes relating to foreign companies	702	2,787
Current tax payables	743	2,787

6.4.29. OTHER CURRENT LIABILITIES

The details of other current liabilities at December 31, 2018 and December 31, 2017 are shown below:

(In thousands of Euro)	31.12.2018	31.12.2017
Social security payables	7,533	6,993
Payables to employees and collaborators	13,670	15,089
Payables for toll-manufacturing	1,063	2,224
Payables to Shareholders for dividends	440	2,193
Other payables	4,460	4,741
Accrued expenses	768	1,164
Grant on investments	315	313
Hungary grant - current portion	612	118
VAT	14,709	5,415
Withholding tax	4,062	3,022
Other current liabilities	47,632	41,272

Social security payables primarily refer to contributions on salaries for December and the fourteenth month salary, allocations for leave not taken, company bonuses and accrued retirement incentives.

Payables to employees include salaries for December, accrued employee severance indemnity for employees who had ceased employment as at 31 December, including any retirement incentive, fourteenth month salary and leave accrued and not taken.

Payables on toll-manufacturing refer to a discount recognised on the litres of plasma processed for certain Italian Regional Authorities as well as a discount applied in the case of advance payment.

Item Other payables mostly regards the following accounts:

- The payable to the partner Sestant S.p.A. for the taxes transferred following the adhesion to the tax consolidation for Euro 2,580 thousand;
- The debt related to a tax imposed by the Romanian authorities on sales in this market for Euro 1,030 thousand;
- The current portion of the debt relating to the definition of the report of findings issued on October 3, 2016 for Euro 519 thousand.

Payables for the capital grant contribution and tax credit of Law 488/92 and Law 388/00 and the subsidy on investments made in the first half of 2015 relate to the shares of the same contributions

for the next twelve months that they are recorded in the income statement on a straight line basis over the expected useful life of the assets to which they refer.

The amount due to the Tax Authorities for tax purposes mainly refers to the withholding taxes related to the wages of the months of November and December and to the thirteenth month salary.

6.5. COMMENT ON THE MAIN ITEMS OF THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS

6.5.1. REVENUES

In the years ended 31 December 2018 revenues from contracts with clients totaled Euro 687,939 thousand. They break down as follows:

REVENUES (In thousands of Euro)	31.12.2018				Consolidated statement
	Plasma derivates	Plasma	Other activities	Eliminations	
Type of goods and services					
Plasma derivates	513,920				513,920
Plasma		318,065		(162,955)	155,110
Other			18,909		18,909
Total revenues	513,920	318,065	18,909	(162,955)	687,939
Geographical area					
US	163,922	191,098	1,042	(73,952)	282,109
Italy	160,165	70,068	14,045	(70,068)	174,209
Rest of the World	125,827	30,532	76		156,435
European Union	64,007	26,366	3,747	(18,935)	75,186
Total revenues	513,920	318,065	18,909	(162,955)	687,939
Timing of revenue recognition					
Goods transferred at a certain time	383,350	318,065	15,162	(162,955)	553,622
Services transferred over a specified period of time	130,570		3,747		134,317
Total revenues	513,920	318,065	18,909	(162,955)	687,939

The Group operates in three business segments:

- *Production and sale of plasma derivatives* , i.e. proteins extracted from human plasma such as albumin, standard and specific immunoglobulins, and coagulating factors;
- *Collection and sale of plasma* collected at the centers owned by the Group;
- *Other activities* including the marketing of synthetic products and toll manufacturing.

An analysis of revenues by business segment for the year ended 31 December 2018 is provided below:

“PRODUCTION AND SALE OF PLASMA DERIVATIVE ” SEGMENT

Revenues from the production and marketing of plasma derivatives products as at 31 December 2018 amounted to Euro 513,920 thousand (74.7% of total revenues), an increase of approximately 4.9% mainly due to the introduction of the new anti-rabies immunoglobulin on the US market, and to an increase in the volume of albumin sold and price increases for standard immunoglobulin. The US plasma-derived products market increased by about 14% compared to the previous year, and all other strategic markets are growing, driven by Italy, Germany and Mexico; within this segment, the US market maintains its leadership over the Italian market.

Moreover, in 2018, the weight of this segment contracted to about 75% due to the strong growth of the plasma segment.

“COLLECTION AND SALE OF PLASMA” SEGMENT

Revenues in the plasma collection and marketing segment as at 31 December 2018 amounted to Euro 155,110 thousand, an increase of 65.2% compared to the previous year. This excellent performance was made possible by the increase in the volumes of plasma available, both purchased from third parties and generated by a growing collection of proprietary American and European centers (managed by the Plasma Business Unit to which KEDPLASMA LLC belongs, KEDPLASMA GmbH and the plasma division within the Hungarian company HUMAN BioPlazma Kft.), the number of which, despite the sale of six centers during the year 2018, increased thanks to the purchase/start-up of 8 owned centers in the United States and one center in Hungary.

“OTHER ACTIVITIES” SEGMENT

Revenues for this segment at 31 December 2018 amounted to Euro 18,909 thousand and relate to the sale of synthetic products and production on behalf of third parties.

One of the synthetic products is the Nuwiq, the recombinant factor VIII obtained in exclusive distribution for Italy by Octapharma with a ten-year agreement. The turnover of this product during this year (Euro 11.9 million) increased by 29% compared to 2017.

In 2018, CERUS product selling continued, of which the exclusive distribution in Italy from 2017 is related to biomedical products used for viral inactivation of platelets and human plasma: the activity was launched both for the commercial synergy with the current Kedrion positioning in the plasma-derived sector both for the possible development of the red blood cell inactivation segment for transfusion use, for which CERUS plans to obtain authorization in the coming years. In 2018 the sale of CERUS materials, generated revenues of Euro 1.6 million, respect to 0.2 million in 2017.

The toll-manufacturing carried out at the Melville and Godollo plant for some operators in the sector, is about Euro 4.8 million, respect to 8.5 in 2017: this segment too has been slowed down by the refitting activity of Melville plant, while the European production, carried out at the Godollo plant, increase respect to the previous year of 11%.

Further information on the distribution of revenues by business segment and by geographical area see the report on operations.

6.5.2. COST OF SALES

The item breaks down as follows:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Consumption of raw materials, accessories and consumables	321,692	241,782
Outsourced processing	33,659	30,967
Service costs	67,295	68,151
Labour costs and related charges	80,052	71,904
Amortisation and depreciation	15,784	15,027
TOTAL COST OF SALES	518,482	427,831

The cost of sales for financial year 2018 amounts to Euro 418,482 thousand with a percentage of revenues of 75.4% compared to 71.0% in 2017. This increase is mainly due to an increase in the cost of plasma, only partially mitigated by the consumption of internally collected plasma, and to the negative effects deriving from the prolonged closure of the Melville plant, which led to an increase in the costs for the period, both for the significant plant costs not absorbed, and for the need to continue production in outsourcing, further reducing margins.

The item consumption of raw materials, accessories and consumables includes the cost of plasma and all the materials used during the production process.

The costs for external processing are attributable to the fractionation and packaging activities carried out at external plants and mainly refer to Melville plant.

The costs for services are related to plant maintenance and other third-party services related to production sites.

Non-recurring transactions relating to cost of sales amounted to Euro 63.7 million and mainly concerned the costs related to the refitting of Melville plant. For more details, please refer to note 6.5.11.

6.5.3. OTHER INCOME

The item is composed as follow:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Recovery of expenses	967	3,039
Capital gains centre's cession	28,451	29,601
Early termination penalty Biotest distribution agreement	0	15,491
Insurance refunds	470	59
Operating grants	2,242	250
Plant and machinery grants	356	374
Utilisation of provisions	885	384
Services	177	269
Others	3,946	3,420
OTHER INCOME	37,494	52,887

Other income shows a significant decrease, mainly due to the effect on other revenues of the penalty paid in 2017 for the interruption of the distribution of a medicinal product for about Euro 15 million.

The items insurance costs recoveries and insurance reimbursements refer to reimbursements and recovery of expenses obtained from suppliers and customers and to reimbursements of claims involving finished and intermediate products.

Grants related to the year refer to the quota for the year relating to research projects partly financed by the Ministry of University and Research and the Region of Tuscany.

Plant grants refer to the amount pertaining to the year of grants paid pursuant to Law 488/92, Law 388/00 and the contribution paid by AIFA in the Program Agreements and the investment contribution of 2015 according to the DL 91/2014.

The item "other" mainly refers to research services carried out on behalf of a third-party US company for 246 thousand, transport costs recognized by customers and for the residual out-of-period income relating to insurance reimbursements relating to claims that occurred in previous years.

An initial sale of three US centers with the simultaneous purchase of other centers was completed in September 2018, and involved an amount of USD 25.3 million (equal to a total of Euro 22.1 million) against a book value of the assets sold of approximately Euro 4.5 million, generating a capital gain of approximately Euro 16.4 million. The second sale, also for three centers, was completed on 27 December 2018 for an amount of USD 24.8 million US Dollars (Euro 21.7 million) against assets sold for a net value of Euro 5.2 million, thus generating a capital gain of approximately Euro 12.1 million.

From a financial point of view, the net price of the sale and purchase relating to the September transaction was entirely collected at the end of August 2018, while the price relating to the December sale was entirely collected on 27 December 2018.

According to the directors, these operations should be seen in the ordinary optimization of the Group's procurement management, within which the excess capacity of collection and/or purchase of plasma is managed through the sale to third parties of plasma or, directly from the centers that are less responsive to the Group's strategic objectives. Consistent with this assessment, the transaction, although it has had a significant effect on the result of the year, is not considered non-recurring and in the cash flow statement the originated that were classified among those generated by operating activities.

6.5.4. GENERAL AND ADMINISTRATIVE EXPENSES

The item breaks down as follows:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Labour cost and related charges	28,755	30,941
Taxes and duties (excluding income tax)	1,375	1,968
Legal and administrative services	12,863	12,581
Directors' and Auditors' fees and expenses	2,616	1,571
Amortisation and depreciation	6,961	7,319
General and administrative insurance	3,237	2,901
Data processing expenses	2,937	2,206
Telephone and postal charges	1,651	2,038
Rentals and operating leases	3,492	3,832
Outsourcing	5,489	3,998
Provisions	1,718	762
Other services and general and administrative costs	12,565	10,640
Total general and administrative expense	83,659	80,757

Provisions for the period relate to the loss in value of trade receivables estimated in application of the new accounting standard IFRS 9 and to the provision for risks for a dispute raised by a commercial partner.

The item other services and general costs includes cleaning costs, car rental costs and membership fees for sector organizations.

Non-recurring transactions relating to general and administrative expenses amount to Euro 7,879 thousand. For more details, please refer to note 6.5.11.

6.5.5. SALES AND MARKETING EXPENSES

The item breaks down as follows:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Labour cost and related charges	16,553	16,596
Consultancy	3,855	4,939
Commissions	3,075	7,014
Convention and conference costs	1,901	1,372
Advertising costs	4,109	2,967
Amortisation and depreciation	135	118
Other	16,686	18,779
Total sales and marketing expenses	46,314	51,785

Commissions, to which the reduction in commercial and marketing expenses is mainly attributable, decreased in 2018 as the new distribution contracts do not provide for the payment of commissions on sales. .

The item "other" mainly includes company cars' rental costs supplied to the sales network and the annual fees for subscription in the sector associations.

Non-recurring transactions relating to commercial and marketing expenses amounted to 882 thousand Euro. For more details, please refer to note 6.5.11.

6.5.6. RESEARCH AND DEVELOPMENT COSTS

The item breaks down as follows:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Labour cost and related charges	17,814	15,256
Consultancy	6,404	2,958
Clinical trials	1,672	1,639
Amortisation and depreciation	3,248	3,231
Other	18,989	11,961
Total research and development costs	48,127	35,045

The item other includes costs for the purchase of materials for clinical trials and services from third parties, in addition to the costs needed for the set-up of the new US collecting centers. Further information on the research projects under way can be found in the Report on Operations. Non-recurring transactions relating to research and development expenses amount to Euro 12,874 thousand. For more details, please refer to note 6.5.11.

6.5.7. OTHER OPERATING COSTS

The item breaks down as follows:

(In thousands Euro)	Period ended at 31 December	
	2018	2017
Labour cost and related charges	3,462	3,635
Consultancy	935	1,231
Amortisation and depreciation	167	200
Product registration fees	2,744	2,219
Other	978	1,040
Total other operating costs	8,286	8,325

Other operating costs mainly regard expenses incurred by the Group for the retention of product registrations in Italy and abroad. The cost substantially unchanged compared to the previous year.

Non-recurring operations relating to operating costs amount to Euro 39 thousand and mainly concern extraordinary incentives to employees.

BREAKDOWN BY TYPE AND BY FUNCTION OF EXPENSE

(in thousands of Euro)	Period ended at 31 December	
	2018	2017
Purchases	384,413	256,908
Change in inventories	(57,676)	(13,399)
Services	161,569	148,270
Amortisation and depreciation	26,295	25,895
Labour cost	146,636	138,332
Use of third party assets	15,204	12,061
Provisions for risks	1,710	761
Other costs	26,717	34,915
Total costs by type	704,868	603,743

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Cost of sales	518,482	427,831
General and administrative expenses	83,659	80,757
Sales and marketing expenses	46,314	51,785
Research and development costs	48,127	35,045
Other operating costs	8,286	8,325
Total costs by function	704,868	603,743

6.5.8. FINANCIAL EXPENSES

The table below provides a breakdown of financial expenses as at 31 December 2018 and as at 31 December 2017:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Bank interest expense	3,078	4,788
Interest due to bondholders	13,192	9,829
Other interest expense	514	520
Net actuarial interest	1,988	2,370
Financial expenses on derivatives	88	552
Financial expenses on leasing contracts	489	645
Other	2,933	6,625
Realised exchange losses	5,396	18,421
Total financial expenses	27,678	43,750

Financial expenses were mainly generated by medium- and long-term debt, including the bonds granted to the Group; this is described in more detail in Note 3.18. The decrease is mainly due to the fluctuation of currencies which generated exchange losses between realized and not equal to Euro 5.4 million with an improvement in financial charges compared to 2017 of approximately Euro 16.1 million.

6.5.9. FINANCIAL INCOME

The item breaks down as follows:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Interest income	501	529
Financial income on derivatives	165	0
Realised exchange gains	14,721	1,424
Total financial income	15,387	1,953

The relevant increase in financial income is mainly due to the currency fluctuation.

6.5.10. INCOME TAXES

Income taxes at 31 December 2018 amount to Euro (3,367) thousand and are broken down as follows:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Current taxes	6,340	8,303
Deferred taxes	(5,189)	2,384
Income / charges from fiscal consolidation	(356)	(3,899)
Tax credits	(4,629)	(4,379)
Charges for tax disputes	0	1,187
Taxes of previous years	467	61
Income taxes	(3,367)	3,657

The result before income taxes, the provision for income taxes for the years ended December 31, 2018 and 2017 and the reconciliation between the theoretical and actual tax rates resulting from the consolidated financial statements are shown in the following table:

(In thousands of Euro)	Period ended at 31 December	
	2018	2017
Income before taxes	8.274	9,848
IRES tax rate for the year	24%	24.00%
Theoretical tax burden	1.986	2,364
IRAP	1.182	1,141
Non-deductible costs	1.117	762
Off-balance sheet tax deductions	(2.119)	(513)
Italian Tax Agency Assessment	0	570
Tax credit on non-deductible foreign dividends	125	311
Tax credit on investments and research	(4.629)	(4,474)
Effect of different theoretical tax rates for foreign subsidiaries	(1.029)	3,496
Total differences	(5.353)	1,293
Total income tax charged to the statement of profit or loss	(3.367)	3,657
Effective Tax rate	(41%)	37.13%

6.5.11. SIGNIFICANT NON-RECURRING, UNUSUAL AND ATYPICAL TRANSACTIONS

During 2018 non-recurring expenses, as determined in Italian Authority "Consob" 15519 resolution, which defines them as "income components (positive and/or negative) deriving from events or transactions whose occurrence is non-recurring or from those operations or events that are not frequently repeated in the usual course of business" amounted to Euro 85.4 million and refer to:

(In thousands of Euro)	Cost of Sales	Other Income	General and administrative expenses	Marketing and sales cost	Research and development cost	Other operating cost	TOTAL	Of which with effect on EBITDA
Refitting Melville plant	63,621	0	0	0	12,416	0	76,037	73,449
Transactions and contractual penalties	0	0	2,459	0	400	0	2,859	2,859
Extraordinary incentives related to ongoing projects	61	0	1,940	623	58	39	2,721	2,721
Non recurrent donations	0	0	453	259	0	0	712	712
Strategic consulting	0	0	1,449	0	0	0	1,449	1,449
TOTAL	63,682	0	6,302	882	12,874	39	83,779	81,190

We summarize below the nature of the cost and revenue items considered as non-recurring:

- Completion of the refitting of the Melville plant, consisting of the unabsorbed costs of both the fractionation and the new production line dedicated to the RhoGAM (which only since the restart of the fractionation have found partial correspondence in production) for Euro 38.0 million, the write-down of inventories of intermediate and finished products made

before the refitting of the plant for Euro 35.4 million and the depreciation for Euro 2.6 million, for a total amount of Euro 76.0 million;

- Litigation and contractual penalties mainly represented by the expenses incurred for the arbitration in progress against the supplier BPL Plasma responsible for the non-compliance with certain contractual conditions (Euro 0.8 million), by a settlement with Biotest for some contractual breaches raised by the German company relating to the supply of intermediates produced in the Godollo plant (Euro 0.7 million), by the legal costs incurred in the various appeals raised on the award of tenders for the processing of Italian plasma as well as the costs of the positive verification of compliance with competition regulations (Euro 0,5 million), from the transaction with the company Bio&Bio for the early termination of the contract for the development of a new product (Euro 0.4 million), from the transaction with a former employee of a plasma collection center (Euro 0.1 million) and disputes still in progress that do not allow for the recovery of sums in a certain time, and finally by other penalties applied by customers and suppliers for failure to supply products in the contractual procedures defined;
- Non-recurring incentives to employees for a total value of Euro 2.7 million;
- Non-recurring donations and promotional activities for Euro 0.7 million;
- Strategic consultancy relating to corporate restructuring operations and revision of the organisational structure of certain functions, aimed to increase efficiency for a total of Euro 1.4 million.

6.6. OTHER INFORMATION

6.6.1. OPERATING SEGMENTS

The Group provides information on the basis of its operating segments. An operating segment is based on the Group's management structure and internal reporting system. Segment results include elements attributable directly to a sector and through the reasonable allocation for costs common to several segments. Revenues, costs and segment results include transfers between segments. These transactions are eliminated at the consolidation stage. Intercompany sale prices are established in a manner similar to transactions with third parties. The Group also provides information on geographical areas.

The Group operates in three operating segments:

- The main segment refers to the production and marketing of plasma derivatives, in particular medicines containing proteins extracted from human plasma such as albumin, standard and specific immunoglobulins, and coagulating factors;
- The collection and marketing of plasma collected at the centers owned by the Kedrion Group;
- Other activities including the toll-manufacturing for intermediates and other products and the marketing of other pharmaceutical specialties including recombinant factor VIII, benefiting from the strong positioning of the Kedrion distribution network.

The Group operates worldwide, segmenting its markets into four geographical macro areas: "Italy", "European Union", "U.S.A." and "Rest of the World".

Sales to foreign customers are based on the geographical location of the customers.

Inter-segment revenues of the segment "Plasma" are realized with the segment "Plasma derivatives".

Information on the operating segments as at 31st December 2017 and 2018 is provided below:

Period ended at 31.12.2017					
(In thousands of Euro)	Plasma derivatives	Plasma	Other activities	Eliminations	Consolidated
Revenues from third parties	490,016	93,906	18,580	0	602,501
Inter-segment revenues	0	130,604	0	(130,604)	0
TOTAL REVENUES	490,016	224,510	18,580	(130,604)	602,501
COST OF SALES	342,773	200,055	12,337	(130,604)	424,561
GROSS MARGIN	147,243	24,455	6,243	0	177,940
% OF REVENUES	30,0%	10,9%	33,6%	-	29,5%
Other income	19,442	30,175			49,617
Operating costs					175,912
OPERATING INCOME					51,645
Net financial expenses					41,797
INCOME BEFORE TAXES					9,848
Income taxes					3,657
GROUP INCOME					6,191
Period ended at 31.12.2018					
(In thousands of Euro)	Plasma derivatives	Plasma	Other activities	Eliminations	Consolidated
Revenues from third parties	513,920	155,110	18,909	0	687,939
Inter-segment revenues		162,948	0	(162,948)	0
TOTAL REVENUES	513,920	318,058	18,909	(162,948)	687,939
COST OF SALES	380,011	288,061	13,359	(162,948)	518,482
GROSS MARGIN	133,909	29,997	5,551		169,457
% OF REVENUES	26.1%	19.3%	29.4%		24.6%
Other income	9,043	28,451	0	0	37,494
Operating costs					186,386
OPERATING INCOME					20,565
Net financial expenses					12,291
INCOME BEFORE TAXES					8,274
Income taxes					(3,367)
GROUP INCOME					11,641

Assets and liabilities as at 31 December 2017

(In thousands of Euro)	Plasma derivatives	Plasma	Other activities	Unallocated	Consolidated
Operating assets	821,621	84,927	4,920	200,812	1,112,280
Liabilities from operations allocated to segments	79,761	35,604	7,157	620,750	743,272

Other segment reporting as at 31 December 2017:

Investments in intangible assets	626	17,893			18,519
Investments in property, plant and equipment allocated to segments	62,825	1,415			64,240
Amortisation/depreciation of intangible and tangible assets allocated to segments	14,139	888			15,027

Assets and liabilities as at 31 December 2018

(In thousands of Euro)	Plasma derivatives	Plasma	Other activities	Unallocated	Consolidated
Operating assets	868,275	160,430	23,438	190,736	1,242,879
Liabilities from operations allocated to segments	87,337	79,912	3,711	688,418	859,376

Other segment reporting as at 31 December 2018:

Investments in intangible assets	325	44,226			44,551
Investments in property, plant and equipment allocated to segments	20,385	2,451			22,836
Amortisation/depreciation of intangible and tangible assets allocated to segments	13,954	1,830			15,784

6.6.2. RELATED PARTY TRANSACTIONS

The following tables provide details of economic and financial transactions with related parties, for the periods ended at December 31 2017 and 2018. The companies indicated were identified as related parties given their direct or indirect relationship to the shareholders of reference.

(In thousands of Euro)	Period Ended at 31.12.2017						
	Revenues	Cost of Sales	G&A	S&A	R&D	Other operating costs	Financial (expense) / income
Il Ciocco S.p.A.	0	77	399	31	63	1	0
Shaner Ciocco S.r.l.	1	10	65	54	8	10	0
Ancora S.r.l.	0	0	70	0	0	58	0
Fondazione Campus	0	0	437	40	78	0	0
Il Ciocco International Travel Service S.r.l.	1	0	1.025	33	0	0	0
Fondo Strategico Italiano S.p.A.	0	0	22	0	0	0	0
Maggio Re S.r.l.	0	0	718	87	118	0	0
Tecno Costruzioni S.r.l.	0	280	9	0	0	0	0
Tecno Immobiliare S.r.l.	0	45	16	0	0	105	0
Validations and Technical Serv. S.r.l.	0	592	54	0	15	0	0
Sestant S.p.A.	0	0	0	0	0	0	0
G.P.S. S.r.l.	0	1,995	833	0	27	27	0
Ai Piani S.r.l.	0	0	18	0	0	0	0
Paola Pardini	0	0	62	0	0	0	0
Wormser, Kiely, G & J LLP	0	0	24	0	0	0	0
Entegriion Inc.	446	0	0	0	0	0	0
TOTAL	448	3,000	3,752	245	309	200	0
Group Total	602,501	427,831	80,757	51,785	35,045	8,325	(41,797)
% incidence	0.1%	0.70%	4.6%	0.5%	0.9%	2.4%	0.0%

Period Ended at 31.12.2018

(In thousands of Euro)	Revenues	Cost of Sales	G&A	S&A	R&D	Other operating costs	Financial (expense) / income
Il Ciocco S.p.A.	0	92	295	42	10	6	0
Nuovi Orizzonti Srl	0	0	0	0	0	0	0
Shaner Ciocco S.r.l.	1	3	60	41	5	8	0
Ancora S.r.l.	0	0	68	0	3	68	0
San Quirico S.r.l.	0	0	96	0	0	0	0
Borgo Ai Conti Srl	0	0	75	0	0	0	0
Tissuelab Srl	7,598	0	0	609	0	0	0
Idrotherm 2000 Srl	0	0	0	0	7	0	0
Fondazione Campus	0	4	535	55	10	7	0
Il Ciocco International Travel Service S.r.l.	0	0	1,103	0	0	0	0
Fondo Strategico Italiano S.p.A.	0	0	26	0	0	0	0
Maggio Re S.r.l.	0	0	824	115	196	120	0
Tecno Costruzioni S.r.l.	0	271	5	0	0	0	0
Tecno Immobiliare S.r.l.	0	73	31	0	0	84	0
Validations and Technical Serv. S.r.l.	0	764	55	0	466	0	0
VTS USA inc.	0	20	0	0	0	0	0
Sestant S.p.A.	0	0	0	0	0	0	0
G.P.S. S.r.l.	0	2,139	693	34	90	76	0
Ai Piani S.r.l.	0	0	7	0	0	0	0
Paola Pardini	0	0	63	0	0	0	0
Refin srl	0	0	240	0	0	0	0
Remo Grassi	0	0	153	0	0	0	0
Entegriion Inc.	494	0	0	0	0	0	0
TOTAL	8,094	3,364	4,329	896	787	369	0
Group Total	687,939	518,482	83,659	46,314	48,127	8,286	(12,291)
% incidence	1.2%	0.6%	5.2%	1.9%	1.6%	4.4%	0.0%

31.12.2017

(In thousands of Euro)	Financial receivables	Receivables	Borrowings	Payables	CAPEX
Il Ciocco S.p.A.	120	0	0	125	0
Shaner Ciocco S.r.l.	0	1	0	40	0
Ancora S.r.l.	0	0	0	0	0
Fondazione Campus	0	0	0	161	0
Il Ciocco International Travel Service S.r.l.	0	4	0	223	0
Fondo Strategico Italiano S.p.A.	0	0	0	3	0
Maggio Re S.r.l.	58	0	0	0	93
Tecno Costruzioni S.r.l.	1	0	0	315	131
Tecno Immobiliare S.r.l.	41	0	0	0	0
Validations and Technical Serv. S.r.l.	0	0	0	387	220
Sestant S.p.A.	0	5,449	0	1,334	0
G.P.S. S.r.l.	0	0	0	390	0
Ai Piani S.r.l.	3	0	0	1	0
Paola Pardini	10	0	0	0	0
Wormser, Kiely, G & J LLP	0	0	0	10	0
Entegriion Inc.	0	125	0	0	0
TOTAL	233	5.579	0	2.989	443
Group Total	11,420	127,969	560,562	122,522	251,215
% incidence	2.0%	4.4%	0.0%	2.4%	0.2%

31.12.2018

(In thousands of Euro)	Financial receivables	Receivables	Borrowings	Payables	CAPEX
Il Ciocco S.p.A.	120	0	0	95	0
Nuovi Orizzonti Srl	0	0	0	0	0
Shaner Ciocco S.r.l.	0	1	0	17	0
Ancora S.r.l.	0	0	0	0	0
San Quirico Srl	0	0	0	0	0
Borgo Ai Conti Srl	0	0	0	0	0
Tissuelab Srl	0	3,745	0	380	200
Idrotherm 2000 Srl	0	0	0	5	0
Fondazione Campus	0	0	0	284	0
Il Ciocco International Travel Service S.r.l.	0	0	0	211	0
Fondo Strategico Italiano S.p.A.	0	0	0	8	0
Maggio Re S.r.l.	65	0	0	0	4
Tecno Costruzioni S.r.l.	1	0	0	134	281
Tecno Immobiliare S.r.l.	56	0	0	0	0
Validations and Technical Serv. S.r.l.	0	0	0	452	587
VTS USA inc.	0	0	0	0	0
Sestant S.p.A.	0	6,409	0	2,580	0
G.P.S. S.r.l.	0	0	0	460	0
Ai Piani S.r.l.	3	0	0	0	0
Paola Pardini	11	0	0	0	0
Refin srl	0	0	0	107	0
Remo Grassi	0	0	0	0	0
Entegriion Inc.	0	288	0	0	0
TOTAL	257	10,444	0	4,734	1,072
Group Total	10,837	106,154	623,558	170,959	349,368
% incidence	2.4%	9.8%	0.0%	2.8%	0.3%

In particular, at the end of 2018 the following details are provided for each related party:

- Il Ciocco: costs mainly relate to property leases for Euro 31 thousand, electricity supplies for Euro 83 thousand and natural gas for Euro 43 thousand, security and porter services for Euro 226 thousand. The payables are of a commercial nature and refer to the services indicated above.
- Nuovi Orizzonti: costs are related to franking services
- Shaner Ciocco: costs mainly relate to hotel and entertainment expenses for 116 thousand Euro. The payables are trade payables and relate to the above-mentioned services.
- Ancora: the costs relate to lease instalments on an office property in Rome for Euro 138 thousand.

- San Quirico: the costs relate to the rental of a property in London for Euro 96 thousand.
- Borgo Ai Conti: the costs relate to the rental of a building for office use in Lucca for Euro 75 thousand.
- Tissuelab: service costs for the marketing and distribution of recombinant factor VIII for Euro 609 thousand and sale of equipment for Euro 200 thousand.
- Idrotherm 2000: security expenses for Euro 7 thousand.
- Fondazione Campus Studi del Mediterraneo: costs refer to training courses for directors and middle management of Kedrion S.p.A., consulting, traslations, and language courses for Euro 611 thousand. The payables are trade payables and relate to the above-mentioned services.
- Il Ciocco Travel: the costs mainly relate to helicopter services for about Euro 800 thousand, hotel reservation services and transfers for a total of Euro 270 thousand, as well as to the management of the car park for Euro 28 thousand. Liabilities are of a commercial nature and refer to the above services. Revenues for Euro 0.5 thousand are due to payroll service. Loans are of a commercial nature and refer to the above-mentioned services;
- FSI S.p.A: the costs concern fees paid to directors;
- Maggio Re Srl: the costs relate to rents, for Euro 1,256 thousand, for the rental of some buildings for office use and capex for offices 12 high apartments for Euro 4 thousand;
- Tecno Costruzioni Srl: costs related to plant construction and maintenance for Euro 275 thousand and Euro 281 thousand for investments;
- Tecno Immobiliare Srl: costs relating to the lease of buildings for Euro 172 thousand;
- VTS Srl: costs are related to costs of approvals and maintenance of plants;
- VTS USA: costs relate to approvals and validations carried out at US plants;
- Sestant: Payables and receivables relate to the transfer of IRES debt and tax credits following the adoption of Tax Consolidation Financial Statements;
- GPS Srl: costs are mainly related to telecommunication services and consulting for 80 thousand Euro, cleaning costs for Euro 1,788 thousand, Canteen service for Euro 1.031 thousand, fuel for Euro 23 thousand and portorage for Euro 111 thousand;
- Ai Piani: costs relate to the rental of a building for office use for Euro 7 thousand;
- Paola Pardini: costs related to property rents for Euro 63 thousand;
- Refin: costs are mainly related to consulting services for Euro 240 thousand;
- Remo Grassi: costs are mainly related to administrator fees and professional appointments;
- Entegriion: revenues relatives to services for a development project.

The annual fees paid to managers with strategic responsibilities in 2018 amounted Euro 3,368 thousand, while those paid to the other members of the Marcucci family for professional services amounted to Euro 2,353 thousand.

6.6.3. ANNUAL FEES TO DIRECTORS, STATUTORY AUDITORS AND THE INDEPENDENT AUDITORS

DIRECTORS' FEES

NAME AND SURNAME	POSITION	FEES	BONUSES AND OTHER FEES	TOTAL FEES
Paolo Marcucci	Chairman and CEO	723,554	388,889	1,112,443
Rodolfo De Dominicis	Vice Chairman	203,554	2,000	205,554
Andrea Marcucci	Director	23,554	200,000	223,554
Marialina Marcucci	Director	23,554		23,554
Remo Grassi	Director	23,334	2,000	25,334
Guido Rivolta*	Director	23,554	2,000	25,554
Umberto Della Sala	Director	23,554		23,554
TOTAL		1,044,658	594,889	1,639,547

* Fees are paid directly to CDP Equity S.p.A.

BOARD OF STATUTORY AUDITORS

NAME AND SURNAME	POSITION	FEES	TOTAL FEES
Fabrizio Redaelli	Chairman	45,000	45,000
Francesco Cirillo	Regular auditor	35,000	35,000
Marco Miccinesi	Regular auditor	35,000	35,000
TOTAL		115,000	115,000

FEES OF INDEPENDENT AUDITORS EY S.P.A

(In thousands of Euro)	2018
Statutory audit of annual accounts	95
Audit of subsidiaries	162
Other certification services	34
Other services	231
TOTAL	522

6.6.4. FINANCIAL RISK MANAGEMENT

EXCHANGE RATE RISK

The Group is active internationally and is therefore exposed to the exchange risk deriving from the various currencies in which it operates. The exposure to exchange rate risk derives from commercial and financial transactions in currencies other than the accounting currency, mainly the US dollar and, to a lesser extent, the Hungarian forint.

The sensitivity analysis performed to assess the Group's exposure to currency risk was conducted by assuming reasonably possible changes in the exchange rates of the US dollar and the

Hungarian forint against the euro. The following tables show the impact on pre-tax income due to changes in the fair value of current assets and liabilities, of a commercial and financial nature, keeping all the other variables fixed.

Period Ending	Change in US Dollar	Effect on income before taxes (in thousand Euro)
31 December 2017	Write-up 10%	15,311
	Impairment 10%	(12,309)
31 December 2018	Write-up 10%	23,179
	Impairment 10%	(19,156)

Period Ending	Change in Hungarian Forint	Effect on income before taxes (in thousand Euro)
31 December 2017	Write-up 10%	4,984
	Impairment 10%	(4,070)
31 December 2018	Write-up 10%	5,183
	Impairment 10%	(4,241)

There were no direct effects on shareholders' equity in that the Group had no exchange rate hedges in place at the end of the year.

INTEREST RATE RISK

Market risk is the risk that changes in interest rates will negatively affect the value of assets and liabilities. Part of the Group's portfolio of payables is exposed to changes in market interest rates. Changes in interest rates do not typically have significant effects on the fair market value of borrowings, but they could have significant effects on the operating result, business activities, financial conditions or the Group's outlooks.

Floating-rate debts expose the Group to a risk arising from the volatility of interest rates. With regard to this risk, for the purposes of the relative hedging, Kedrion has used interest rate swaps (IRS), which transform the floating rate into a fixed rate.

Kedrion has two fixed rate bonds of Euro 58 and Euro 350 million and two revolving credit facilities of Euro 158 and Euro 30 million at floating rates, both fully hedged with interest rate swaps, until April 2019 the first and until 2022 the second, which constitute the majority of medium-long term financial debts. The interest rate risk to which the Group is exposed is therefore today limited mainly to short-term loans. Kedrion Group monitors financial market conditions on interest rates in order to assess opportunities for hedging to further reduce risk exposure.

The table below shows the situation with regard to the type of hedging transaction carried out and the outcome of the same as at 31 December 2018:

Type	Debtor rate (fixed)	Creditor rate (variable)	Initial date	Maturity date	Notional capital (Euro)	Fair value 31.12.2018 (Euro)
Fixed for Floating Interest Rate Swaps	0.05%	Euribor 1 month	04.04.2016	24.04.2019	158,303,789	(156,298)
Fixed for Floating Interest Rate Swap	0.39%	Euribor 6 months	17.01.2018	01.04.2022	30,000,000	(520,213)
Fixed for Floating Interest Rate Swap	0.30%	Euribor 1 months	24.04.2019	22.04.2022	15,000,000	(201,070)

Derivative instruments have been designated as cash flow hedge instruments and have direct impacts on equity.

The analysis of the table below is conducted with reference to reasonable potential changes in the key variables (Euribor), keeping all other variables unchanged, and shows the impact on income before taxes and on equity due to changes in the fair value of the financial instrument (IRS) outstanding at the end of the financial year as at 31 December 2018:

(In thousands of Euro)	Effect on the result before taxes	Effect on equity
+ 100 basis points	0	1,897
- 50 basis points	0	(971)

LIQUIDITY RISK

The Group manages liquidity risk by means of strict control of the elements making up the net working capital. In addition, the Group does not make full use of the credit lines granted by banks. At December 31, 2018, the Group had available and unused credit lines of Euro 135.2 million, of which more than 40% is short-term.

In order to make cash flow management more efficient, avoiding the dispersion of liquidity and minimizing financial charges, the Group has also adopted concentration and centralized management of the liquidity of the main Group companies (cash pooling) on the Kedrion S.p.A

(In thousands of Euro)	On demand	Less than 3 months	From 3 to 12 months	From 1 to 5 years	> 5 years	Total
Financing and loans	33,121	19,086	80,705	490,645	0	623,557
Trade payables and other payables	51,114	32,441	135,035	2	0	218,591
TOTAL	84,235	51,527	215,739	490,647	0	842,148

For more details on the maturity analysis of the medium-long term debt, refer to note 6.4.19.

CREDIT RISK

Most of the Group's trade receivables are due from Italian hospital authorities and other public authorities, whose credit rating is considered to be reasonably sound. The Group has in fact never recorded credit losses with this type of customer, with the exception of the renunciation of default interest. Likewise, even receivables from US customers, given the very short payment terms and the financial soundness shown by the customers themselves, are considered to be reasonably certain and solvent. Residual receivables are mainly due from foreign customers (Middle East,

Asia, Africa and South America) with consolidated knowledge and long-term partnerships, while in the case of new business relationships, particularly in new markets, coverage with letters of credit or other guarantees is generally required. Furthermore, all receivables are constantly monitored by a recently implemented dedicated central structure capable of preventing exposures that are not in line with Group policies, for example unauthorised shipments during overdue positions or in excess of commercial credit granted.. The Group therefore believes that it does not have to implement specific credit risk management policies, given the low risk of insolvency of its customers.

CAPITAL MANAGEMENT POLICY

The primary objective of the Group's capital management is to guarantee that capital indicators are maintained at sufficient levels in order to support business activities. The Group manages and modifies the capital structure according to changes in economic conditions. To maintain or adjust the capital structure, the Group can adjust dividends paid to shareholders, repay the capital or issue new shares.

The Group controls its capital by means of a debt/capital ratio, namely the ratio between net debt and total capital plus the net financial position. For more information on financial debt and the debt/equity ratio, refer to the Report on Operations.

FINANCIAL ASSETS AND LIABILITIES

All the Group's financial instruments are entered in the financial statements at carrying amount, with the latter being equal to fair value.

6.6.5. COMMITMENTS AND RISKS

This item includes sureties, guarantees and third party assets held by the Group. For the years ended 31 December 2018 and 2017, the item is summarised as follows:

(In thousands of Euro)	Period Ended at 31 December	
	2018	2017
Risks	49,320	40,286
- Sureties	38,688	35,226
- Guarantees	10,632	5,463
Third party assets held by the Group	24,391	40,286
TOTAL	73,711	75,376

RISKS

As at 31 December 2018, risks comprised sureties provided for taking part in public tenders for a total of Euro 17,881 thousand and other insurance guarantees issued in favour of public authorities for Euro 17,345 thousand. Endorsement guarantees have been issued to support foreign commercial activities, mainly for supply and lease contracts.

THIRD PARTY ASSETS HELD BY THE GROUP

These refer entirely to third party assets held by the Group mainly for the Italian plasma processing activities performed by Kedrion on behalf of the Regional Authorities.

COMMITMENTS

Commitments from operating leases:

The Group has entered into commercial lease contracts for several vehicles and machines. These leases have an average life of three to five years, with no renewal clauses. The stipulation of these contracts has not resulted in restrictions for the Group.

Future lease payments for non-terminable operating leases, including leases, outstanding at December 31 are as follows:

(In thousands of Euro)	31 December 2018
Within 12 months	2,907
Over one year but within 5 years	31,177
Over 5 years	39,122
TOTAL	73,206

Financial leases and commitments to purchase:

The Group has entered into finance leases and commitments to purchase on various plants and machinery. These leases include renewal clauses but not options to purchase or clauses setting out revaluation of the rental. Renewal may occur based on the intention of the lessee company. The table below breaks down the amounts of future rentals from finance leases and rental contracts, and the present value of the rentals:

(In thousands of Euro)	2018		2017	
	Minimum payments	Present value of payments	Minimum payments	Present value of payments
Within 12 months	6,761	6,759	6,565	6,564
Over one year but within 5 years	7,150	7,144	10,750	10,741
Over 5 years	0	0	0	0
Total minimum payments (net of interest)	13,911		17,315	
Present value of lease rentals		13,903		17,305

6.6.6. DIVIDEND POLICY

Pursuant to Article 30.3 of the Bylaws of Kedrion S.p.A, the net profits resulting from the financial statements duly approved by the Shareholders' Meeting will be broken down as follows: a) at least 5% to the legal reserve fund until it has reached the fifth of the share capital; b) not less than 50% as a distribution of dividends after the Shareholders' Meeting resolution and subject to verification by the Board of Directors in compliance with any contractual restrictions.

6.6.7. SUBSEQUENT EVENTS

KEDPLASMA LLC acquired two new centers (Hickory and Anderson) from Immunotek Biocenters LLC, the transfer of which was completed in early January 2019 for the Hickory centre, and on 4 March 2019 for Anderson. Also in March, a contract was signed with the German company Haema AG for the sale of the four German plasma collection centers. With these transactions, the total number of plasma collection centers owned by the Kedrion Group is 25.

In January 2019, the FDA approved the IND (Investigational New Drug) application for the development of KIG10. From this date Kedrion is authorized to start clinical trials. Currently, production for clinical studies is carried out in the Godollo plant and then, once these studies have been completed, in the Castelveccchio plant (purification phase, while fractionation is carried out in the Melville plant).

In February 2019, following the inspection in August 2018, the FDA reactivated the authorization of the Melville fractionation plant for the production of the intermediates Fraction II+III, Fraction V and Cryo Paste.

On March 19, 2019, the FDA approved the new RhoGAM product filling and packaging line at the Melville plant.

None of these events has an impact on the 2018 budget.

6.6.8. DISCLOSURE PURSUANT TO LAW 124/2017

The following table shows the public grants received by the Parent Company in 2018:

Receiving Body	Granting Body	Amount Received 2018	Collection date	Causal
Kedrion S.p.A C.F. 01779530466	MIUR	307,863	27/09/2018	PON R&C 2007-2013 DECRETO DIRETTORIALE PROTOCOLLO N. 1_RIC 18- 01-2010 PON01-01426F
Kedrion S.p.A C.F. 01779530466	MIUR	190,793	18/12/2018	PON R&C 2007-2013 DECRETO DIRETTORIALE PROTOCOLLO N. 1_FOR_18- 01-2010 PON01-01426F
Kedrion S.p.A C.F. 01779530466	MIUR	646,676	09/08/2018	GPS DECRETTO MINISTERIALE 28896
Kedrion S.p.A C.F. 01779530466	Regione Toscana	314,583	31/12/2018	POR FESR 2014-2020 BANDI R&S 2017 BANDO 1

Castelveccchio Pascoli, 29 March 2019

On behalf of the Board of Directors
The Chairman
Paolo Marcucci

KEDRION
BIOPHARMA

