Mabion S.A.
Directors' Report for the year 2016

Konstantynów Łódzki, 25 April 2017

MABION S.A.
Directors' Report
for the year 2016

Contents:

1 ORGANIZATION OF MABION S.A.

1.1 Basic information about the Company

Mabion S.A. was established on 29 October 2009 as a result of transforming Mabion spółka z ograniczoną odpowiedzialnością (a limited liability company) with its registered office in Kutno, registered on 30 May 2007, into a joint-stock company.

Currently, Mabion S.A. is registered in the Register of Businesses of the National Court Register maintained by the District Court for Łódź-Śródmieście in Łódź, 20th Business Department of the National Court Register, with the reference number KRS 0000340462.

The Company was assigned a tax identification number NIP: 7752561383 and a REGON statistical identification number: 100343056.

Contact details

Company name:	Mabion Spółka Akcyjna
Registered office:	Konstantynów Łódzki
Address:	ul. gen. Mariana Langiewicza 60, 95-050 Konstantynów Łódzki
Telecommunication numbers:	tel. (+48 42) 207 78 90
	fax (+48 42) 203 27 03
E-mail address:	info@mabion.eu
Website:	www.mabion.eu

1.2 Branches

The Company has no isolated branches within the meaning of the Accounting Act.

Currently, the Company has two centres (plants) – Centrum Badawczo-Rozwojowe (CBR[1]– a research and development centre) in Łódź, ul. Fabryczna 17, and Kompleks Naukowo-Przemysłowy Biotechnologii Medycznej (a medical biotechnology scientific and industrial complex) in Konstantynów Łódzki, ul. Langiewicza 60, which is also the Company's statutory registered office.

1.3 Changes in the Company's management

Mr Maciej Wieczorek, who had been Chairman of the Management Board, resigned from the job and from the Management Board, as of 14 December 2016. On the same date, the Company's Supervisory Board passed a resolution appointing Mr Artur Chabowski Chairman of the Management Board as of 14 December 2016.

Due to the above change to the composition of the Management Board, the tasks and responsibilities of the management body were reorganized. The current scope of responsibilities of particular Board members are shown in the schedule below (Table 2):

Table 2. Current scope of responsibilities of the Management Board of Mabion S.A.

Chairman of the Board Artur Chabowski	**Responsible for supervision over:** • initiating, developing and updating the Company's strategy; • comprehensive risk management at the Company's corporate level; • fulfilling formal information and publication duties in the scope required by law; • performing communication and image-related actions; • developing human resources policies; • developing the Company's resources base and complying with innovation policies; • administration; • the Company's finances and accounting; • acquiring strategic partners for the Company.

[1] Proper name.

Management Board Member Jarosław Walczak	**Responsible for supervision over:** • pharmaceutical regulations governing the Company; • clinical trial regulations; • registering drugs.
Management Board Member Sławomir Jaros	**Responsible for supervision over and management of:** • research and development – designing drugs, developing technology, developing analyses, technological platforms; • manufacture, controlling and ensuring quality, and implementing technological and analytical processes in the pharmaceutical environment; increasing the scale of processes, quality, time and cost optimization of processes;clinical trials – operational and scientific management; support of internal processes related to clinical trials; • safety at work and control over pharmaceutical risk; • operational management – including cooperating with external partners regarding technology, science and commerce; • integration between areas – drawing up a development strategy for new products and technologies in a manner enabling their implementation in pharmaceutical industry; compatibility of scientific, technological and analytical processes; integration of the work of particular departments.

1.4 Organizational or equity relationships

Mabion S.A. does not own any shares in any entities, there are no circumstances which could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1. 4) of the Commercial Companies Code.

The Company is not held directly or indirectly by any other entity. According to the Company's best knowledge, there are no entities which would meet the premises of the definition of the Company's parent pursuant to Article 4. 14) of the Act on Public Offerings and the terms for introducing financial instruments to the regulated market, and on public companies (the Act on Public Offerings) and of the definition of the Company's parent pursuant to Article 4 § 1. 4) of the Commercial Companies Code. Furthermore, according to the Company's best knowledge, the shareholders and members of the Company's authorities are not connected by the agreement referred to in Article 87. 1. 5), Article 87. 4 of the Act on Public Offerings. Significant shareholders have no voting rights other than those following from the shares held.

2 OPERATIONS OF MABION S.A.

2.1 Schedule

January	On 8 January 2016 the Company received a decision from the Chief Pharmaceutical Inspector dated 31 December 2015 issuing a permit to Mabion S.A. for "Manufacturing the researched medicinal product" in the scientific and industrial medical biotechnology complex – Kompleks Naukowo-Przemysłowy Biotechnologii Medycznej Mabion S.A. in Konstantynów Łódzki. The permit of the Chief Pharmaceutical Inspector was necessary to begin the process of manufacturing drugs in the Complex in Konstantynów Łódzki.
February	On 5 February 2016 the Management Board of Mabion S.A. received a post-inspection report following the inspection which took place on 3 February 2016 and related to meeting the condition for obtaining the permit for operating in the area of the Łódź Special Economic Zone in the research and development centre for biotechnological medicinal products – Centrum Badawczo -Rozwojowe Biotechnologicznych Produktów Leczniczych. Based on the inspection actions conducted, it was determined that the condition for granting the permit with respect to incurring qualified expenditure of at least PLN 20 million within the Zone – in Centrum Badawczo -Rozwojowe Biotechnologicznych Produktów Leczniczych located in Łódź, ul. Fabryczna 17, in the Łódź SEZ, Subzone Łódź, Complex 10 – was met.

April	On 22 April 2016 the Management Board of Mabion S.A. received information on the District Court for Łódź-Śródmieście in Łódź, 20th Business Department of the National Court Register registering an increase in the Company's share capital and amendments to the Company's Articles of Association on 21.04.2016. The Company's share capital was increased from PLN 1,116,000 to PLN 1,150,000 as a result of the issue of 340,000 ordinary bearer N-series shares with a nominal value of PLN 0.10 each. After registration of the said change in the share capital, the Company's share capital amounted to PLN 1,150,000 and consisted of 11,500,000 shares with a par value of PLN 0.10 each.
May	Between 9 and 10 May 2016 the Company participated in Bioforum Central Europe. On 16 May 2016 Mabion had a presentation at the second Polish Capital Markets Conference organized by the Warsaw Stock Exchange, IPOPEMA Securities and Auerbach Grayson in New York. The purpose of the conference was to promote Polish companies and the Polish market among the US extensive investment institutions market. On 23 May 2016, the Company's Management Board passed a resolution on increasing the Company's share capital to reach the target amount by way of issuing O-series shares without pre-emptive rights. On 24 May 2016 agreements were concluded for subscribing ordinary O-series shares, based on which Twiti Investments Ltd. – a company controlled in 50% by a Member of the Supervisory Board of the Company, Mr Robert Aleksandrowicz, took up 200,000 shares for a total amount of PLN 9.4 million, and Glatton Sp. z o.o.– a company controlled 100% by the Chairman of the Management Board Mr Maciej Wieczorek, took up 100,000 shares for a total of PLN 4.7 million.
June	The Company's Ordinary General Shareholders' Meeting passed a resolution on transferring the Company's registered office from Kutno to Konstantynów Łódzki. On 21 June 2016 the Company's Management Board informed of the current status of clinical trials of MabionCD20 drug and of the progress in negotiations with the potential partners. As at 20 June 2016 the number of patients increased after the first dose of the drug in both trials. The Company's Management Board additionally informed that negotiations are advanced with three entities with global experience in the sale, distribution and assessment of biosimilar drugs who may potentially become the Company's partners in selling and distributing MabionCD20 in the European Union.
July	On 4 July 2016 the Management Board of Mabion S.A. received information on the Registration Court for Łódź-Śródmieście in Łódź, 20th Business Department of the National Court Register registering an increase in the Company's share capital. The Company's share capital was increased from PLN 1,150,000 to PLN 1,180,000 as a result of the issue of 300,000 ordinary bearer O-series shares with a nominal value of PLN 0.10 each. After registration of the said change, the Company's share capital amounted to PLN 1,180,000 and consisted of 11,800,000 shares with a par value of PLN 0.10 each. On 15 July 2016 the Management Board of Mabion S.A. decided to limit the number of new patients from the sub-group PK/PD to be included in the clinical trial of MabionCD20 in respect of Rheumatoid Arthritis (RA). On 29 July 2016 the change in the Company's registered office from Kutno to Konstantynów Łódzki was registered with the Registration Court.
August	On 8 August 2016 the Management Board of Mabion S.A., after analysing the report "Analysis of the number of patient populations that may be qualified for PK analyses in the MABRA PK/PD trial" passed a resolution on ending the recruitment of patients for the sub-trial MabionCD20 RZS – PK/PD.

September	On 30 September 2016 the Company's Management Board passed a resolution on discontinuing to accept patients for screening-diagnostics qualifying them to participate in the MabionCD20 RZS trial.
October	On 6 October 2016 the Company participated in the conference "Łódź – City to Explore" organized by Hanna Zdanowska – Mayor of the City of Łódź. Between 6 and 7 October 2016 the Company was present at the International Bioeconomy Congress in Łódź. On 12 October 2016 representatives of Mabion S.A. signed a contract with the Faculty of Biotechnology and Food Sciences of the Łódź University of Technology. On 13 October 2016 the fourth scientific consultations were held with the European Medicines Agency "Follow-up Scientific Advice Rituximab – MabionCD20" relating to the drug development program, in particular analyses of biosimilarity (MabionCD20 vs. MabThera) and a program of clinical trials.
November	On 8 November 2016 Mabion S.A. signed a long-term cooperation agreement with Mylan Ireland, a 100% subsidiary of Mylan N.V. – a lead global pharmaceutical company. The agreement provides for Mylan to hold exclusive rights to the sale of MabionCD20 – an oncological drug similar to the preparation MabThera/Rituximab in all European Union and Balkan states. Additionally, based on the agreement, Mylan will support the Company in the process of registering the MabionCD20 drug by the European Medicines Agency.
December	On 14 December 2016 Mr Maciej Wieczorek, who had been Chairman of the Management Board, resigned from the job and from the Management Board. On 14 December 2016, the Company's Supervisory Board appointed Mr Artur Chabowski Chairman of the Management Board. On 22 December 2016 the independent commission of DSMB (Data and Safety Monitoring Board), which supervises the course of the clinical trial and the safety of patients with Rheumatoid Arthritis participating in the comparative research of MabionCD20 vs. the reference product MabThera, met for the sixth time. After assessing the reports on the overall course of the clinical trial and other data presented on the safety and effectiveness of the therapy, the DSMB Committee positively assessed the trial recommending its further conduct without the need to introduce any changes to the clinical trial protocol.

2.2 Market Environment

Mabion engages in developing and preparing the newest generation of biotechnological drugs based on the monoclonal antibodies technology for commercialization. The technology constitutes the present day basis for combatting various types of conditions, mainly tumours, thanks to two exceptional characteristics – their specificity and safety. The drugs developed by the Company are targeted therapeutics characterized by their ability to recognize a factor – such as a receptor – whose excessive expression is related to the development of the tumour and reacting exclusively with the tumour. Appropriate engineering of the structure of such drugs and in consequence, their high similarity to the patients' bodily proteins causes the immunological system to treat the therapeutical antibody as its own protein. This guarantees low toxicity of the therapies developed by the Company and is a great benefit to the patient.

Currently, Mabion's product at the latest stages of development is a biosimilar drug MabionCD20, a referential to MabThera/Rituxan (Roche), currently in Phase III of clinical development.

Monoclonal antibodies

Monoclonal antibodies (mAb) are some of the most important tools in modern medicine, which have conditioned and continue to condition its fast development. The use of antibodies comprises a wide range of laboratory diagnostic aspects and therapy of tumours and autoimmunological diseases. The usage spectrum expands in line with the development of biotechnology and molecular biology techniques. Currently, mAb are used in over thirty therapies, and many others are at the clinical trial phase.

A drug such as Rituximab [Rituxan] is an example of using mAb as anti-cancer drugs – it is an antibody aimed at the CD20 antigen of B lymphocytes, approved for treatment of B-type non-Hodgkin lymphomas in 1997 and Trastuzumab [Herceptin] – an antibody registered in 1998 which is applied in the treatment of metastatic breast cancer.[2]

The sale of drugs based on monoclonal antibodies is characterized by growth dynamics which significantly exceed the growth dynamics of all other biotechnological drugs. Based on analyses of this market, it is assumed that the trend will be maintained.

The monoclonal antibody market was valued at USD 85.4 billion in 2015 and is expected to achieve a value of USD 138.6 billion by 2024.[3] The growing demand for personalized medicine is a material factor responsible for the growth of therapeutic antibodies which may be applied in targeted therapies. Furthermore, the application of monoclonal antibodies for therapeutical purposes brings about such benefits as reduction in side effects, uniformity, specificity and possibility of production on a large scale, which translates into a significant market increase.[4]

Data shows that for many years some of the leading medicines have been drugs on which Mabion has been working.

Table 3. Pharmaceutical products by revenue in 2016 – EP Vantage 2016 [5]

1.	Humira (adalimumab) - $15.7B
2.	Harvoni (ledipasvir/sofosbuvir) - $11.6B
3.	**Rituxan (rituximab) - $7.3B**
4.	Avastin (bevacizumab) - $7.0B
5.	Lantus (insulin glargine) - $6.9B
6.	Herceptin (trastuzumab) - $6.8B
7.	Revlimid (lenalidomide) - $6.7B
8.	Prevnar 13 (pneumococcal 13-valent conjugate vaccine) - $6.1B
9.	Remicade (infliximab) - $5.8B
10.	Advair (fluticasone/salmeterol) - $5B

In its annual report for 2016, Roche states that in that year the average increase in sales of MabThera/ Rituxan was 3%. This drug's sales are increasing despite competitive pressure which is related to increased demand for the drug in China, USA and in Europe.[6]

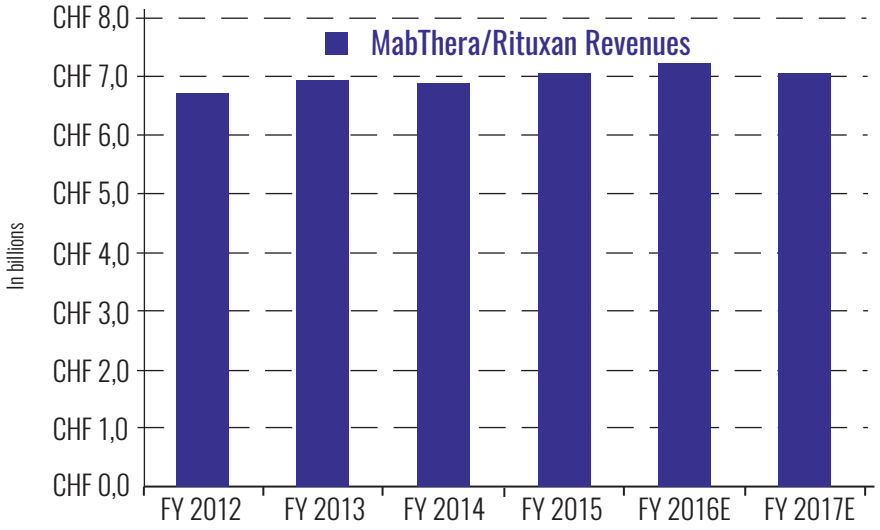
In accordance with the data included in the annual reports of Roche, in the past few years, the value of MabThera/Rituxan global sales increased from USD 4.8 billion in 2006 to USD 7.22 billion in 2016[7].

2 Przeciwciała monoklonalne – zastosowanie w medycynie, http://www.pfb.info.pl/files/kwartalnik/2_2009/08.%20Zielinski.pdf
3 http://www.grandviewresearch.com/press-release/global-monoclonal-antibodies-market
4 http://www.grandviewresearch.com/press-release/global-monoclonal-antibodies-market
5 https://www.drugs.com/slideshow/looking-ahead-pharma-projections-for-2016-and-beyond-1230
6 Annual Report 2016, Roche, http://www.roche.com/dam/jcr:ee2f197f-5487-4629-9e28-66b77c9cbbab/en/ar16e.pdf
7 Ibid.

Table 4. Global sales of MabThery (source: Roche Finance report, 2016).

(USD m) 2016	(USD m) 2015	% change (CER)	% of sales (2016)	% of sales (2015)
MabThera/Rituxan in oncology				
5,76	5,58	+2	15	15
MabThera/Rituxan in immunology				
1,46	1,39	+5	4	4

Table 5. Sales of MabThery in particular years (source: http://marketrealist.com/2016/03/will-gazyva-able-replace-roches-mabthera/)



Source: Roche Filings, WallStreet Estimates

Prospects of the biosimilar drugs market

Analysing demand for biosimilars, including oncological drugs, demographic, civilization and market factors should be taken into consideration first and foremost.

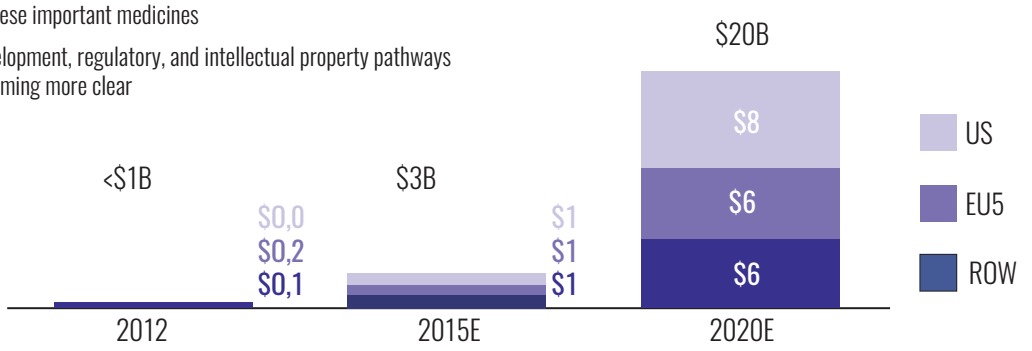
In consequence of the ageing of the population and the growing risk of contracting cancer with age (over 2/3 of cancer cases are diagnosed in persons aged 65 and above), the demand for oncological drugs is expected to grow. The forecasts of the World Health Organization (WHO) show that over the next 15–20 years, the number of new cancer cases globally will double. The World Cancer Report forecasts that in 2025 the number of new cancer cases will increase from 14.1 million to 19.3 million a year, in 2030 – to 22 million and in 2035 – to as many as 24 million.[8]

New "Global Biosimilar Market Outlook 2020" research conducted by RNCOS discloses that the market of biosimilars which was worth USD 1.89 billion in 2014 should reach a value of USD 25.53 billion by 2020, showing an imposing annual growth rate of 54.4%.[9] Although the sector of biosimilars is developing rapidly, and some of them have already been admitted to trading in the EU and USA, it is only the beginning of the development path, as the evolution of the regulations of the market show.

[8] http://www.uicc.org/wcd-report
[9] http://www.insightpharmareports.com/Affiliated-Reports/RNCOS/Global-Biosimilar-Market-Outlook-2020/

Table 7. Biosimilars – an attractive market.

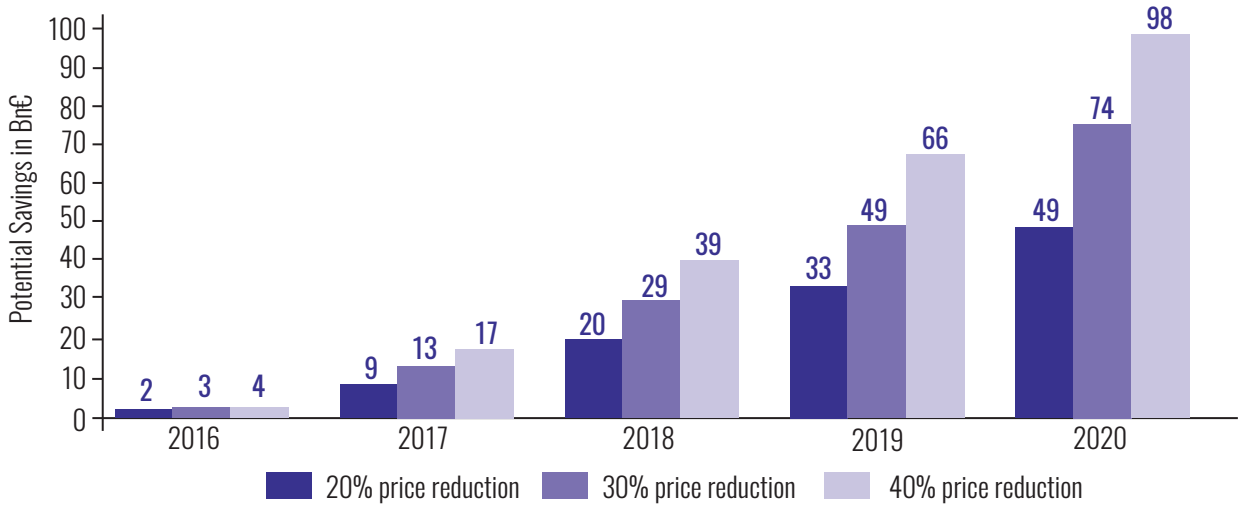
- >$100B of biologics lose patent protection in next 5-10 years
- Biosimilars are the potential lever to provide savings and efficiencies to healthcare systems as well as to expand access in many markets to these important medicines
- Development, regulatory, and intellectual property pathways becoming more clear



Source: Decisions Resources 2012 for US/EU5. RoW based on assumed 30% of worldwide total

Biosimilars are cheaper equivalents of reference drugs, which on the demand side, allows both replacing the current drugs with their equivalents and covering a larger group of patients with treatment. The coincidence of the end of the patent protection period of the reference drug group will lead to increased dynamics in the growth trends in the biosimilars demand segment. Additionally, the appearance of biosimilars on the market gives patients and doctors access to modern treatment both directly and indirectly, as due to its cost-effectiveness they release funds which may be used on research and development of further methods. According to IMS in Europe alone biosimilars will allow savings of USD 110 billion in 2020.[10]

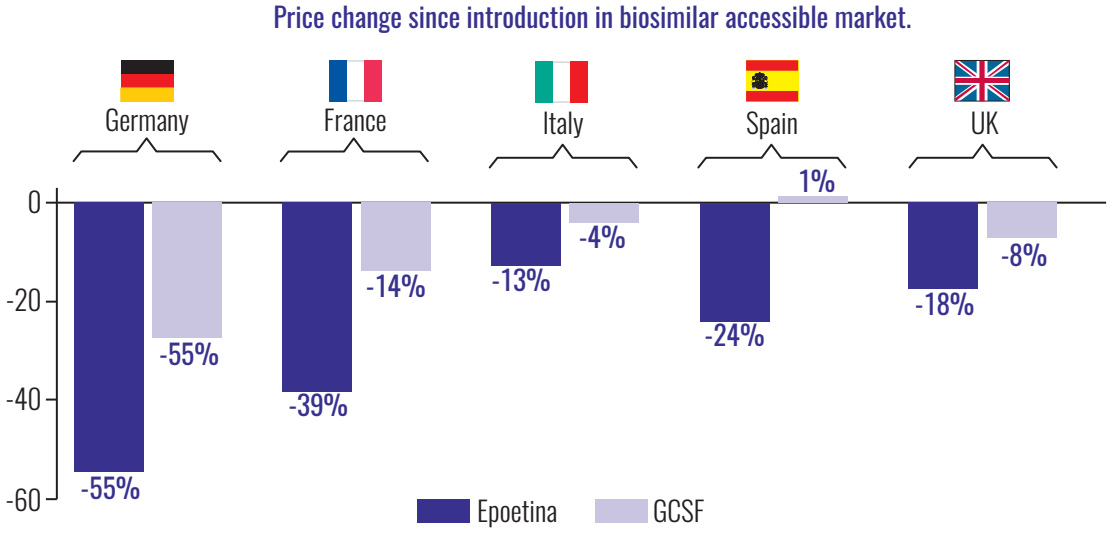
Table 8. Potential savings of healthcare systems in the EU and USA resulting from the introduction of biosimilars.[11]



Source: IMS Health, MIDAS, IMS Health Market Prognosis; IMS Institute for Healthcare Informatics, Dec 2015

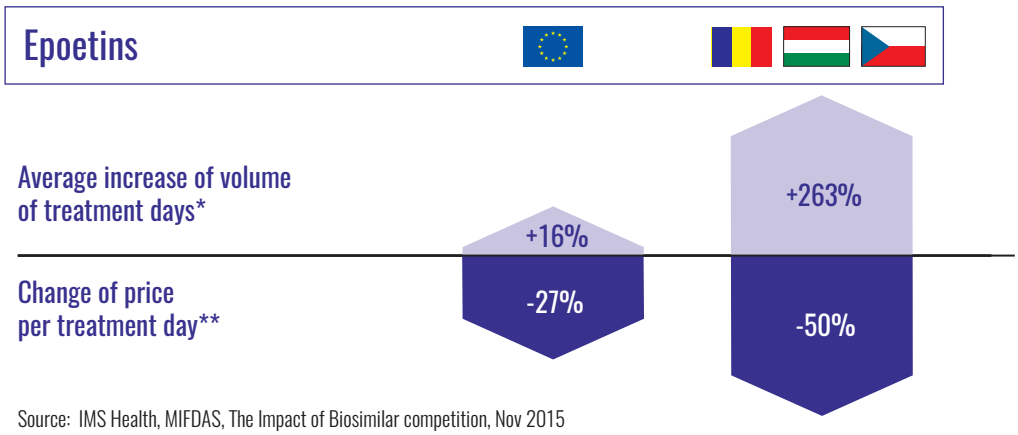
[10] http://www.insightpharmareports.com/Affiliated-Reports/RNCOS/Global-Biosimilar-Market-Outlook-2020/
[11] http://www.raps.org/Regulatory-Focus/News/2016/03/29/24671/IMS-Biosimilars-Could-Save-Up-to-110B-in-EU-US-Through-2020/

Table 9. Long-term erosion of prices after introducing biosimilars[12].



Source: IMS Health, The Impact of Biosimilar Competition, Nov 2015
Note: Analysis based on publicity available prices

Table 10. Price erosion vs volume increases.[13]



Source: IMS Health, MIFDAS, The Impact of Biosimilar competition, Nov 2015
Notes: Pricing and discounts: the report is based on publically available prices. Discounts occurs, especially in contracting with hospitals and in countries using tenders for biological drug procurement with lead to larger price fluctuations than is visible through the reported IMS Health data.
* Change of volume of treatment days in total market between launch and 2014
** Change of price per treatment day in total market between launch and 2014

In accordance with IMS Health analyses, areas in which the biosimilars developed by Mabion will be used rank highest among the leading classes of therapeutical drugs on a global scale:

» Oncology – treatment of cancer will remain the key area.
» Autoimmunological diseases, including Rheumatoid Arthritis. Analysts of Decision Resources estimate that the global market for the preparations used in joint inflammation therapies will note an increase to approx. USD 15.2 billion by 2021. The increase in drugs for Rheumatoid Arthritis in the period 2016–2020 is expected to grow by approx. 3.4%.

It should be noted that the demand for drugs used in oncology and in autoimmunological diseases is limited by the financial capabilities of domestic healthcare systems. The appearance of new and cheaper solutions will have a two-way impact on the increase in demand, both by treating patients who cannot afford treatment and by the possibility of treating patients who react badly to less safe treatments.

[12] Ibid.
[13] Ibid..

The situation in Poland where expenses on drugs comprise over 25% of total expenses on healthcare is an important example of the indirect impact of new products on demand in a given segment. Insufficient financing of the healthcare system is the main barrier which limits patient access not only to drugs, but also to medical services. The cost of refunding MabThera by the National Health Fund (NFZ) is one of the largest budget expenses. In 2016 it amounted to over PLN 180 million (based on data published by the NFZ head office on 24.01.2017[14]). The introduction of the biosimilar drug MabionCD20 could allow a wider group of patients to benefit from therapy due to the lower price.

To summarize, demand for the biosimilar drug MabionCD20 is huge, and launching it on the market will result in a revolution in the oncological treatment segment.

According to the guidelines for the development of biosimilars issued by EMA and FDA, to be admitted to the market as a biosimilar, the drug's registration documentation should include the results of clinical trials which have been designed and completed based on "equivalence", i.e. proving equivalence between the candidate for the biosimilar drug and the reference drug. In practice this means that two thresholds are required in a clinical trial – the floor, below which the drug would be considered "worse" and the cap, above which the drug would be considered "better". In terms of clinical properties, a biosimilar drug must be between the floor and the cap; it cannot be "better" or "worse". This requires a large number of patients in each trial. Clinical trials of the biosimilar rituximab are conducted in two different populations – patients with Rheumatoid Arthritis (RA) or those with blood cancer in the form of a lymphoma. RA patients are a more uniform population and are a more clinically sensitive model, therefore, the statistical inference will be higher in this population.

In accordance with information provided by Quintiles IMS in 2016, it is expected that global expenses on prescription drugs will reach a level of USD 1.5 billion by 2021.[15] The annual rate of growth of those expenses during the next five years is forecast to be 4–7%, mainly due to new oncological drugs, drugs for diabetes and autoimmunological diseases, sold on the developed markets.[16]

2.3 Regulatory environment

All around the world, registration standards for biosimilars are complex and very demanding. Restrictive quality, safety and efficacy criteria are required by regulators in highly regulated markets (e.g. Europe, the United States, Japan, Canada). Companies which intend to register a medicine in a regulated market must present detailed product characteristics (physiochemical and biological analyses), toxicological (animal testing), and clinical data, including pharmacokinetic and pharmacodynamic analyses of a biosimilar and its reference medicine in order to demonstrate that there are no significant clinical differences between them. Therefore, given that biosimilars must imitate the effects of the original medicine, clinical trial requirements will differ from those for innovative biological medicines.

On the one hand, phase 2 of clinical trials intended to determine the effective dosage is not necessary in the development of biosimilars, as the appropriate reference dosage is already known. On the other hand, a clinical data package is smaller than for an innovative medicine, therefore all the data taken together, including an extensive set of analytical data, is key to demonstrating a high similarity to the reference medicine.

Regulatory agencies may register the given medicine for the indications analysed during the clinical trials (US and Canada) or for all the indications authorized for the reference medicine (EU).

On 1 July 2015, a revision of the EMA Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues came into effect, comprising regulations for biosimilar biotechnological medicines took effect, concerning:

» non-clinical in-vitro and in-vivo testing;
» clinical pharmacokinetic and pharmacodynamic trials;
» clinical trials of safety and efficacy.

Such regulations focus on the need to demonstrate the biosimilarity of the product developed to the original medicine.

[14] http://www.nfz.gov.pl/aktualnosci/aktualnosci-centrali/komunikat-dgl,6958.html
[15] http://www.reuters.com/article/us-health-pharmaceuticals-spending-idUSKBN13V0CB
[16] Ibid.

The United States Federal Drug Administration (FDA) is the equivalent of the EMA in the United States and it is responsible for marketing authorization decisions for medicinal products. On 28 April 2015, the following guidelines were issued: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product and Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product. The former guideline comprises the qualitative data and the scientific basis for analyses of the structure, functions, toxicity for animal models, pharmacokinetics, pharmacodynamics of immunogeneity, and safety and efficacy. It also comprises the proposed approach to data obtained for a non-US reference product.

Whereas, the latter guideline comprises guidelines for analytical studies used for characterization purposes, identifying similarity to a reference product, and concerning viral safety and control of the production process, and specifications.

Two guidelines involving the CTD (Common Technical Document) also took effect in 2016: ICH HARMONISED GUIDELINE - Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use M4 and Harmonised Technical Guidance for eCTD Submissions in the EU.

One guideline mainly addresses the organization of the information to be provided in registration documentation for pharmaceutical products (including biotechnological products).

The other one addresses electronic Common Technical Document (eCTD) submissions for all medicinal products lying within the authority of national competition protection institutions in the EEA, and the EMA.

Pharmaemerging countries, e.g. China, Brazil, India, Russia, Mexico, Turkey and South Korea, and other countries of the world, have developed or are developing their own legal regulations setting forth the biosimilar registration conditions. Such legal regulations are often imprecise; the very definition of biosimilars is imprecise as well. Unclear legal regulations and insufficient patent protection in many pharmaemerging countries are to blame for the fact that products similar to patented original medicines have already been registered in those markets. India may be a case in point here, where a medicine which is a copy of rituximab has been on the market since 2007 but it was registered on the basis of a far less extensive clinical trial programme than the one required in the European Union. Also in China, medicines biosimilar to the original oncological products and erythropoietin have been registered. Whereas, a medicine called Kikuzubam was registered in Mexico. It was, however, quickly withdrawn from the market. It was rather dissimilar to the reference medicine at the analytical level and the related clinical trial was improperly structured. This example proves the proposition that regulatory agencies are more and more strict even in less regulated markets, which, in Mabion S.A.'s opinion, is good for the Company.

2.4 Product range

In the future, the Company's core business activities will be the sale of medicines which are now at various stages of development. In the past, the Company's revenues were sourced from contract research and development activities in the area of development of technologies of production of various types of biotech medicines for external companies. In 2016, the Company focused on development work on MabionCD20 and did not carry out any contract research and development activities.

2.5 Sales markets

In 2016, Mabion S.A. continued its cooperation with Plexus Ventures LLC, which supports the Company in seeking a partner for the sale and distribution of MabionCD20 on the EU and US markets. In 2016, Mabion S.A. reviewed proposals submitted by several potential partners and finally decided to enter into an agreement with Mylan Ireland, a 100 percent subsidiary of Mylan N.V. – a leading global pharmaceutical company.

[17] Monoclonal Antibody and Fusion Protein Biosimilars Across Therapeutic Areas: A Systematic Review of Published Evidence, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5126212/

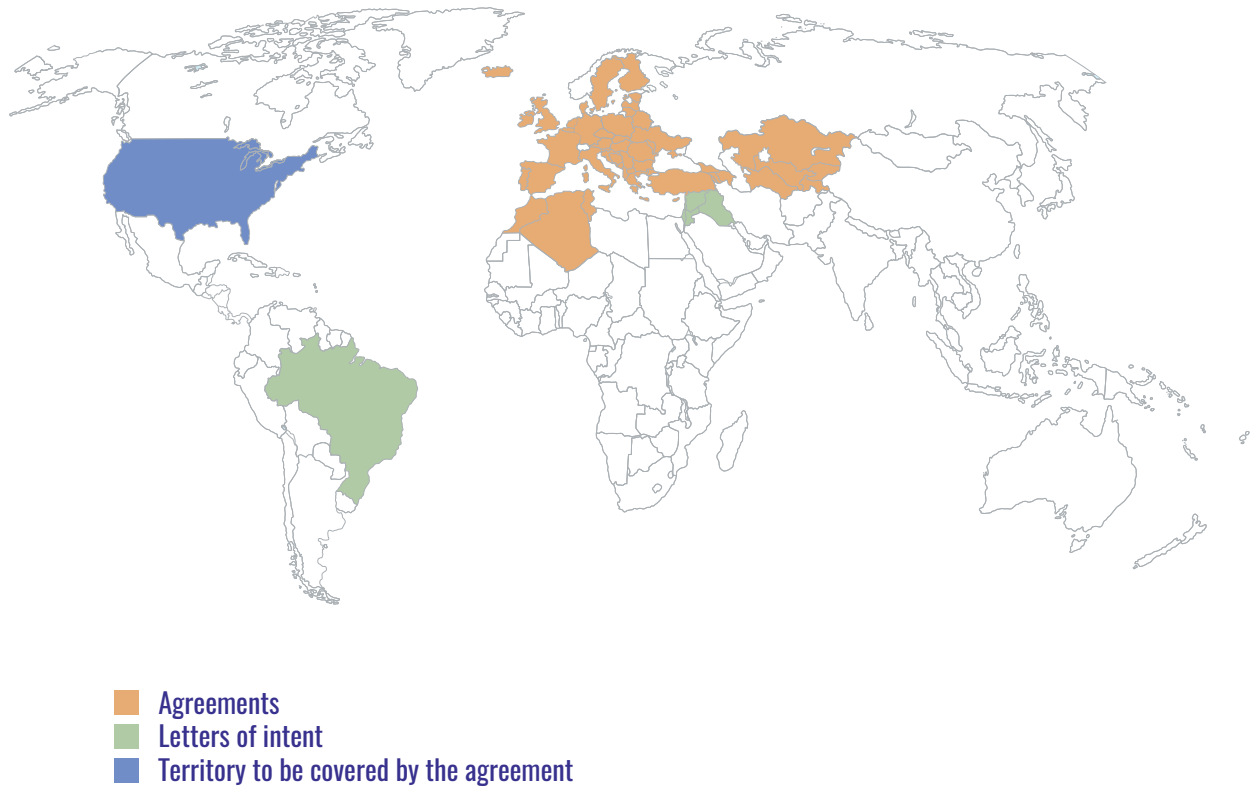
Under the agreement, Mylan gains exclusive rights to sell MabionCD20 – an oncological medicine biosimilar to MabThera/Rituximab – in all the European Union countries and in the Balkan countries. Moreover, under the agreement, Mylan will support the Company in the process of registration of MabionCD20 medicine by the European Medicines Agency.

In accordance with the contractual provisions and under certain conditions, in November 2016, Mabion S.A. received an upfront payment of USD 10m from Mylan and it will receive additional milestone payments in the total amount of up to USD 35m, contingent on the submission and approval of the marketing authorization for and the marketing of the product in key countries, and royalties due dependent on annual net sales.

Mylan N.V. is a global pharmaceutical company focusing on generic and specialty medicines. Mylan employs around 40 thousand employees, has a portfolio of 2,700 generic and specialty products, and serves clients in more than 165 countries. The global R&D and production base of Mylan is more than 50 facilities, which makes it one of the largest manufacturers of active pharmaceutical ingredients in the world. Mylan's annual turnover is nearly USD 10 billion.

In August 2016, Mabion terminated its agreement with Laboratorio LKM S.A., Argentina, for the distribution of MabionCD20 in Argentina, by mutual agreement. Currently, the Company considers the territory of the European Union and the United States as its key target sales markets for MabionCD20, however it does not exclude enlisting distributors in other markets, including the Argentine market, depending on the market conditions and the Company's future position. The remaining agreements between Mabion and its partners for the distribution of MabionCD20 in other markets remain in force.

Table 12. Forecast - distribution and letters of intent of Mabion S.A.



Agreements	
Company/country	**Markets**
Mylan/ Ireland	EU and the Balkan countries
LYFIS/ Iceland	Iceland
Farmak/ Ukraine	Ukraine, Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan and Uzbekistan
ONKO/ Turkey	Turkey
Sothema Laboratories/ Morocco	North African countries (Morocco, Algeria, and Tunisia)
Letters of intent with companies from the following countries:	
Country	**Market**
Biolotus/ Brazil	Brazil
Lebanon	Middle Eastern countries
Croatia	Balkan countries
Territory to be covered by the agreement	
USA	

Mabion's business partners in the above countries depend on their ability to register MabionCD20 in the countries where they have a presence and where they intend to sell MabionCD20. At the moment, regulators in those countries recognize the EMA's and the FDA's guidelines as leading, which means that MabionCD20's registration in any of those countries is unlikely before its registration with the EMA or the FDA.

2.6 Procurement sources

Mabion conducts development work on the production of biotechnological medicines. Projects are in various stages of development. In the year ended 31 December 2016, work was under way on every possible molecular level, from developing molecular biology methods at DNA level, through producing proteins in cell systems, to protein purification and analysis of protein purity and quality, including its physiochemical and biological properties. The advanced technologies developed at Mabion S.A. and a very diverse project range translate into the Company using a very wide range of products and services available on the market. Research and development is characterized by high diversity and volatility, which is reflected in the number of procurement sources used by Mabion. In addition to its research and development activities, the Company is conducting a clinical trial. Its conduct requires the supply of the MabionCD20 medicine, which is produced on an on-going basis by the Company, to clinical trial sites. The production of such an advanced biotechnological product as a monoclonal antibody requires that appropriately sterile conditions and purity zones are maintained, certified and input materials, including disposable materials. The eventually produced end product undergoes quality control release procedures which require the use of properly characterized reagents or performance of analyses commissioned externally from appropriate certified entities.

In 2016, purchases from the following suppliers amounted to at least 10 percent of the Company's annual operating expenses:
- Altiora LLC – providing clinical trial advisory services (share of purchases of about 16.2 percent)
- Sartorius Stedim Poland Sp. z o.o. – supplying consumables (share of purchase of about 14.5 percent)
- Komtur Polska Sp. z o.o. – supplying the MabThera reference medicine and production supplies (share of purchase of about 10.9 percent)

The above entities are not related to the Company.

The Company is not dependent on any of its suppliers.

2.7 Key local and international investments

In 2016, the Company did not make any investments in securities, financial instruments, intangible assets or properties.

On 30 December 2016, the Łódź Special Economic Zone issued another, already the third, permit whereunder Mabion S.A. is going to invest at least PLN 20m and hire at least five new employees at the Medical Biotechnology Scientific and Industrial Centre in Konstantynów Łódzki.

The capital expenditure project underlying the permit application involves increasing the production capacity at the existing Centre and it is going to involve an upgrade of the existing production line and purchase and assembly of plant and machinery for the second production line. The proposed capex project will make it possible to increase the production capacity two times and improve the effectiveness of the production process. If the Company takes advantage of a tax exemption on account of its new capital expenditure, the maximum amount of qualified capital expenditure will amount to PLN 26m. If the Company takes advantage of a tax exemption on account of its job creation, the maximum amount of qualified expenditure will amount to PLN 650 thousand over a two year period.

2.8 Agreements executed by MABION S.A.

2.8.1 Significant agreements concerning operating activities

On 8 November 2016, Mabion signed a long-term agreement for the development and commercialization of MabionCD20 medicine with Mylan Ireland, a subsidiary of Mylan N.V., a leading global pharmaceutical company. Under the agreement, Mylan gains exclusive rights to sell MabionCD20 medicine in all European Union countries and in the Balkan states. Moreover, Mylan will support the Company in the process of approval of MabionCD20 by the European Medicines Agency (EMA).

Under the agreement, Mylan made an upfront payment of USD 10m to Mabion S.A. Moreover, Mabion will receive milestone payments in the total amount of USD 35m upon approval and marketing of MabionCD20 in key markets, and royalties dependent on annual net sales.

2.8.2 Agreements concerning loans received in 2016

The Company entered into loan agreements with related parties in 2016.

Some of the loans were converted into the Company's shares by way of share issues The total amount of the loans thus converted amounted to PLN 11,750,000 in 2016.

The loans taken out by the Company in 2016 are presented in the table below

Lender	Agreement date	Loan amount	Currency	Maturity date	Repayment method	Repayment method
Twiti Investments Limited	22.02.2016	2 350 000	PLN	31.05.2016	WIBOR3M + 1,5p.p.	Converted into 'O' shares
Glatton Sp. z o.o.	26.02.2016	2 350 000	PLN	31.05.2016	WIBOR3M + 1,5p.p.	Converted into 'O' shares
Glatton Sp. z o.o.	24.03.2016	2 350 000	PLN	31.05.2016	WIBOR3M + 1,5p.p.	Converted into 'O' shares

Twiti Investments Limited	31.03.2016	3 700 000	PLN	31.07.2016	WIBOR3M + 1,5p.p.	Converted into 'O' shares
Twiti Investments Limited	18.05.2016	1 000 000	PLN	31.07.2016	WIBOR3M + 1,5p.p.	Converted into 'O' shares
Twiti Investments Limited	10.06.2016	1 100 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Twiti Investments Limited	14.07.2016	1 500 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Glatton Sp. z o.o.	8.08.2016	400 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Twiti Investments Limited	11.08.2016	500 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Twiti Investments Limited	19.08.2016	1 200 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Glatton Sp. z o.o.	29.08.2016	200 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Glatton Sp. z o.o.	1.09.2016	300 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Glatton Sp. z o.o.	15.09.2016	600 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Twiti Investments Limited	16.09.2016	1 000 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds
Glatton Sp. z o.o.	4.10.2016	530 000	PLN	31.12.2016	WIBOR3M + 1,5p.p.	Repaid from own funds

As at 31 December 2016, the Company has no outstanding loans.

On 12 October 2016, the Company entered into an overdraft facility agreement for PLN 25,000,000 with Alior Bank S.A. The overdraft facility was provided on arm's length terms for the period to 28 September 2017.

The interest rate on the facility is variable and based on the WIBOR 3M rate, plus the bank's margin. The overdraft facility is intended for working capital purposes, including the cost of launching the production of MabionCD20. The overdraft facility was released in two equal tranches and the condition for the release of the second tranche was, among other things, the submission of a signed contract with an EU distributor of MabionCD20 medicine to the Bank. The overdraft facility is secured with, among other things, a conventional mortgage capped at PLN 37.5m on the title of ownership to the property in Konstantynów Łódzki, together with an assignment of amounts due under an insurance policy, the power of attorney in respect of the Company's bank accounts with the Bank, the Company's statement on voluntary submission to enforcement, and pledges and other forms of security provided by the Company's related parties.
In the reporting period, there were no breaches of any key terms and conditions of the Company's loan agreements, including default on payments.

2.8.3 Agreements terminated in 2016

In 2016, the Company did not terminate any of its loan agreements.

2.8.4 Agreements concerning loans made

In the year ended 31 December 2016, the Company did not make any loans.

2.8.5 Other agreements in place

In the year ended 31 December 2016, the Company did not execute any significant agreements other than as described in sections 2.8.1 to 2.8.2.

On 12 October 2016, Mabion S.A. signed an agreement with the Faculty of Biotechnology and Food Sciences of the Łódź University of Technology. Under the agreement, Mabion S.A. will run lab classes for students and give lectures on advanced technologies used in the biomedical and biotechnological industries. Moreover, the Company may comment on and modify the existing courses and co-author new courses in order to bring students' knowledge and skills in line with the current needs of the labour market and help graduates map their career paths. In the future, the Company also intends to provide students with job offers at Mabion S.A. and launch an internship scheme. The agreement is open-ended.

2.8.6 Pledges and guarantees

In the year ended 31 December 2016, the Company did not receive or give any pledges or guarantees other than the pledges concerning the overdraft facility received from Alior Bank S.A. (see 2.8.2).

2.8.7 Transactions with related parties

In 2016, no transactions other than on an arm's length basis were concluded with related parties.

2.9 Other significant events

2.9.1 Significant events and factors during the financial year

January

On 8 January 2016, the Company learned about the decision of the Chief Pharmaceutical Inspector of 31 December 2015 to grant Mabion S.A. a permit for "The Production of a Trial Drug" at the Medical Biotechnology Scientific and Industrial Centre in Konstantynów Łódzki. The permit obtained from the Chief Pharmaceutical Inspector will make it possible to commence the production of medicines at the Centre in Konstantynów Łódzki. The Company announced that it had received the permit in its ad hoc report no. 1/2016.

February

On 5 February 2016, Mabion received a report following an audit which had taken place on 3 February 2016 and which had involved the Company's compliance with the terms and conditions of Permit No. 167 for operating in the Łódź Special Economic Zone at the Research and Development Centre for Biotechnological Medicinal Products at ul. Fabryczna 17. Based on the audit procedures performed, the permit's condition to spend at least PLN 20m in qualified capital expenditure in the Zone had been met. In the course of its operation in the Zone, the Company may take advantage of a tax exemption on account of capital expenditure incurred; the maximum amount of qualified expenditure is PLN 35.92m. The Company incurred qualified capital expenditure in the total amount of PLN 30m (paid in full). The remaining condition to be met by the Company was to maintain employment at a level of at least 25 employees until the end of December of 2016. This condition was met, as confirmed by an audit conducted on 11 January 2017 (post balance sheet event). This provides the basis for the Company to exercise its right to a tax exemption of up to 70 percent of qualified expenditure until 2026. The Company announced the fact in its ad hoc report no. 4/2016.

June

On 21 June 2016, the Company's Management Board announced the current status of its clinical trials. The status as at 20 June 2016 showed an increase in the number of patients following the first administration of the medicine in both clinical trials:

Clinical trial status as at 11 May 2016 (Report for Q1 2016)	Clinical trial status as at 20 June 2016
NHL » 17 patients in the clinical trial including: » 9 patients after the first administration of the medicine	NHL » 38 patients in the clinical trial including: » 28 patients after the first administration of the medicine
Rheumatoid arthritis (RA) » 801 patients in the clinical trial including: » 583 patients after the first administration of the medicine including: » 105 patients after the first administration of the medicine as part of the PK/PD subtrial	Rheumatoid arthritis (RA) » 887 patients in the clinical trial including: » 622 patients after the first administration of the medicine, including: 141 patients after the first administration of the medicine as part of the PK/PD subtrial, which is the effect of recruitment of PK/PD patients[1] in Poland and Ukraine. Extension of the collaboration with Ukrainian sites to include the PK/PD option was intended to speed up the process of patient recruitment for the PK/PD subtrial

The above information was announced in the Company's ad hoc report no. 18/2016.

July

On 15 July 2016, the Company decided to limit the enrolment of new patients from the PK/PD subgroup in the clinical trial of MabionCD20 medicine in respect of rheumatoid arthritis (RA). The decision was taken due to the fact that the number of patients enrolled in the clinical trial exceeded the number required for statistical analyses by an amount approximating the historical level of drop-outs. The Company's Management Board launched procedures to verify the completeness of clinical data, being the information necessary for taking a decision to completely close recruitment for the RA trial. The decision was announced in the Company's ad hoc report no. 21/2016.

On 29 July 2016, the Company announced that talks with three entities with a global experience in the sale, distribution and evaluation of biosimilars in order to enlist an exclusive distributor for the purpose of sale and marketing of MabionCD20 medicine in the European Union were still advanced. Each of the entities expressed great interest in MabionCD20. The Company's intention was to have an agreement signed with the partner selected over a matter of weeks. The above information was announced in the Company's ad hoc report no. 22/2016.

August

On 8 August 2016, the Company's Management Board, having analysed the report *An Analysis of the Size of Population of Patients Qualifiable for PK Analyses in the MABRA PK/PD Trial* (the "Report") adopted a resolution to close the recruitment of patients for the MabionCD20 RA - PK/PD subtrial. The Report consists of the following sections:

(i) Laboratory analysis results to date in the area of PK – double-blind, summary data – without a breakdown into the two groups treated with MabionCD20 and MabThera, respectively;

(ii) A tabular summary of patients rejected from the PK analysis due to the occurrence of significant deviations during the trial, preventing the patients from being taken into account in a statistical analysis (e.g. a visit outside the set period, withdrawal from the clinical trial), together with a description of each case;

(iii) A tabular summary of patients who may be included in a statistical analysis despite the occurrence of non-critical deviations from the protocol during the clinical trial, together with a description of each case;

(iv) General statistics of the clinical trial:
- Number of patients enrolled in the PK/PD trial – without deviations, did not complete the trial;
- Number of patients enrolled in the PK/PD trial – without deviations, completed the trial;
- Number of patients rejected from a statistical analysis in the PK/PD trial;
- Number of patients who may be included in a statistical analysis in the PK/PD trial despite the occurrence of non-critical deviations from the protocol (as analysed into patients who have completed the trial and those who are still in the trial);
- Drop-out rate (the percentage of patients who do not complete the trial or, due to significant deviations from the protocol, cannot undergo a statistical analysis);
- Number of patients who may undergo a statistical analysis, without taking the drop-out rate into account;
- Number of patients who may undergo a statistical analysis, taking the drop-out rate into account.

The decision not to recruit any further patients for the MabionCD20 RA – PK/PD trial was due to the fact that, based on comparing the number of patients required for a PK statistical analysis with the number of patients in the MabionCD20 RA – PK/PD trial who could undergo a statistical analysis as at 8 August 2016, the required number was exceeded by about 27 percent. The above percentage exceeded the drop-out rate for the trial (21.2 percent), which meant that the statistical analysis would not be at risk even if the drop-out rate rose above the level as at 8 August 2016. The closing of recruitment for the PK/PD subtrial was an important step as recruitment for a PK/PD subtrial is more difficult than for other RA patients and it is on the basis of analyses of that trial group that some of the fundamental clinical trial endpoints are obtained. The Company's decision was announced in its ad hoc report no. 24/2016.

September

On 30 September 2016, the Management Board of Mabion S.A. decided to end the recruitment of patients for screening to qualify for the MabionCD20 RA clinical trial. Taking the statistics available as at 30 September 2016 into account, it was possible to calculate the existing rate of patients who, for various reasons, could not undergo a statistical data analysis. It amounted to about 10 percent. On the resolution date, the Company's Management Board held data indicating that the number of patients who had not completed the trial yet, plus the number of patients who had already completed the trial and can undergo a statistical analysis, exceeds 624, i.e. the number required by the protocol, by 13 percent. The recruitment of the last patient for a clinical trial is not tantamount to its completion; the last recruited patients must go through the entire clinical trial procedure, including the administration of the medicine, analyses and a six-months' observation period. The Company's decision was announced in its ad hoc report no. 26/2016.

November

On 8 November 2016, Mabion S.A. signed a long-term agreement with Mylan Ireland, a 100 percent subsidiary of Mylan N.V. – a leading global pharmaceutical company. Under the agreement, Mylan gains exclusive rights to sell MabionCD20 – an oncological medicine biosimilar to MabThera/Rituximab – in all the European Union countries and in the Balkan countries. Moreover, under the agreement, Mylan will support the Company in the process of registration of MabionCD20 medicine by the European Medicines Agency. Under the Agreement, Mabion S.A. received an upfront payment of USD 10m from Mylan in 2016. Moreover, the Company will receive milestone payments in the total amount of up to USD 35m, contingent on the submission and approval of the marketing authorization for and the marketing of the product in key countries, and royalties due dependent on annual net sales. The above information was announced in the Company's ad hoc report no. 31/2016.

December

On 14 December 2016, Mr Maciej Wieczorek, the existing President of the Company's Management Board stepped down as President and member of the Management Board.

On 14 December 2016, the Company's Supervisory Board decided to appoint Mr Artur Chabowski as President of the Company's Management Board. The Company announced the fact in its ad hoc report no. 33/2016.

On 22 December 2016, the independent Data and Safety Monitoring Board (DSMB) committee held its sixth meeting. The DSMB committee oversees the clinical trial and the safety of rheumatoid arthritis patients who participate in the comparative clinical trial of MabionCD20 medicine and the MabThera reference product. The DSMB committee analysed clinical data and safety data obtained from patients up to 28 March 2016 (the database cut-off date for the purpose of statistical data analysis) comprised in a report submitted to the Committee which had been drawn up by an independent statistical firm, as well as data obtained from the database closing date to 21 December 2016 (not processed for statistical purposes – raw data).

The statistically analysed data (i.e. as at 28 March 2016) was obtained from 561 randomized patients. The additional data, which were not statistically analysed – descriptive data (i.e. the data obtained between 28 March 2016 and 21 December 2016) was obtained from a further 148 patients qualified for the clinical trial. As at 21 December 2016, 709 patients had received all the medicine administrations as envisaged in the protocol. The number of patients required to complete the clinical trial is 624. The drop-out rate in the main clinical trial (patients who were unable to undergo a statistical analysis for various reasons) is lower than originally assumed in the clinical trial protocol and currently stands at 11.16 percent.

During the meeting, DSMB members also confirmed that no further recruitment for the PK/PD subtrial was needed, confirming that the size of the sample was sufficient for a statistical analysis.

All the patients enrolled in the clinical trial in Georgia and Lithuania had already completed their participation in the clinical trial, having completed all the visits envisaged in the protocol, and their data is undergoing verification. The database in Georgia and Lithuania is ready for the final closing.

To date, adverse effects observed in the clinical trial in either group of patients do not deviate significantly in terms of their scope or intensity from typical adverse effects characteristic for treatment with the MabThera reference medicine. Moreover, no adverse effects were observed which, in the investigators' opinion, may be associated with the treatment used and which had not been discussed in the reference product safety sheet. In the Company's opinion, the above may suggest that regulatory risks involved in MabionCD20's safety profile in respect of MabThera have diminished.

Having reviewed the reports on the general progress of the clinical trial and other data presented on the safety and efficacy of the treatment, the DSMB Committee favourably assessed the clinical trial and recommended that it should be continued without any amendments to the clinical trial protocol. The above information was announced in the Company's ad hoc report no. 34/2016.

2.9.2 Significant events and factors after the end of the financial year

On 3 January 2017, the Management Board of Mabion was notified of the issue of Permit No. 301 for operating in the Łódź Special Economic Zone. The permit set the following terms and conditions for the Company's operations in the Zone:

1) Spending at least PLN 20m in capital expenditure in the Zone until 31 December 2019;

2) Increasing the number of employees involved in operating in the Zone by at least five new employees until 31 December 2018 and maintaining the Company's employment in the Zone at the level of at least 100 employees until 31 December 2021. If the Company reaches employment of at least 100 employees (including five employees hired after the permit date) before 31 December 2018, the period for maintaining employment in the Zone at a level of at least 100 employees will be three years

after the first day of the month following the month in which the Company notifies the Zone Manager in writing of reaching the required level of employment.

3) Completing the capex project by 31 December 2021.

If the Company takes advantage of a tax exemption on account of its new capital expenditure, the maximum amount of qualified capital expenditure will amount to PLN 26m. If the Company takes advantage of a tax exemption on account of its job creation, the maximum amount of qualified expenditure will amount to PLN 650 thousand over a two year period.

Thanks to the permit, the Company may obtain the benefit of a corporate income tax exemption of up to 45% of qualified expenditure incurred, which will be the basis for the tax relief amount. The capital expenditure project underlying the permit application involves increasing the production capacity at the existing Medical Biotechnology Scientific and Industrial Centre of Mabion S.A. located in the Zone and will involve an upgrade of the existing production line and purchase and assembly of plant and machinery for the second production line. The proposed capex project will make it possible to increase the production capacity two times and improve the effectiveness of the production process. The above information was announced in the Company's ad hoc report no. 2/2017.

On 11 January 2017, an audit involving the Company's compliance with the two terms and conditions of Permit No. 167 issued in August 2010 for operating in the Łódź Special Economic Zone (the "Zone" or the "ŁSEZ") at the Research and Development Centre for Biotechnological Medicinal Products, was carried out. What was audited was the Company's compliance with the conditions of maintaining employment at a level of at least 25 employees at the research and development centre located in Łódź at ul. Fabryczna 17, in the Zone, until the end of 2016, and completing the capex project involving operating at the research and development centre by the end of December 2016. As part of the capex project, the Company incurred qualified capital expenditure in the Zone over and above the maximum amount of PLN 30m, as set in the permit. The maximum qualified labour costs as set in the permit are PLN 5.92m. Based on the audit procedures performed, both conditions stated above have been fulfilled. Therefore, all the conditions of Permit No. 167 have been met, which provides the basis for the Company exercising its right to a tax exemption of up to 70 percent of qualified expenditure until 2026. The above information was announced in the Company's ad hoc report no. 4/2017.

On 11 January 2017, an audit involving the Company's compliance with the terms and conditions of Permit No. 203 issued in April 2012 for operating in the Łódź Special Economic Zone (the "Zone" or the "ŁSEZ"), to the extent of incurring qualified capital expenditure of at least PLN 30m until the end of 2016 and employing at least 30 employees for the purpose of operating in the Zone by the end of 2016, was carried out. Based on the audit procedures performed, both conditions stated above have been fulfilled.

The qualified capital expenditure involves the construction of a new production facility, i.e. the Medical Biotechnology Scientific and Industrial Centre in Konstantynów Łódzki. In the period from the issue of the permit to 31 December 2016, capital expenditure reached more than PLN 72m. At the moment, the Company employs 95 employees at its production facility in the Zone. Under the terms and conditions of the permit, as part of its operating in the Zone, the Company may utilize a tax exemption of up to 70 percent of qualified expenditure until 2026, where PLN 45m, i.e. the maximum amount of qualified capital expenditure as set in the permit, will be the basis for the calculation of the exemption allowed on account of capital expenditure incurred (as the Company's capital expenditure has exceeded the maximum limit of qualified expenditure), plus qualified labour expenditure (whose maximum limit is PLN 8m). The other conditions of Permit No. 203 are maintaining employment at the level of at least 30 employees until the end of the first quarter of 2019 and completing the capital expenditure project by the end of 2018, with the latter condition already satisfied. The above information was announced in the Company's ad hoc report no. 5/2017.

On 21 February 2017, the Company's Management Board learned that a total of 140 patients had been enrolled in the MabionCD20 – 002 NHL clinical trial concerning the non-Hodgkin lymphoma (NHL) indication. All the patients are after the first administration of the medicine. Therefore, the number of patients enrolled in the clinical trial exceeds the number required

for statistical analyses (112 patients). The Company's Management Board is now going to review the available data to verify whether the previously adopted drop-out rate (the difference between 140 and 112, i.e. 28 patients, or 20%) is appropriate in the light of the data available as at the report date, and analyse the risk of an increase in the rate in the coming months. Therefore, this does not mean that the recruitment of patients has been ended but rather suspended pending a final decision. A decision to end the recruitment of patients for this clinical trial is going to be finally taken after the above analyses are completed and after consultations with Mylan Ireland (the distribution partner for the European markets). The above information was announced in the Company's ad hoc report no. 15/2017.

On 30 March 2017, the Company's Management Board adopted a resolution concerning the plan of a medicinal product development strategy. The plan was drawn up following the completion of an internal analytical project involving nearly 50 potential drug development candidates, taking into account, inter alia, patent expiry dates for reference medicines, today's and forecast size of the reference medicine market, the Company's medicine production technology, team competence, MabionCD20 experience, and competition in the area of biosimilars. In accordance with the objectives adopted, the Company, while continuing the existing MabionCD20, MabionHER2, MabionEGFR, MabionVEGF_Fab medicine research projects (the last medicine developed together with a partner), is going to commence research involving the following further medicines in 2017:

1. MabionAI2 - a medicine used in the area of autoimmunology; the anticipated year of commencement of clinical trials: 2021; the market size based on analysts' estimates for 2022: USD 1-2 billion;
2. MabionAI3 - a medicine used in the area of autoimmunology; the anticipated year of commencement of clinical trials: 2022; the market size based on analysts' estimates for 2022: USD 3-5 billion;
3. MabionTR - a medicine used in the area of traumatology; the anticipated year of commencement of clinical trials: 2023; the market size based on analysts' estimates for 2022: USD 2-3.5 billion;
4. MabionON4 - a medicine used in the area of cancer treatment; the anticipated year of commencement of clinical trials: 2024; the market size based on analysts' estimates for 2022: USD 1.5-2.5 billion;
5. MabionON5 - a medicine used in the area of cancer treatment; the anticipated year of commencement of clinical trials: 2024; the market size based on analysts' estimates for 2022: USD 2-3 billion;
6. MabionHER2_ADC - a conjugate based on MabionHER2, used in the area of cancer treatment; the anticipated year of commencement of clinical trials: 2025; the market size based on analysts' estimates for 2022: USD 1-2 billion;
7. MabionAI4 - an innovative medicine used in the area of autoimmunology; the anticipated year of commencement of clinical trials: 2025; the market size based on analysts' estimates for 2022: USD 4-6 billion.

The Company also announced that it would update its plan of a medicinal product development strategy every year. The above information was announced in the Company's ad hoc report no. 20/2017.

On 19 April 2017, the Management Board of Mabion S.A. learned that following a review of the Medical Biotechnology Scientific and Industrial Centre of Mabion S.A. in Konstantynów Łódzki, the Company was issued a GMP (Good Manufacturing Practice) certificate for the Centre in Konstantynów Łódzki by the Chief Pharmaceutical Inspector.

The Company underwent the review in the period from 17 to 19 January 2017, according to the national review programme and in connection with the manufacturing permit announced by the Company in its report no. 1/2016 dated 8 January 2016. The certificate obtained is evidence of compliance of the manufacturing conditions with Good Manufacturing Practice requirements, as ascertained during the review. The certificate is valid for three years after the last day of the review. The GMP certificate issued to the Company covers manufacturing operations involving sterile, biological study medicinal products and quality control operations. The above information was announced in the Company's ad hoc report no. 15/2017.

2.9.3 Other events

In August 2016, Mabion terminated its agreement with Laboratorio LKM S.A., Argentina, for the distribution of MabionCD20 in Argentina, by mutual agreement. The Company does not rule out enlisting another distributor in Argentina in the future, depending on market conditions and the Company's future circumstances.

On 24 October 2016, Mabion executed an amendment to the agreement concerning the project titled *Clinical Development and Registration of a Humanized Monoclonal Antibody Binding with the HER2 Receptor, Used in Breast Cancer Treatment* with the National Research and Development Centre, as part of the Innomed programme.

The amendment makes it possible to extend the project completion date by two years, to 31 May 2019. An application for an extension of the project completion date was submitted by the Company in 2015, which was notified by the Company in past periodical reports.

2.9.4 Exceptional factors and events

In the Company's opinion, there were no exceptional factors or events in the financial year 2016, other than as discussed below and in Sections 2.9.1 and 2.9.3.

On 16 February 2017, the Extraordinary General Shareholders' Meeting of the Company adopted a resolution to change the accounting policy and start preparing the Company's financial statements in accordance with International Accounting Standards, International Financial Reporting Standards and related interpretations, published as regulations of the European Commission, starting with the financial statements for the financial year beginning on 1 January 2016, which ended on 31 December 2016. The above change, as discussed in the Company's ad hoc report no. 9/2017, contributed to a change of the approach to the recognition of development costs and EU project grants in the Company's books of account, and had an effect on the Company's results of operations for the year 2016. The effect of the change on the Company's results of operations was presented in the Company's ad hoc report no. 23/2017.

As far as development costs are concerned, in accordance with the existing accounting policies in line with Polish Accounting Standards (PAS), they used to be recognized as deferred costs until a decision to implement the outcome of development work in production and sales or a decision to discontinue such work was taken. Due to the transition to IAS/IFRS, development costs are not recognized as an asset in the balance sheet until the Company is certain that it can implement the outcome of such costs in production, i.e. in the Company's industry, until the given medicinal product is registered by the relevant regulator. Therefore, the Company reclassified the total of its development costs capitalized as deferred costs under PAS as at 31 December 2016, i.e. PLN 153.2m, as expenses in its income statements for the years 2016, 2015, and prior years.

As far as EU project grants are concerned, the existing accounting policy of the Company in accordance with PAS used to be to recognize them as deferred income. Due to the transition to IAS/IFRS, a part of EU project grants in the amount of PLN 27.4m were recognized as income of the year 2015 and prior years.

Therefore, research and development costs of PLN 44.2m, PLN 39.0m, and PLN 70.0m were recognized as expenses in the income statements for the years 2016, 2015, and prior years, respectively, whereas grants of PLN 1.4m and PLN 26.0m were recognized as revenue in the income statements for the year 2015 and prior years, respectively.

As a result of the changes presented above, the Company's equity was reduced by PLN 125.8m and PLN 81.6m as at 31 December 2016 and 2015, respectively. Moreover, as a result of the changes presented above, the Company's net loss increased by PLN 44.2m and PLN 37.6m for the years ended 31 December 2016 and 2015, respectively. The Company's equity is PLN 3.7m in its IFRS balance sheet as at 31 December 2016.

Further details of the effects of changes in the Company's accounting policies and transition to IFRS/IAS are disclosed in Note 6 to the financial statements.

3 ANALYSIS OF THE COMPANY'S FINANCIAL POSITION

3.1 Selected financial information

Table 1. Selected financial information of Mabion S.A.

	in PLN'000		in EUR'000	
Selected financial information	**2016**	**2015**	**2016**	**2015**
Net sales	0	2 733	0	653
Operating profit (loss)	-55 531	-42 098	-12 691	-10 060
Profit (loss) before tax	-55 826	-42 541	-12 758	-10 166
Profit (loss) before tax	-55 826	-42 541	-12 758	-10 166
Net cash used in operating activities	-15 221	-32 399	-3 479	-7 742
Net cash used in investing activities	-2 491	-859	-569	-205
Net cash from financing activities	26 464	32 379	6 048	7 737
Total net cash flows	8 752	-879	2 000	-210
	31.12.2016	**31.12.2015**	**31.12.2016**	**31.12.2015**
Total assets	91 247	84 049	20 625	19 723
Liabilities and provisions for liabilities	87 518	38 594	19 783	9 056
Non-current liabilities	14 060	16 152	3 178	3 790
Current liabilities	73 458	22 442	16 604	5 266
Equity	3 729	45 455	843	10 666
Share capital	1 180	1 116	267	262
Number of shares (not in thousands)	11 800 000	11 160 000	11 800 000	11 160 000
Weighted average number of shares (not in thousands)	11 682 000	10 878 000	11 682 000	10 878 000
Net profit (loss) per ordinary share	-4,78	-3,91	-1,09	-0,93
Book value per share	7,81	7,73	1,77	1,81
Dividend declared or paid per share	0	0	0	0

The individual financial statements of Mabion have been prepared using the accounting policies consistent with International Financial Reporting Standards (IFRS), including International Accounting Standards (IAS), Interpretations of the Standing Interpretation Committee and interpretations of the International Financial Reporting Interpretations Committee (IFRIC), endorsed by the European Union (EU) and effective as at the end of 2015. The financial statements have been prepared on the historical cost basis, with the exception of derivative financial instruments, available-for-sale financial assets, which were measured at fair value. These individual financial statements, with the exception of the cash flow statement, have been prepared on an accruals basis.

The scope of the individual financial statements is consistent with the Decree of the Finance Minister on ad hoc and periodical reporting by issuers of securities and criteria of recognition of information required by laws of non-members of the EU as

equivalent of 19 February 2009 (consolidated text: *Journal of Laws of 2014*, item 133) and it covers the annual reporting period from 1 January 2016 to 31 December 2016 and the comparative period from 1 January 2015 to 31 December 2015.

Assets, liabilities and equity in the balance sheet have been translated into euro at the average exchange rate ruling on each balance sheet date, as announced for euro by the National Bank of Poland: (31/12/2016: PLN 4.4240; 31/12/2015: PLN 4.2615). Items of the income statement and the cash flow statement have been translated into euro at the exchange rate being the arithmetical mean of the average exchange rates announced for euro by the National Bank of Poland, ruling on the last day of each month of the financial year (2016: PLN 4.3757; 2015: 4.1848).

3.2 Key business and financial metrics

In the year ended 31 December 2016, the Company did not make any sales due to focusing on MabionCD20 development. In the 12 months ended 31 December 2016, the Company's operating expenses amounted to PLN 58,157 thousand, which was mainly attributable to development costs, of PLN 44,218 thousand in 2016, and general administrative expenses which amounted to PLN 13,939 thousand. The Company's operating loss for 2016 was PLN 55,531 thousand, up PLN 13,433 thousand compared with 2015. The Company's net loss reached PLN 55,826 thousand by the end of December 2016.

The Company's total assets amounted to PLN 91,247 thousand as at the end of December 2016, up PLN 7,198 thousand compared with the end of December 2015. As at the end of 2016, non-current assets, of PLN 68,217 thousand, were a significant proportion of total assets, including property, plant and equipment (mainly PPE items involved in the Konstantynów Łódzki capex project). As at the end of December 2016, cash and cash equivalents amounted to PLN 14,826 thousand and corresponded to the overdraft facility received from Alior Bank in October 2016 and amounts received from Mylan Ireland, the Company's distribution partner, in November 2016. Whereas, as far as the Company's liabilities and equity are concerned, the end of 2016 saw a decrease in equity, which was brought about by the Company's net loss in the reporting period, an increase in non-current liabilities, mainly due to an upfront payment received from Mylan Ireland, and an increase in the current liability for the loan from Alior Bank.

The financial statements have been prepared on the assumption that the Company will continue in operation as a going concern for at least 12 months after the date of publication. The Management Board of Mabion S.A. is not aware of any circumstances which are evidence of any serious threats to the Company's continuing in operation as a going concern.

As at the end of December 2016, the Company's financial position is stable and the Company has funds to pay its liabilities as and when they fall due.

3.3 Financial and non-financial ratios

Profitability ratios	Measure	Definition	01.01.2016 - 31.12.2016	01.01.2015 - 31.12.2015
Gross margin ratio	%	Gross margin / sales	not applicable	13,3%
Operating margin ratio	%	Operating profit / sales	not applicable	-1 540,4%
Profit margin	%	Net profit / sales	not applicable	-1 556,6%
Return on assets (ROA)	%	Net profit / total assets at year-end	-61,2%	-50,6%
Return on equity (ROE)	%	Net profit / equity at year-end	-1 497,1%	-93,6%

The Company's ratios have been mainly driven by:
» no sales in 2016
» costs of MabionCD20 development
» capital expenditure on plant and machinery used for development and production of medicines
» increased equity due to a new 'O' share issue
» increased trade payables, loans and advances

3.4 Segmental analysis of sales by business and geographical area

In 2016, Mabion S.A. did not generate any sales.

The Company is not dependent on any one customer and no customer accounts for more than 10 percent of the Company's sales revenue.

In November 2016, the Company received an upfront payment of USD 10m from Mylan Ireland Ltd. on account of exclusive distribution rights to MabionCD20 in 36 European countries. The upfront payment was not recognized in sales by the Company but rather in liabilities as a repayable upfront payment for distribution rights (see Note 20 to the financial statements).

3.5 Financial instruments used

In 2016, the Company did not use any financial instruments in respect of price, credit, cash flow or liquidity risks.

In 2016, the Company did not use any derivative instruments

3.6 Financial risk management objectives and methods

The Company does not have a formal financial risk management system. Decisions to apply instruments hedging forecast transactions are taken based on up-to-date analyses of the Company and its environment.

3.7 Assessment of financial resource management

Going concern assumption

The individual financial statements have been prepared on the assumption that the Company will continue in operation as a going concern for at least 12 months after the date of publication. As at the date of approval of this Directors' Report, the Management Board of Mabion S.A. is not aware of any circumstances which are evidence of any serious threats to the Company's continuing in operation as a going concern. The intended duration of the Company is unlimited.

Financial resource management in 2016

In 2016, the Company's operations were most affected by development costs, in the first instance clinical trials and costs involved in the production of MabionCD20 medicine.

As at 31 December 2016, equity corresponded to 4.1 percent of the Company's total equity and liabilities. As at the end of December 2016, the Company's debt ratio involving non-current and current trade payables and loans is about 76.6 percent.

In evaluating its financing needs, the Company takes the following factors into account:
» current and budgeted level of cash generated by operating activities;
» current structure of financing of non-current and current assets;
» anticipated capital expenditure level;
» budgeted scale of core operations (research and development).

Further financing plans

The assumed payback of expenditures incurred to date involves ensuring the Company's liquidity in the development phase and our assumptions that the Company's key product MabionCD20 will obtain a marketing authorization and that its sales will generate sufficient future cash flows.

The Company assumes that the financing for its continuing in operation as a going concern, including:
- launch of commercial scale production at the Scientific and Industrial Centre in Konstantynów Łódzki;
- design and preparatory work for the launch of construction of another production facility on the existing plot of land of Mabion in Konstantynów Łódzki;
- completion of research and development work on and registration of MabionCD20;
- marketing and continued sales of the medicine on the Polish market and in selected Central and East European countries;
- continuation of the project titled Clinical Development and Registration of a Humanized Monoclonal Antibody Binding with the HER2 Receptor, Used in Breast Cancer Treatment;
- research and development work on further medicines developed by Mabion, will be, in the first instance, derived from:
  - future share issues;
  - expected distribution fees for MabionCD20 medicine (milestone payments);
  - performance of contracts for the provision of research and development services;
  - aid from EU funds;
  - loans provided by banks;
  - funds obtained under operating or finance leases.

3.8 Assessment of viability of capex projects

The Company's capex plans include commercial scale production at the Scientific and Industrial Centre in Konstantynów Łódzki, completion of research and development work on and registration of MabionCD20 product, and research and development work on further biosimilars.

The Company intends to finance capex projects with its internal funds from the sale of distribution and licence rights to MabionCD20 product, performance of the existing contracts for the provision of research and development services, aid from EU funds and VAT credits.

The Management Board focuses its efforts on the matching of the maturity structure of each payment involved in the carrying out of capex projects, first of all, with the periods of inflows of relevant funds.

There is a risk of problems with the promptness of cash inflows from government institutions (amounts receivable in respect of a project co-financed by the National Research and Development Centre or potential new aid projects, VAT credits), however that should not significantly affect the scope of the Company's operations.

There is a risk involving revenues in the case of delayed distribution fee tranche payments due to failure to reach budgeted milestones by specified dates. This may adversely affect the Company's liquidity. In such event, the Management Board will propose using alternative sources of working capital financing.

The Company is looking for ways to secure further co-financing of capital expenditure from other sources.

On 16 February 2017 (a post balance sheet event), the Extraordinary General Shareholders' Meeting authorized the Company's Management Board to increase the Company's share capital once or several times by an amount of up to PLN 450,000 thousand through the issue of not more than 4,500,000 ordinary bearer shares of PLN 0.10 par value each, where:
- a share capital increase by an amount of up to PLN 400,000 through an issue of not more than 4,000,000 ordinary bearer shares of PLN 0.10, may take place under open subscription of shares arrangements within the meaning assigned by Article 431.§2.3 of the Commercial Companies Code, where shares will be issued in a public offering

outside the territory of the Republic of Poland and listed on a stock exchange in Europe (which includes the regulated market operated by the Warsaw Stock Exchange) or the United States; and

» a share capital increase by an amount of up to PLN 50,000 through an issue of not more than 500,000 ordinary bearer shares of PLN 0.10, may take place under private subscription of shares arrangements within the meaning assigned by Article 431.§2.(1) of the Commercial Companies Code, in the territory of the Republic of Poland.

The above resolution of the Extraordinary General Shareholders' Meeting was registered in the National Court Register on 23 March 2017.

3.9 'O' share issue and application of proceeds from the issue of shares

On 23 May 2016, the Company's Management Board, acting under § 9a.1 of the Company's Memorandum and Articles of Association, adopted a resolution to increase the Company's share capital from authorized capital through an issue of 'O' shares, excluding subscription rights. 'O' shares were allotted under private subscription arrangements. 'O' shares were issued on 24 May 2016. 300,000 'O' shares were allotted.

The following 'O' ordinary bearer share allotment agreements were entered into at the issue price of PLN 47 per share:

» the 'O' share allotment agreement with Twiti Investments Ltd, the key shareholder of the Company, 50% controlled by Chairman of the Company's Supervisory Board, Mr Robert Aleksandrowicz, whereby Twiti Investments Ltd. was allotted 200,000 'O' shares for a total amount of PLN 9,400,000;

» the 'O' share allotment agreement with Glatton Sp. z o.o., a shareholder of the Company, 100% controlled by the President of the Company's Management Board, Mr Maciej Wieczorek, whereby Glatton Sp. z o.o. was allotted 100,000 'O' shares for a total amount of PLN 4,700,000.

The above shares have been paid up in full.

Share issue proceeds were used to finance research and development work on MabionCD20 medicine, in the first instance its clinical trials. Unused share issue proceeds remained as cash in the Company's bank account.

On 4 July 2016, the increase in the Company's share capital was registered by the District Court for Łódź-Śródmieście in Łódź, 20th Division of the National Court Register. The Company's share capital was increased from PLN 1,150,000 to PLN 1,180,000 as a result of an issue of 300,000 of 'O' ordinary bearer shares of PLN 0.10 par value each.

3.10 Dividend policy

In the year ended 31 December 2016, the Company did not pay any dividend. The Company's Management Board adapts its dividend policy to the Company's changing business situation, taking into account the scope of necessary capital expenditure projects. Currently, the Company is in the growth stage and it does not intend to pay any dividend.

3.11 Reconciliation of results of operations and formerly published forecasts

The Company's Management Board decided to withdraw financial forecasts published in 2010 (drawn up in connection with efforts to introduce 'I' shares into an alternative trading system) and not to present any forecasts of its results of operations.

4 PROSPECTS OF MABION S.A.

4.1 Development prospects

Since its establishment, the Company has focused mainly on research and development work on biosimilars such as therapeutic monoclonal antibodies and insulin analogues. The products developed by Mabion are highly specialist drugs which are much more cost-effective in production than the manufacture of original products thanks to the technologies developed by the Company, including:

» proprietary genetic, cellular and process engineering technologies, which enable achieving high productivity in drug manufacturing;
» fully integrated disposables technology, which enables the flexible use of manufacturing potential and reducing fixed manufacturing costs;
» industrial orbital shaking technology, which enables the cost-effective development of biofermentation processes.

The technology of manufacturing monoclonal antibodies is a relatively new area of medical biotechnology explored by the largest global pharmaceutical concerns, which has been dynamically developing over the last 20 years. The process of manufacturing therapeutical drugs – one of the most eminent achievements of modern biotechnology, enables the manufacture of targeted drugs which selectively interfere with cancer cells, ensuring the better effectiveness and lower toxicity of therapies. Those medicines allowed departure from treatment of cancer based on surgery, radiotherapy and cytotoxic drugs which damage not only cancerous cells, but healthy tissue as well. Mabion is a pioneer company in the area of modern biotechnology, not only on a domestic scale, but also in the area of Central and Eastern Europe. Large international pharmaceutical corporations are the exclusive global suppliers of biosimilars. In the past several years Mabion S.A. had competencies to manufacture random biotechnological drugs, from the stage of designing them through the selection of the technological path to manufacturing the finished drug. Only a few companies in Europe have the capability of conducting the comprehensive process of developing a biotechnological drug.

The selection of biosimilars in the form of therapeutic monoclonal antibodies used in oncology and immunology as the products developed by our company was dictated by the dates of expiry of the patent protection of respective reference medicines and the huge value of the reference drugs market for the products developed by Mabion S.A. referred-to above. The said protection on the territory of the European Union expires over several years, beginning from 2014.

The Company intends to independently go through the registration process of the therapeutic monoclonal antibodies according to the centralized procedure in the whole EU area, where the system for the registration of biosimilars is well regulated. In Poland and in neighbouring countries, the Company will sell its drugs independently, and in other EU countries Mylan Ireland has exclusive distribution rights to those drugs. The Company also has an important goal of introducing the drugs to the American market. In respect of regions with a less regulated registration system, in Asia and Africa, Mabion plans to conduct the whole registration procedure and sales of the drugs via lead local pharmaceutical companies, based on distribution agreements.

On 14 December 2016, the Company's Supervisory Board passed a resolution on appointing Mr Artur Chabowski Chairman of the Company's Management Board. Mr Artur Chabowski will be responsible for the next stage of development of the Company and for reviewing potential strategic options supporting the Company's further development, which may in particular cover acquiring business partners in the USA, acquiring finance on foreign markets and floating the Company on one of the other European countries or in the USA. The Company's former chairman, Mr Maciej Wieczorek, will now be responsible for managing the Company's Scientific & Advisory Board. This body will comprise persons with scientific achievements in the area of Mabion's operations and its aim will be to support the Supervisory Board in sketching the strategic development directions for the portfolio and the use of technology in the foreseeable future.

It follows from a review of the information made available in ClinicalTrials.gov and Pharma Global Data databases conducted by the Company that currently the following clinical trials competitive to those of MabionCD20 (data as at the date of publication of this report) are being conducted:

- NCT02296775 trial by Dr. Reddy Laboratories Limited Comparative Pharmacokinetic, Pharmacodynamic, Safety and Efficacy Study of Three Anti-CD20 Monoclonal Antibodies in Patients with Moderate to Severe Rheumatoid Arthritis. The study is being conducted on a group of approx. 276 patients with Rheumatoid Arthritis. There is no information on the current status of the study. Due to the location of the centres participating in the clinical trial, it seems that the development of the drug is concentrated on unregulated markets;
- NCT01419665 GP2013 clinical trial in the treatment of Patients With Previously Untreated, Advanced Stage Follicular Lymphoma conducted by Sandoz is active. Recruitment of patients has been completed. The estimated date of completion of the study is March 2018. The clinical trial is planned to cover 618 patients;
- NCT01274182 clinical trial GP2013 in the treatment of RA Patients Refractory to or Intolerant of Standard Therapy conducted by Sandoz. The study was completed in December 2016;
- NCT02268045 clinical trial conducted by mAbxience on a group of 250 patients. Recruitment of patients has been completed. The expected date of completion of the trial is July 2017. Due to the location of the centres participating in the clinical trial, it seems that the development of the drug is concentrated on unregulated markets;
- NCT02260804 clinical trial, phase III conducted by Celltrion "To Compare Efficacy and Safety Between CT-P10 and Rituxan in Patients with Low Tumour Burden Follicular Lymphoma". The clinical trial is being conducted on a group of 174 patients. The planned date of completion of the study, pursuant to the available data, is August 2018;
- a clinical trial by Amgen: A Randomized, Double-Blind Study to Compare Pharmacokinetics and Pharmacodynamics, Efficacy and Safety of ABP 798 With Rituximab in Subjects With Moderate to Severe Rheumatoid Arthritis conducted on a group of 300 patients. The expected completion date of the study is July 2018;
- a clinical trial by Amgen A Randomized, Double-Blind Study Evaluating the Efficacy, Safety and Immunogenicity of ABP 798 Compared with Rituximab in Subjects with CD20 Positive B-Cell Non-Hodgkin Lymphoma (NHL) conducted on a group of 250 patients. The planned date of completion of the study is March 2018;
- the NCT02213263 clinical trial by Pfizer: A Study Of PF-05280586 (Rituximab-Pfizer) Or MabThera® (Rituximab-EU) For The First-Line Treatment Of Patients With CD20-Positive, Low Tumor Burden, Follicular Lymphoma (REFLECTIONS B328-06). Patients are still being recruited. Pfizer is planning to recruit 394 patients. The planned date of completion of the study is December 2017.

The status of the clinical trial by Mabion S.A. as at the date of publication of the annual report:

Status of the clinical trial as at 25 April 2017:
NHL » 190 patients covered by clinical trial procedures including: » 140 patients after the first administration of the drug
Rheumatoid Arthritis (RA) » 993 patients covered by clinical trial procedures including: » 708 patients after the first administration of the drug including: 212 after the first administration of the drug under the PK/PD sub-trial.

4.2 Pursuit of the development strategy

The basic objective of Mabion's operations is the development, manufacture and launch to trading of oncological drugs biosimilar to the original biotechnological drugs already existing on the market (the so-called reference drugs).

Currently, the Company's priority is to launch its product MabionCD20 on the largest possible number of global markets. The Company intends to independently go through the registration process according to the centralized procedure in the whole EU area, where the system for the registration of biosimilars is well regulated.

In 2016 the following actions were successfully completed by the Company:
- » the permit for manufacturing for the plant in Konstantynów Łódzki was obtained;
- » manufacturing for the clinical trials in Łódź was completed;
- » the required qualification procedures for all premises, systems and plant in Konstantynów Łódzki were conducted; transfer of the selected process plant from the Manufacturing Plant in Łódź to the Plant in Konstantynów Łódzki was completed;
- » the area and the documentation necessary for preparing the first (technical) batch on a pilot scale in the Plant in Konstantynów Łódzki were prepared;
- » the technical batch and the validation batches were prepared in the Konstantynów Łódzki Plant; all series were produced on a pilot scale (bioreactor culture with a volume of 2x250 L) and cleaned using the technological line for producing antibodies on an industrial scale;
- » the area and the documentation necessary for preparing the first (technical) batch on an industrial scale in the Plant in Konstantynów Łódzki were prepared (currently at early stages);
- » the GMP certificate for the Quality Control Department laboratory located at ul. Fabryczna 17 was obtained;
- » work started on the physiochemical laboratory of the Quality Control Department in Konstantynów Łódzki in the GMP system, which was preceded by a transfer of analytical methods;
- » validation and revalidation of the analytical methods used in the laboratory of the Quality Control Department were conducted to release the finished product for the clinical trials;
- » inclusion of patients in the RA study (the main trial) and in the PK/PD trials was completed;
- » a positive opinion was obtained with reference to the clinical trial during the sixth DSMB meeting.

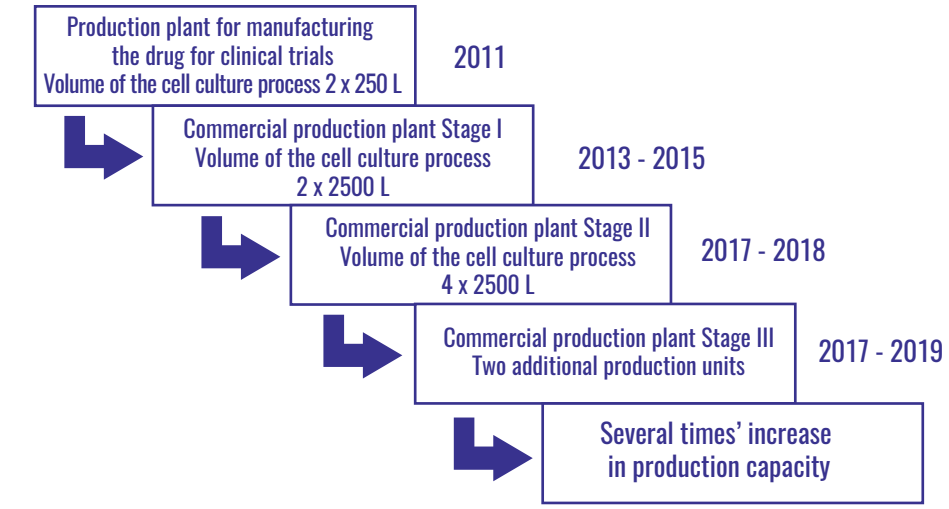
The Company's current production capabilities enable it to provide the drug exclusively for the purpose of the clinical trials conducted and to cover the estimated demand of European Union customers to a very small extent. Upon registering the MabionCD20 drug by EMA, the drug will be sold throughout the territory of the European Union, therefore, adequate production capacity must be achieved. Therefore, the necessary next stage of the Company's development will be providing additional equipment and expansion of the Plant in Konstantynów Łódzki.

The scientific and industrial complex Kompleks Naukowo-Przemysłowy Biotechnologii Medycznej Mabion S.A. located in Konstantynów Łódzki currently constitutes approximately 1/3 of the target size of the complex. The Company planned the expansion project in stages, by building the first of the three planned production modules in the years 2013-2015.

The capital expenditure project which constitutes the subject matter of the permit no. 301 in the Łódź Special Economic Zone will consist of increasing the production capacity of the plant and will cover:
- » additional equipment for the existing production line 2x2500 L; and
- » purchase and installation of a production plant for the second production line 2x2500 L, which will be located in the existing building.

The Company is planning to start the above project in the 3rd quarter of 2017 and to complete it before 31 December 2021

MabionCD20 – developing processes and production capacity

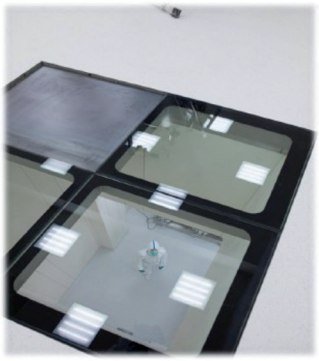


Source: Developed by the Company

Significant development of production capacity in the Konstantynów Łódzki Plant

Additional equipment for the existing production plant;

capital expenditure on two new production buildings



The biotechnological drugs market is already very attractive, and its value is expected to significantly increase over the next few years. The strategy adopted by Mabion S.A. stipulates continuation of research and development work with reference to consecutive biotherapeutics. The core sources of finance for the development strategy should be own funds and subsidies from EU and domestic funds.

The anticipated return on the expenditure incurred to-date is related to ensuring the Company's financial liquidity at the stage of development work and the assumptions for admitting the Company's key product MabionCD20 to trading and generating sufficient future cash flows from the sale of the product in the future.

4.3 Material development factors

Standards relating to studies

The research and development work of Mabion S.A. are conducted according to the highest quality standards. The drugs are manufactured according to the Good Manufacturing Practice. This was confirmed by obtaining the GMP certificate from the Chief Pharmaceutical Inspectorate:

» in November 2014 for the Research and Development Centre in Łódź, at ul. Fabryczna 17;
» in April 2017 for the scientific and industrial complex Kompleks Naukowo-Przemysłowy Biotechnologii Medycznej Mabion S.A. in Konstantynów Łódzki, at ul. gen. M. Langiewicza 60.

Research and development work on new drugs, and quality control analyses are conducted in accordance with Good Laboratory Practice. This was confirmed by obtaining the GLP certificate in March 2014 from the Bureau for Chemical Substances (Biuro do spraw Substancji Chemicznych). Holding such a certificate indicates high quality of the research and analyses conducted. Analyses in terms of drug quality parameters and clinical parameters provide unbiased, reliable results acceptable by drug registration offices throughout the world.

Clinical development of MabionCD20 is conducted according to Good Clinical Practice. The plans for the clinical development were consulted four times with experts from the European Medicine Agency in London. Obtaining scientific advice and acceptance of the academics from the European Medicine Agency for detailed clinical trial protocols minimizes the risk of rejection of future registration applications filed for the MabionCD20 drug.

The clinical trials for MabionCD20 are monitored by an independent DSMB (Data and Safety Monitoring Board) Committee. An independent, unbiased evaluation of the quality of the trials and safety of patients in clinical trials is very important for the reliability of the presented clinical data.

Information on collective experiences and knowledge of the key technical personnel

During its existence, the Company gathered a stable and experienced research personnel team. The team whose knowledge is of key importance to the results of research and development operations comprises:

» Prof. Tadeusz Pietrucha (member of the Company's Supervisory Board, previously Member of the Management Board, assistant professor of medical sciences at the Medical University in Łódź in the area of medical biology and professor of the Medical University in Łódź);
» Dr Maciej Wieczorek (Member of the Company's Supervisory Board, previously Chairman of the Management Board and doctor of medical sciences of the Medical University in Łódź (Medical Biology);
» Jarosław Walczak (Member of the Management Board, graduate of the Łódź University of Technology, Faculty of Food Chemistry and Biotechnology (specialty: Food Technology) and graduate of the post-graduate studies at the Poznań University of Economics (Marketing on the Pharmaceutical Market);
» Dr Sławomir Jaros (Member of the Management Board, scientific director of the Company, graduate of the Warsaw University of Life Sciences, Inter-faculty Biotechnology Studies (specialization: Biotechnology in production and animal health protection), doctor of biological sciences in the Institute of Parasitology of the Polish Academy of Sciences and graduate of Polish-American Studies Executive MBA (University of Maryland).

On 12 October 2016 the Company signed a cooperation contract with the Faculty of Biotechnology and Food Sciences of the Łódź University of Technology. On 9 January 2017 (post-balance-sheet date) an agreement was concluded with the Faculty of Biology and Environment Protection of the Łódź University. Those agreements enable the Company to cooperate in the area of information sharing, conducting research, scientific expert studies, and establish partnership relations in respect of traineeships in the Company for the best students of both universities.

Additionally, the Company earmarks significant funds for the participation of its key personnel in the most prestigious conferences and foreign training. In 2016 these included:

» Proteins & Antybodies, Oxford Global (18/04/2016);
» Biosimilary & Biobetters, Oxford Global (19/04/2016);
» Host Cell Protein Conference, BEBPA (19/05/2016);
» EudraVigilance Training on Electronic Reporting of ICSRs in the EEA, EMA (15/06/2016);
» Extended EudraVigilance Medicinal Product Dictionary. Face to face training course, EMA (17/06/2016);
» Annual Bioassay Conference, BEBPA (28-30/09/2016);
» Extended eudravigilance medical product dictionary. Face to face training course, EMA (18/11/2016);
» EudraVigilance Training on Electronic Reporting of ICSRs in the EEA, EMA (14/12/2016).

In 2016 the Company also intensively developed its personnel's competencies through their participation in internal and external training. There were over eighty such training courses during the reporting period.

4.4 Risk factors and threats

4.4.1 Significant risk factors and threats

Risk related to the macroeconomic conditions

Potential unfavourable changes in the macroeconomic conditions on the markets where the Company is planning to sell its drugs, in particular the slow-down in the rate of economic growth or reducing expenditure on healthcare may have a negative impact on the Company's operations and financial results. Significant economic factors which have an impact on the results achieved by our Company include the level of GDP, average wages, unemployment level, inflation level, level of expenditure on healthcare. The Management Board monitors the situation on the target markets on a current basis, trying to adapt the Company's strategy to the changes respectively in advance.

Risks related to changes in legal regulations and their interpretation

Frequent changes in regulations may cause a potential risk for the Company which may lead to outdating the Company's business forecasts and to deterioration in the Company's financial condition, potentially up to a complete crisis.

The changes in regulations with the largest impact on the Company's operations are amendments to the Pharmaceutical Law, tax law and intellectual property law.

Amendments to the above regulations may lead to a significant change in the Company's legal environment and influence its results.

Also discrepancies in interpretation of the legal order prevailing in Poland and in the EU constitute a material factor which may have an impact on the development prospects, results achieved and financial position of the Company. Inconsistency of interpretations by local courts and public administration authorities, and by Community courts may lead to consequences which will have an indirect or a direct impact on the Company.

The Management Board monitors amendments to legal regulations which are key to the Company and the manner of their construction, trying to adapt the Company's strategy to those changes in a proactive manner.

Risk related to the tax policy

One of the main elements with an impact on the entrepreneurs' decisions is Polish tax law which is characterized by the frequent changes and lack of precision of its regulations, which often cannot be interpreted in a uniform way. Both the practices of tax authorities and court judicature relating to tax issues are based on inconsistent legal regulations which translate into increased business risk in Poland compared with the more stable tax systems in countries with more mature economies. Gradually, the

process of standardization of the tax regulations is taking place, allowing determining their unambiguous interpretation by entrepreneurs and tax authorities.

As of 1 January 2016 the amended Tax Code came into force based on which the rule in dubio pro tributario was adopted which allows resolving doubtful content of tax law regulations to the benefit of the taxpayer. Applying this clause will enable better protection of the taxpayers' rights. This is important for the Company with respect to its operations in the territory of the Łódź Special Economic Zone and future tax relief relating to the capital expenditure incurred.

Risk related to administrative decisions

The Company is unable to ensure that it will obtain particular permits, licences and consents required to complete biotechnological projects, or that no current or future permits, licences and consents will be revoked. Such situations may lead to delays in completion or to the need to change original projects and have a negative impact on the operations and results of the Company.

Foreign exchange risk

The Company purchases most of its laboratory equipment and reagents for conducting research in foreign currencies, mainly in EUR and USD. Unfavourable foreign exchange fluctuations (weakening of PLN compared to other currencies) may have a negative impact on the level of capital expenditure incurred by the Company and lead to an increase in research and development expenses, which in turn may contribute to deterioration in the Company's financial results. Due to the fact that Mabion intends to sell its drugs on foreign markets (mainly denominated in EUR and USD), the risk related to foreign exchange fluctuations will be limited in the future. This risk is to some extent mitigated due to the finalization of the investment project in Konstantynów Łódzki, where part of the suppliers were from outside Poland, but it remains material – the decisive majority of costs relating to the clinical trials of MabionCD20 is incurred in euros.

Market risk

The basic objective of the Company's operations is the development, manufacture and launch to trading of drugs biosimilar to the original biotechnological drugs (the so-called reference drugs). The biotechnological drugs market is already very attractive, and its value is expected to significantly increase over the next few years. However, there is a risk that if the reference drugs are withdrawn from the market or replaced with newer generation drugs, the Company's potential revenues from the biosimilars developed will be lower than previously assumed or will not find buyers.

The Management Board monitors the reference drug market on a current basis and to mitigate this risk it is prepared to undertake work on other biosimilars.

Risk of inventing and launching other drugs used in respect of the same indications as Mabion S.A.'s drugs

Oncological conditions, on which the currently conducted research is focused, are the most intensely researched group of conditions in biomedical studies. It is estimated that approx. 30% of all capital expenditure on research and development in biotechnological companies is spent on oncology. Additionally, genetics and molecular biology are developing quickly.

As a result, it is probable that over the next few years innovative medicines will be launched which will have an advantage over the drugs developed by the Company in terms of their efficacy or tolerance by the human body. Additionally, there is a risk that other treatment methods will be invented – such as vaccines – which could be used against conditions currently subjected to therapies which could use the Company's future drugs. The emergence of new drugs and therapies could have a negative impact on the amount of future sales revenues and the Company's results.

The Management Board monitors scientific progress in the area of new therapies and drugs for conditions in which the Company's medicines are to be used on a current basis. Additionally, most oncological schemes use therapy sequences (a consecutive

drug with a different operating mechanism is used after the potential of the first drug is exhausted), and polytherapies (several drugs with different operating mechanisms are applied at the same time), which significantly reduces the risk of erosion of the drugs applied in tumour therapies.

Competitive risk

The drugs which the Company develops are biosimilar to the original reference drugs which are protected with patents for publicly known periods. It follows from the published information that currently there are many entities on the market which develop biosimilars and work on some of them is highly advanced.

In December 2016 EMA issued a positive opinion on the registration of a biosimilar of rituximab called Truxima by Celltrion, and in April 2017 on the registration of Rituximab GP2013 by Sandoz.[18] These actions are not surprising to Mabion and will not have any impact on the time schedule for the clinical studies adopted by the Company or on the strategy related to launching MabionCD20 on the market. In accordance with the information which had been provided earlier, Mabion S.A. intends to begin the registration procedure of MabionCD20 after completing the clinical tests.

It should be noted that the biosimilars market has high entry barriers. They comprise, among other things, high requirements relating to clinical trials, in particular on developed markets, to prove that the drug is biosimilar to the original medicine. Even if commercialization of a MabThera /Rituxan biosimilar will be successful for several entities, analyses show that the market has growth potential. Despite the very high current sales of the original drug produced by Roche, it should be noted that many sick people do not have access to this therapy at present. In many countries therapy for people with NHL using MabThera /Rituxan is not refunded by the public healthcare systems, and the therapy for those with RA is even more limited.

Risk related to the research and development process

The biotechnological industry, in particular manufacture of modern biosimilar drugs, is characterized by high labour-intensiveness and the need to incur significant expenditure on research and development. Not only the possibility of launching the developed drugs on the market but also the efficiency of production processes and therefore also the manufacturing costs depend on the results of the conducted research and development work. To-date Mabion has expended most of the funds obtained on research and development.

There is a risk that part or all of the objectives of the Company's scientific work will not be achieved in the planned scope or time, which would lead to the inability to recover significant or all the expenditure spent on the research. That would have a material negative impact on the possibility of completion of the Company's strategic plans, and therefore also on the results achieved.

The results of the research and development work to-date attest to the Company's capability to produce proprietary biosimilars, and in the opinion of the Management Board significantly mitigate the risk of not achieving ultimate success. Additionally, the Management Board monitors the course of the research and development work on a current basis and implements operating and procedural solutions which ensure high effectiveness of the said work.

Risk of underestimating the manufacturing costs and launching the MabionCD20 drug

According to assumptions very generally adopted by the biotechnological industry, the development and production of a single biosimilar which meets global standards lasts around 7-9 years and costs approximately up to several dozen million USD. Guidelines relating to biosimilars are only now being formed and each case is analysed by market regulators individually, therefore, the scope of requirements relating to the technology, documentation, analytics and clinical development is not strictly specified. Therefore, the exact scope of research and development work cannot be determined and the development costs of the drugs cannot be precisely anticipated.

[18] In the event that the drug is finally registered, Sandoz is to launch the biosimilar rituximab under two trade names: Rixathon and Riximyo. Based on: http://www.bankier.pl/wiadomosc/Komitet-EMA-wydal-pozytywna-opinie-ws-rejestracji-biopodobnego-rituximabu-Sandozu-7512699.html

In the Company's opinion, the policy for developing proprietary research and development competencies, investing in the Company's own production capacity and consulting with the European Medicine Agency (EMA) with reference to the clinical program of MabionCD20 allow significant cost reduction compared to industry assumptions.

It cannot be precluded that the actual costs of production and launching the developed drugs (including MabionCD20) on the market will be much higher than currently anticipated. A material increase in the costs of production and market launch of the developed drugs may have a negative impact on the financial results achieved by the Company.

Industry dynamics, both in respect of the regulations which are being formed and the technologies which arise and are constantly being enhanced, may lead, among other things, to the following direct reasons for underestimating the costs of drug development, which includes MabionCD20:

- amendments to the regulations concerning the production of drugs and the need to use more expensive technological solutions or creating new ones;
- an increase in the costs of purchase of raw materials and materials used to manufacture drugs, following from the market conditions or new guidelines;
- amendments to regulations concerning the scope of analyses needed to characterize the product, e.g. the need to perform additional costly analyses or develop new analytical methods or tools;
- increasing the requirements concerning registration documentation, e.g. the need to perform additional trials or studies;
- increasing the scope of the clinical trials as a result of the biological variability of patients, in response to treatment, the drug's metabolism, the patients' or doctors' non-compliance with the study protocol;
- increasing the scope of the clinical trials as a result of the biological variability of patients higher than that given in the available clinical literature based on which the study was designed;
- increasing the cost of the clinical trials due to strong competition on the clinical trials market and limited availability of research centres and patients.

Risk related to the work schedule

Achievement of the Company's strategic goal, which is the registration and market launch of biosimilars, is possible after the expiry of patent protection of the original drugs, and is connected with the need to develop a detailed work schedule for several years. The possibility of pursuing this schedule is conditioned by many various factors, both internal and external. Potential unexpected delays in the adopted time schedule may lead to not achieving the planned sales revenue in the expected period and have a negative impact on the Company's financial results. The Management Board monitors all works related to the development of drugs and if necessary implements the required operating solutions to minimize the impact of unexpected events on future time schedules.

Risk of being unable to complete research work on MabionCD20 before the date of expiry of the patent protections of the reference drug in the USA

In 2007 the Company initiated the research and development process of MabionCD20, which is a drug directly competitive with the currently marketed drug MabThera/Rituxan by Roche. In Europe the basic patent protection for this drug expired in the period: and end of 2013 – end of 2014, and the basic patent protection in the USA will expire in 2018[19].

The Company's goal is to launch MabionCD20 on the market as quickly as possible after the patent protection expires, which would enable the Company to temporarily achieve competitive advantage. Delays in patient recruitment for clinical trials, delays in conducting clinical research and the time needed to complete the procedure for registering the drug MabionCD20 (in Europe this as a rule lasts 210 days) may cause the market launch of the drug to be delayed compared with the Company's current assumptions.

The Company has taken actions aimed at mitigating such risk in the past and is taking such actions now, to mitigate both the registration risk and the risk of extending the time to registration, by conducting the scientific advice procedure with the European Medicine Agency (EMA) thrice – in December 2011, in November 2012, in October 2015 and in October 2016.

[19] http://www.fiercepharma.com

As a result of those consultations the Company received written responses in which the scopes of the clinical trials and the documentation requirements were agreed. It is worth emphasizing that thanks to the non-typical design of the clinical trial (focusing on the application of MabionCD20 to treat RA, which materially distinguishes the trial from competitive trials), agreed with EMA during the scientific advice, it gained advantage both in terms of the basic trial period and the rate of recruiting patients for the trial. The target patient group in the MabionCD20 trial is numerous and widely available, therefore it is possible to recruit them quickly.

Additionally, in consideration of the trial statuses of competitive companies published, the Company concludes that even if there are delays, the Company will maintain its favourable position, in terms of time, on regulated markets compared with other entities conducting clinical trials of Rituximab biosimilars.

Risk related to low quality or loss of biological material

The basic material used in Mabion S.A. products is biological material. It is both manufactured by the Company and delivered by third party suppliers. Selecting optimal cell clones which form the basis for further drug production on a larger scale is very important for the process of developing and producing biotechnological drugs. The quality of the biological material and its storage in strictly determined conditions is of key importance for the success of the work. There is a risk that the biological material acquired from third party suppliers will be of a low quality or that the material produced by the Company will be damaged or destroyed, which would have a negative impact on achieving the Company's assumed revenues and financial results.

Mabion S.A. entered into cooperation with verified suppliers, it controls the quality of the supplies and stores the biological material in specialist devices, using monitoring and two independent power sources. Additionally, the original deposit of the biological material used by the Company for the production of drugs is stored in an independent storage place outside Poland so as to be able to continue its production in another external facility in case of any unexpected events.

The Company also monitors the course of production and the quality of the manufactured products introducing necessary organizational, human resources, and technological changes following from the quality management processes.

Risk related to the production process

One of the key elements of production of biotechnological drugs is the production process which must be conducted in compliance with the previously planned parameters. The production process of such drugs comprises several stages and even the smallest change in any of them may have an impact on the drug's properties (e.g. in terms of its effectiveness or safety). Transferring from the small laboratory scale to industrial scale (up-scaling) is an extremely important element of the drug production process. Ensuring the consistency, stability and sterility of the whole production process is extremely important. Mabion laboratories were equipped with modern apparatuses which ensure the maximum accuracy and repeatability of the results obtained. The materials used in the production sphere are appropriately attested for use in the pharmaceutical industry. The installed production line was wholly based on sterile materials. The Management of particular Departments of Mabion S.A. comprises high-class specialists, with professional education, appropriately trained and prepared for working in the scope of duties they have been assigned both by internal and external experts.

In 2015 the Company made several changes in its human resources and organizational structure, including in managerial positions, which enabled it to overpass the difficulties related to the production process. The implemented organizational changes facilitated the Company control over the work of each of the team members. Their work is constantly monitored and appraised in accordance with the procedures adopted by the Company, which turned out to be effective in respect of other divisions, which enabled the Company to systematically strive to reduce the level of risk related to the production staff. The Company meets the requirements of Good Laboratory Practices (GLP) and Good Production Practices (GMP), it has the necessary attestations and permits (including the permit of the Chief Pharmaceutical Inspector for producing the tested medicinal products).

Risk of achieving production capacity compliant to demand

Currently, it is difficult to assess the exact demand for MabionCD20, nevertheless, the expectations of Mabion's global partner related to the supply plans for sale on the EU and USA markets may result in the need to increase production capacity over the level achievable in the current building in the scientific and industrial complex Kompleks Naukowo-Przemysłowy in Konstantynów Łódzki. The Company is aware of this risk and has capabilities to add another building to the existing one in the same location and on the same plot. The building may to a larger extent be used for production purposes (part of the current building is used for office purposes). The Company's experience in investment and technological processes related to the current building will be used in the potential new project. Additionally, it will be possible to use part of the industrial plant installed in the current building in the added part, which will enable using the additional space for installing the maximum number of bioreactors. The final needs, dates and scope of such an investment will depend on consultations with the global partner in respect of the planned deliveries of MabionCD20 to the EU and USA market.

Risk related to attestations for the laboratory and production plant

Maintaining appropriate conditions on the premises where work is conducted on the Company's products is extremely important. Currently Mabion has all the required attestations for the equipment and laboratory and production premises in both plants.

The risk of not obtaining or delay in obtaining the pharmaceutical acceptance by the Chief Pharmaceutical Inspectorate of Kompleks Naukowo-Przemysłowy in Konstantynów Łódzki. Nevertheless, due to the number of stakeholders (differentiated supply and service channels, the human factor, etc.), the Company's Management Board cannot guarantee that the attestations will be maintained in the future.

Risk related to clinical trials

One of the material stages of work on the preparation for registration and launching a drug on the market are clinical trials conducted on human beings.

The Company began the clinical development of MabionCD20 in 2012, when the first applications for permits to conduct clinical trials were filed. After obtaining the necessary permits for conducting clinical trials from regulators, in June 2013 the process of active recruitment began and the first drugs were administered to patients with Rheumatoid Arthritis in Polish, Lithuanian and Georgian centres. Currently, the Company has consents to conduct clinical trials in Polish, Georgian, Serbian, Bosnian, Lithuanian and Ukrainian centres.

Conducting clinical trials is always exposed to the risk related to the insufficient effectiveness or safety of application of the Tested Medicinal Product. At the current stage of the trials the state of the Company's knowledge allows stating that the risk in respect of MabionCD20 is moderate.

Mabion regularly presents data relating to the efficiency and safety of the MabionCD20 drug to the Data and Safety Monitoring Board (DSMB). This is an independent Committee comprising specialists in the area of rheumatology, pharmacology and statistics. To-date, the Committee met six times (the last meeting was in December 2016) and each time it positively appraised the study, recommending its further conduct without the need to introduce any changes to the protocol and procedures, also commenting on the great benefits to the participating patients. Should DSMB not give its positive opinion on the study, it would be exposed to the risk of discontinuation.

Risk related to registering drugs

The basic purpose of Mabion is the introduction of the developed biosimilars to global markets, mainly to the markets of the European Union and the USA, which is related to the duty to register those drugs by relevant authorities – appropriately the European Medicines Agency (EMA) and the American Food and Drug Administration (FDA). The work conducted by Mabion S.A. on the development and implementation of drugs are complaint with the EMA guidelines. FDA issued several regulations

regarding biosimilar drugs, nevertheless, instances of registering such drugs in the USA have been few to-date and it is impossible to widely verify the regulations in practice.

There is a risk that in the event of e.g. procedural changes or errors in documentation, the process of registering the drug in the area of the European Union may be delayed or impossible to finalize. Additionally, there is a risk that further regulations adopted by the FDA will be more restrictive than the EMA guidelines and that potentially successfully completed clinical trials conducted by Mabion will be challenged by the FDA, and will have to be repeated to register the drug in the USA. In such cases the Company would be exposed to the need to incur additional costs or to fully discontinue activities on the American market, which would have a negative impact on the level of financial results achieved by the Company.

From the beginning of work on developing biosimilars Mabion S.A. has been cooperating with EMA on the issue of compliance with all the guidelines and procedures related to the registration process in the European Union (the last, fourth scientific advice took place on 13.10.2016) and monitors the development of the FDA guidance in respect of registering biosimilars within the territory of the UAS. However, the risk that the working methodology, the scope of work and its nature adopted by the Company, as well as the form of collecting data and their details may be assessed by the EMA as insufficient for the registration of the drug.

Risk related to launching and maintaining the drugs on the market

After registering the drugs Mabion is planning to launch them on the market as quickly as possible, which is related to preparing the drug as a market product (production, marketing, distribution and sales) and requires significant financial expenditure and good organizational preparation. Due to the very specific product and differentiated specificity of the markets on which Mabion S.A. intends to operate, the Management Board expects a diversified promotion and distribution strategy for the drugs produced.

In accordance with the adopted assumptions, marketing and distribution of the drugs in Poland and in selected Central and Eastern European countries will be conducted independently by the Company. In other European countries and other countries globally, marketing and distribution activities will be conducted by global and local partners.

There is a risk that launching the Company's drugs on particular global markets will not be compliant with the current assumptions or that as a result of negligence or error in sales, logistics or distribution the drugs will be found unsellable on a given market which could have a negative impact on the sales revenue earned by Mabion and on its financial results. Mabion S.A. acquired a distribution partner for the EU and Balkan region and currently is actively looking for an experienced and strong partner to effectively sell Mabion S.A. drugs in the USA. This is being done via Plexus Ventures LLC (the Company informed about it in its current report no. 16/2014). The process is complex and long – it consists of contacting companies, signing confidentiality agreements and presenting data at various levels of detail depending on the stage of development of the process. At the same time, the companies are updating their offers.

Members of the Management Board and the current shareholders with a significant interest in the Company and those who actively support it have significant legal and technical insight in organizing hospital sales and wide experience in launching and maintaining pharmaceuticals on the market.

Risk related to refunding drugs

The costs of developing and producing the newest generation of biosimilar drugs are very high, which is related to their relatively high market price later. There are drugs whose sales are refunded by state budgets or other non-budgetary payers on the market. The Management Board's intention is to cover the drugs produced by Mabion with refunds in the largest possible number of countries in which they will be admitted to sale. There is a risk that in the event that the goal is not achieved or is only partly achieved, and the reference drugs or biosimilars produced by competitors are refunded, demand for Mabion S.A.'s medicines will be lower than planned. As a result, this may have a negative impact on the level of revenues earned by the Company and its financial results.

Risk of withdrawing the permit for admitting the Company's products to trading and product liability risk

In cases stipulated by the law the permit for admitting the drugs to trading (or the production permit) in the area in which the drugs had previously been admitted to trading may be withdrawn.

For example, pursuant to Polish law the Minister of Health withdraws permits for admission of medicinal products to trading, among other things, in the case of determining unexpected, serious undesirable effects of the product which are a threat to human life or health, lack of declared therapeutic effectiveness of the product, determining risk of use disproportionate to the therapeutic effect or determining that the medicinal product is launched on the market in a manner non-compliant with the permit or legal regulations. Withdrawal of a permit for admitting Mabion S.A.'s medicinal products to trading would have a significant unfavourable impact on the Company's development perspectives and on the financial results achieved.

Irrespective of the above, in some circumstances (e.g. in the event of a justified suspicion that the medicinal products do not meet the respective requirements) the provincial pharmaceutical inspector uses decisions on suspending trading in certain series of the product in the area of operations of the said inspector.

In the indicated circumstances and in other cases where the use of the Company's products may cause damage to individual entities, Mabion may be liable for damages which is related to the risk of claims being filed in respect of the Company under civil law proceedings. The Company may also incur liability if the product is found to be dangerous. For example, pursuant to Polish law, a dangerous product is a product which does not ensure the safety that may be expected during normal use of the product. Whether the product is safe is decided in circumstances when it is introduced to trading, in particular the manner in which it is presented on the market and the information provided to the consumer about the product's properties. Also the need to satisfy potential claims for damages addressed to the Company may have a material negative impact on the operations and financial position of the Company.

Risk of loss of key personnel

Mabion S.A. conducts its operations based on the knowledge and experience of highly qualified managers and scientific and research personnel.

There is a risk of the Company's key personnel leaving the Company in the future, which could have a negative impact on the quality of the products offered. It could also cause loss of repute and difficulties in acquiring new orders, and lead to the deterioration of financial results. The Company's Management Board pursues an active personnel policy aimed at retaining the most valuable specialists in the Company.

The Company's employees may count on the possibility of developing professionally in a comprehensive manner, which includes participation in training (internal and external), support in starting doctoral studies, and inclusion in the promotion procedure – the principles for obtaining these benefits are formalized, open and unbiased (e.g. the promotion procedure, implementing bonus programs for employees with long service, implementing loyalty schemes and bonus programs).

Risk related to disclosure of trade secrets

The pursuit of Mabion's plans may depend on keeping the Company's confidential information in secrecy, in particular information relating to the trials conducted and the technological processes. Disclosure of this information and its use by persons cooperating with the Company, in particular its employees, cannot be eliminated, and the effect of such disclosure may be its use by entities conducting competitive business operations. In such instance, the Company's legal defence rights, in particular the claims it may lodge, may prove insufficient to protect it from the negative effects of such events.

The Company undertook several legal steps to eliminate this risk.

Risk related to disputes concerning industrial and intellectual property rights

Mabion operates in an area where industrial and intellectual property rights regulations and their protection are of great importance. There is no litigation pending in respect of any violations of industrial or intellectual property rights. The Company intends to engage in business so as not to violate any third party rights in this respect. However, potential claims lodged by third parties against the Company in respect of industrial and intellectual property rights violations cannot be eliminated, in particular at the stage of research work and at the stage of obtaining permits for admitting the Company's medicinal products to trading. If such claims are lodged, even if they are unjustified, it could have an unfavourable impact on the time needed to obtain the said permit, and defence against such claims may involve the need to incur significant costs which in effect may have a negative impact on the Company's financial results.

Risk related to the funding granted

In 2016 Mabion S.A. was party to one contract for co-financing from public funds in connection with research and development, and implementation projects (relating to MabionHER2). The contract precisely stipulates the dates and scopes of tasks which are covered by additional funding. There was a risk that in the event that the Company uses all or part of the co-financing funds not in conformity with the purpose of the funding or that, without keeping to the binding procedures, collects all or part of the funding it was not due or an excessive amount thereof, it will be obliged to return part or the full amount of the co-financing plus interest. Therefore, should the conditions for a liability arising occur, the Company's financial position may deteriorate significantly, which in the longer perspective could threaten the achievement of the Company's strategic goals.

Liquidity risk

The Company does not generate on-going revenue from sales of market products, and its operations to-date have been financed with funds from the issuance of shares, co-financing from public funds and – to some extent – sales of research and development services. The Management Board is planning to acquire funds for financing the Company's further operations from a distribution contract signed with Mylan Ireland, from new EU projects and from the issuance of shares.

In accordance with the provisions of the agreement with Mylan, Mabion S.A. will receive payments for completing the milestones specified in the agreement depending on the filing for and obtaining the trading admittance and launching the MabionCD20 preparation in the market in key countries, and licence receivables based on annual net sales revenues.
Potential delays in meeting the planned time schedule may lead to a delay in receiving the assumed tranches from the distributor.

If the application for additional aid funding from the EU is unsuccessful and if the issue of shares is delayed, Mabion S.A. may be exposed to serious liquidity problems and to the need to obtain an alternative source of funding.

Risk related to operations in the Łódź Special Economic Zone

Mabion S.A. conducts research and development, and production operations, and has built a fully-equipped scientific and industrial complex in the Łódź Special Economic Zone. In accordance with the Act on Special Economic Zones, the income earned on business activities in the special economic zone, under the permit received, is exempt from Corporate Income Tax. Mabion S.A. is exempt from the tax until 31 December 2026.

There is a risk that due to an amendment to the legal regulations on the operation of the zones and principles relating to the tax exemptions, as well as the Company's potential non-compliance with the ratios specified in the permits, which entitle it to the tax exemptions, the conditions for the Company's further operations in the ŁSEZ may become unattractive in terms of taxes or the Company may lose its rights to use the said tax reliefs.

4.5 Risk management system

The Company does not have a formalized financial risk management system. Decisions on applying instruments hedging the planned transactions are taken based on a current analysis of the Company's position and its environment.

The Management Board of Mabion S.A. manages risk on a constant basis in all significant areas of the Company's operations. Due to the dynamic situation on the pharmaceutical market, the Company's Management Board monitors, audits and updates potential risks on a current basis, at several stages:

- anticipating and identifying potential risk groups, in-depth understanding of the type of risk to enable its active prevention
- constant monitoring and controlling of existing risks;
- avoiding risks – abandoning certain activities which expose the Company to high risk;
- taking preventive actions – developing operating plans and appropriate procedures which may be immediately implemented in the event of potential risk arising;
- maintaining risk within predetermined limits or implementing plans to minimize the risks;
- reporting on the risks identified and their nature;
- applying Best Practices for WSE Listed Companies.

5 STATEMENT OF COMPLIANCE WITH CORPORATE GOVERNANCE PRINCIPLES

5.1 The set of corporate governance principles

In 2016 the Company was governed by corporate governance principles specified in the document "Best Practices for WSE Listed Companies 2016" adopted by the Board of the WSE by a resolution of 13 October 2015, which entered into force on 1 January 2016 (the document is available on the official website of the Warsaw Stock Exchange concerning corporate governance in use on the Main Market of the WSE, at the address: https://www.gpw.pl/dobre_praktyki_spolek_regulacje).

At the same time, the Company explains that it does not apply any corporate governance good practice principles other than those indicated above, including those which exceed the requirements of the Polish law.

5.2 Corporate governance principles and recommendations which the Company renounced

In 2016 the Company did not apply two DPSN 2016 recommendations: VI.R.1., VI.R.2.

In 2016 the Company did not apply six DPSN 2016 detailed principles: II.Z.2., III.Z.2., III.Z.3., III.Z.4., V.Z.6., VI.Z.1.

In 2016 four recommendations did not apply to the Company: I.R.2., IV.R.2., IV.R.3., VI.R.3., as well as four detailed principles: I.Z.1.10., I.Z.2., IV.Z.2., VI.Z.2.

Explanations relating to recommendations or detailed DPSN 2016 principles:

I.R.2. Where a company pursues sponsorship, charity or other similar activities, it should publish information about the relevant policy in its annual activity report.

This principle does not apply to the Company.

The Company's comment: The Company does not pursue sponsorship, charity or other similar activities.

I.Z.1.10. A company operates a corporate website and publishes on it, in a legible form and in a separate section, in addition to information required under the legislation:
financial projections, if the company has decided to publish them, published at least in the last 5 years, including information about the degree of their implementation.

This principle does not apply to the Company.

The Company's comment: The Company does not publish financial forecasts.

I.Z.2. A company whose shares participate in the exchange index WIG20 or mWIG40 should ensure that its website is also available in English, at least to the extent described in principle I.Z.1. This principle should also be followed by companies not participating in these indices if so required by the structure of their shareholders or the nature and scope of their activity.

This principle does not apply to the Company.

The Company's comment: The Company's shares do not participate in the exchange index WIG20 or mWIG40 and the Company's shareholding structure or the nature and scope of its operations do not address applying this principle. At the same time, the Company is making efforts to make its website available in English to the widest possible extent.

II.Z.2. A company's management board members may sit on the management board or supervisory board of companies other than members of its group subject to the approval of the supervisory board.

This principle is not applied.

The Company's comment: The Company's internal regulations and agreements with Members of the Management Board do not impose such restrictions.

III.Z.2. Subject to principle III.Z.3, persons responsible for risk management, internal audit and compliance should report directly to the president or another member of the management board and should be allowed to report directly to the supervisory board or the audit committee.

This principle is not applied.

The Company's comment: There is no isolated unit responsible for risk management, internal audit and compliance. Therefore, currently no-one is responsible for managing those areas and they report directly to the Chairman or another Management Board Member, and may also report to the Supervisory Board or the Audit Committee.

III.Z.3. The independence rules defined in the generally accepted international standards of the professional internal audit practice apply to the person heading the internal audit function and other persons responsible for such tasks.

This principle is not applied.

The Company's comment: There is no isolated unit in the Company responsible for internal audit; therefore, currently no-one manages the internal audit function and no other people are responsible for the function to which the independence principles specified in generally acceptable international professional internal audit practice standards apply.

III.Z.4. The person responsible for internal audit (if the function is separated in the company) and the management board should report to the supervisory board at least once a year with their assessment of the efficiency of the systems and functions referred to in principle III.Z.1 and table a relevant report.

This principle is not applied.

The Company's comment: There is no isolated unit in the Company responsible for internal audit; therefore, currently no-one manages the internal audit function and no other people are responsible for the internal audit function. The Company's Management Board presents to the Supervisory Board his/her own assessment of the efficiency of the systems and functions referred to in principle III.Z.1 and submit a relevant report.

IV.R.2. If justified by the structure of shareholders or expectations of shareholders notified to the company, and if the company is in a position to provide the technical infrastructure necessary for a general meeting to proceed efficiently using electronic means of communication, the company should enable its shareholders to participate in a general meeting using such means, in particular through:
1) real-life broadcast of the general meeting;
2) real-time bilateral communication where shareholders may take the floor during a general meeting from a location other than the general meeting;
3) exercise of the right to vote during a general meeting either in person or through a plenipotentiary.

This principle does not apply to the Company.

The Company's comment: Applying the adequacy principle to the Company's shareholding structure does not enable the shareholders to participate in the General Meeting using means of electronic communication.

IV.R.3. Where securities issued by a company are traded in different countries (or in different markets) and in different legal systems, the company should strive to ensure that corporate events related to the acquisition of rights by shareholders take place on the same dates in all the countries where such securities are traded.

This principle does not apply to the Company.

The Company's comment: Securities issued by the Company are only traded in Poland.

IV.Z.2. If justified by the structure of shareholders, companies should ensure publicly available real-time broadcasts of general meetings.

This principle does not apply to the Company.

The Company's comment: Applying the adequacy principle to the Company's shareholding structure, the Company does not enable the shareholders to participate in publicly available real-time broadcasts of the General Meeting in real time.

V.Z.6. In its internal regulations, the company should define the criteria and circumstances under which a conflict of interest may arise in the company, as well as the rules of conduct where a conflict of interest has arisen or may arise. The company's internal regulations should, among other things, provide for ways of preventing, identifying and resolving conflicts of interest, as well as rules for excluding members of the management board or the supervisory board from participation in reviewing matters subject to a conflict of interest which has arisen or may arise.

This principle is not applied.

The Company's comment: Currently the Company has no internal regulations which would determine the criteria and circumstances under which a conflict of interest may arise in the company, as well as the rules of conduct where a conflict of interest has arisen or may arise, apart from indicating in the Supervisory Board Regulations the obligation of one Member of the Board to inform Members of the Supervisory Board and withholding from voting on issues where a conflict of interests may arise. The issuer will verify the current practice in this respect and will consider the possibility of implementing appropriate internal regulations in the future.

VI.R.1. The remuneration of members of the company's governing bodies and key managers should follow the approved remuneration policy.

This principle is not applied.

The Company's comment: The Company does not have a remuneration policy and remuneration of particular Members of the Management Board are determined each time by the Supervisory Board as a result of negotiations, and for the Supervisory Board – by the General Meeting.

VI.R.2. The remuneration policy should be closely tied to the company's strategy, its short- and long-term goals, long-term interests and results, taking into account the solutions necessary to avoid discrimination on whatever grounds.

This principle is not applied.

The Company's comment: The Company does not have an official remuneration policy, but avoiding discrimination is a binding rule, and the remuneration policy, in particular the level of remuneration, results from long- and short-term financial plans.

VI.R.3. If the supervisory board has a remuneration committee, principle II.Z.7 applies to its operations.

This principle does not apply to the Company.

The Company's comment: There is no remuneration committee in the Company's operating structure.

VI.Z.1. Incentive schemes should be constructed in a way necessary among other things to tie the level of remuneration of members of the company's management board and key managers to the actual long-term financial standing of the company and long-term shareholder value creation as well as the company's stability.

This principle is not applied.

The Company's comment: The Company does not have incentive schemes for its Management Board and key managers dependent on the long-term financial standing of the Company and long-term creation of shareholder value as well as the Company's stability.

VI.Z.2. To tie the remuneration of members of the management board and key managers to the company's long-term business and financial goals, the period between the allocation of options or other instruments linked to the company's shares under the incentive scheme and their exercisability should be no less than two years.

This principle does not apply to the Company.

The Company's comment: The Company does not have an incentive scheme for Members of its Management Board and key managers based on options or other share-linked instruments.

6 INFORMATION ON SHARES AND THE SHAREHOLDING STRUCTURE OF MABION S.A.

6.1 The Company's share capital

As at 31 December 2016 the Company's share capital amounted to PLN 1,180,000 and consisted of 11,800,000 shares with a per value of PLN 0.10 each, including:

- 450,000 registered A-series preferred shares;
- 450,000 registered B-series preferred shares;
- 450,000 registered C-series preferred shares;
- 450,000 ordinary D-series bearer shares;
- 100,000 registered E-series preferred shares;
- 100,000 registered F-series preferred shares;
- 20,000 registered G-series preferred shares;
- 2,980,000 ordinary H-series bearer shares;
- 1,900,000 ordinary I-series bearer shares;
- 2,600,000 ordinary J-series bearer shares;
- 790,000 ordinary K-series bearer shares;

- 510,000 ordinary L-series bearer shares;
- 360,000 ordinary M-series bearer shares;
- 340,000 ordinary N-series bearer shares;
- 300,000 ordinary O-series bearer shares.

A, B, C, E, F and G-series registered shares are preferred as to votes – each share gives the right to two votes at the General Meeting. The total number of votes resulting from all the issued shares is 13,370,000.

On 4 July 2016 the District Court for Łódź-Śródmieście in Łódź, 20th Business Department of the National Court Register registered an increase in the Company's share capital. The Company's share capital was increased from PLN 1,150,000 to PLN 1,180,000 as a result of the issue of 300,000 ordinary bearer O-series shares with a nominal value of PLN 0.10 each.

6.2 Shareholders with significant shareholdings in the Company

According to the Company's Management Board's knowledge, as at the publication date of this Report, i.e. as at 25 April 2017, the following shareholders have at least 5% voting rights at the Company's General Meeting:

	Number of shares	% share in share capital	Number of votes	Share in total number of votes
1. Twiti Investments Limited*	2 509 457	21,27%	3 098 757	23,18%
2. Maciej Wieczorek indirectly, including through:	1 624 876	13,77%	2 117 726	15,84%
Glatton Sp. z o.o.	1 004 526	8,51%	1 004 526	7,51%
Celon Pharma S.A.	620 350	5,26%	1 113 200	8,33%
3. Polfarmex S.A.	1 437 983	12,19%	1 920 833	14,37%
4. Funds managed by Amathus TFI S.A	988 042	8,37%	988 042	7,39%
5. Generali OFE*	1 094 707	9,28%	1 094 707	8,19%
6. Others	4 144 935	35,13%	4 149 935	31,04%
TOTAL	**11 800 000**	**100,00%**	**13 370 000**	**100,00%**

* *Pursuant to the list of shareholders at the Extraordinary General Meeting of the Company held on 16 February 2017.*

** *Mr Maciej Wieczorek has 100% of shares in the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 66.67% in the share capital of Celon Pharma S.A. and 75% in the total number of voting rights in Celon Pharma S.A.*

6.3 Shareholdings in the Company and shares in related entities held by management and supervisory personnel

As at the publication date of this Report, i.e. as at 25 April 2017, Members of the Company's Management and Supervisory Boards hold the following shares in the Company:

	Shares held as at the date of filing the Report for 2016 (25 April 2017)
Management Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% interest in the share capital) and Celon Pharma S.A. (in which, through Glatton Sp. z o.o., he holds 66.67% of interest in the share capital) he holds jointly 1,624,876 of the Company's shares with a nominal value of PLN 0.10 each, which constitute 13.77% of the Company's share capital and give 15.84% voting rights at the General Meeting.
Artur Chabowski	indirectly, through FL Real Investments Holding Limited with its registered office in Nicosia (Cyprus), in which Artur Chabowski holds 100% interest in the share capital, holds jointly 29,649 of the Company's shares with a nominal value of PLN 0.10 each, which constitutes 0.25% of the Company's share capital and gives 0.22% voting rights at the General Meeting.
Supervisory Board	
Robert Aleksandrowicz	holds directly 132,094 of the Company's ordinary bearer shares with a nominal value of PLN 0.10 each, which constitute 1.12% of the Company's share capital and give 0.99% voting rights at the General Meeting;
	indirectly, through Twiti Investments Limited with its registered office in Nicosia (Cyprus), in which Robert Aleksandrowicz holds shares constituting 50% of the share capital and 50% of voting rights at the General Meeting of the company, is a Mabion shareholder and holds jointly 2,509,457 of the Company's shares with a nominal value of PLN 0.10 each, which constitute 21.27% of the Company's share capital and 23.18% voting rights at the General Meeting.
Tadeusz Pietrucha	indirectly, through Bio-Tech Consulting Sp. z o.o. with its registered office in Łódź (in which Tadeusz Pietrucha holds shares constituting 97% of the share capital) hold jointly 5,000 of the Company's shares with a nominal value of PLN 0.10 each, constituting 0.04% of the Company's share capital and 0.07% voting rights at the General Meeting.

As at the date of this Report, i.e. as at 25 April 2017, other Members of the Company's Management and Supervisory Boards hold no shares in the Company. Members of the Management Board and Supervisory Board of Mabion S.A. hold no shares in the Company's related entities.

6.4 Employee share plan

Mabion does not run any employee share programs.

6.5 Purchase of treasury shares

In 2016 the Company did not purchase or sell its shares.

6.6 Holders of securities with special control rights attached

A, B, C, E, F and G-series registered shares are preferred as to votes – each share gives the right to two votes at the General Meeting. Shareholders holding registered shares are vested with pre-emptive rights and right of first refusal in respect of registered shares held for sale. There are no securities in the Company which would give any special control rights.

Series	Number of shares	Shareholder	Number of shares held by the shareholder as at 18.04.2017
A	450.000	Celon Pharma S.A.	450.000
B	450.000	Polfarmex S.A.	450.000
C	450.000	Twiti Investments Limited	450.000
E	100.000	Celon Pharma S.A.	32.850
		Polfarmex S.A.	32.850
		Twiti Investments Limited	34.300
F	100.000	Celon Pharma S.A.	10.000
		Twiti Investments Limited	85.000
		Bio-Tech onsulting Sp. z o.o.	5.000
G	20.000	Twiti Investments Limited	20.000

6.7 Restrictions as to voting rights

The Company's Articles of Association do not stipulate any restrictions regarding exercising voting rights or provisions according to which, in cooperation with the Company, equity rights attached to securities would be isolated from the securities. With reference to the Company, restrictions regarding voting rights may result only from generally binding legal regulations.

6.8 Restrictions as to transferring ownership rights to securities

The Company's Articles of Association do not stipulate restrictions in trading in the Company's D, H, I, J, K, L, M, N and O-series shares. The Company's A, B, C, E, F and G-series shares are registered shares. Shareholders holding registered shares are vested with pre-emptive rights and right of first refusal in respect of registered shares held for sale.

6.9 Agreements which could result in future changes in the proportion of shares held by the existing shareholders or bondholders

According to the Company's best knowledge there are no determinations which could lead to a change in the Company's control in the future. The Company's Articles of Association do include provisions relating to the principles of selling registered preferred A, B, C, E, F and G-series shares (pre-emptive rights and pre-emptive rights in respect of registered shares for other holders of the Company's registered shares), based on which a registered share may be sold to persons other than shareholders vested from registered shares only on condition that those entitled to pre-emptive rights and right of first refusal do not exercise those rights.

7 THE COMPANY'S BODIES

7.1 Management Board

7.1.1 Composition, changes in composition and principles of appointing Members of the Management Board

In 2016 the composition of the Management Board was as follows:

Mr Maciej Wieczorek	–	Chairman of the Board (until 14/12/2016)
Mr Sławomir Jaros	–	Management Board Member
Mr Jarosław Walczak	–	Management Board Member
Mr Artur Chabowski	–	Management Board Member (from 14/12/2016 Chairman of the Management Board)

Mr Maciej Wieczorek, who had been Chairman of the Management Board, resigned from the function and from being on the Management Board, as of 14 December 2016. On the same date, the Company's Supervisory Board passed a resolution on appointing Mr Artur Chabowski Chairman of the Management Board.

On 10 March 2017 (post-balance-sheet event) the Supervisory Board passed resolutions on removing all the Management Board Members as follows: Mr Artur Chabowski, Mr Jarosław Walczak and Mr Sławomir Jaros, and on appointing all the Members referred to above to the first joint term of office of the Management Board, including on appointing Mr Artur Chabowski Chairman of the Management Board and Mr Jarosław Walczak and Mr Sławomir Jaros Members of the Management Board. The first joint term of office of Members of the Management Board ends on the date of the General Meeting of the Company approving the financial statements for the financial year 2021.

The passing of resolutions on removing and appointing Members of the Management Board is the result of amendments to § 26 of the Company's Articles of Association passed by the General Meeting on 16 February 2017, i.e. introducing the resolution on the joint term of office of the Management Board which lasts 5 years. The previously binding provisions of the Company's Management Board determined individual terms of office for particular Management Board Members.

The above-mentioned resolutions on removing and appointing Members of the Management Board became binding upon entering amendments to the Company's Articles of Association by the Registration Court in the Register of Businesses of the National Court Register on 23 March 2017, introduced by section 10 of the Resolution of the Extraordinary General Meeting No. 7/II/2017 dated 16 February 2017, i.e. upon entering the amendments to § 26 of the Company's Articles of Association.

Members of the Management Board are appointed by the Supervisory Board (par. 26 of the Company's Articles of Association) for a five-year term of office. Each Member of the Management Board may be suspended or removed by the Supervisory Board or General Meeting (par. 26 of the Company's Articles of Association.

7.1.2 Rights and description of operations of the Management Board

The Management Board exercises all rights relating to managing the Company with the exception of the rights reserved by the law or the Company's Articles of Association to the competencies of the General Meeting or the Supervisory Board (par. 26 of the Company's Articles of Association). The General Meeting has the right to take the decision on issuing or redeeming shares (par. 17 of the Company's Articles of Association). The Chairman of the Management independently, in recognition of the provisions of par. 27 or two Members of the Management Board acting jointly, or one Member of the Management Board acting with the proxy are entitled to make declarations of intent on behalf of the Company. In accordance with par. 27 two Members of the Management Board acting jointly, or one Member of the Management Board acting with the proxy are entitled to make declarations of intent on behalf of the Company in respect of actions aimed at incurring liabilities or managing ownership rights with a value exceeding PLN 200,000.

Additionally, the Management Board is entitled to increase the Company's share capital by issuing new shares with a total value of up to PLN 100,000.00 (par. 9a of the Articles of Association) to attain the target capital. This authorization expires 3 (three) years from entering the amendments to the Company's Articles of Association passed by the Extraordinary General Meeting dated 30 September 2015.

On 16 February 2017 (post-balance-sheet event) the Extraordinary General Meeting (NWZ) authorized the Company's Management Board to increase the Company's share capital once or twice by an amount no higher than PLN 450,000 by issuing no more than 4,500,000 ordinary bearer shares with a value of PLN 0.10 each. The above resolution of NWZ was registered with the National Court Register on 23 March 2017.

7.1.3 Remuneration, bonuses and terms and conditions of employment contracts of Members of the Management Board

The table below shows the value of fixed remuneration received by Members of the Management Board for performing functions on the Company's Management Board.

Management Board Member	Remuneration for 2016, gross
Maciej Wieczorek	PLN 66 000
Sławomir Jaros*	PLN 44 000
Jarosław Walczak**	PLN 44 000
Artur Chabowski	PLN 271 601

* *Mr Sławomir Jaros additionally received remuneration under his employment contract of PLN 249,000.03 including PLN 73,000.00 of bonuses paid. This amount was not accounted for in the schedule above.*

** *Mr Jarosław Walczak also received remuneration under a civil law agreement of PLN 2,198.00. This amount was not accounted for in the schedule above.*

The Company does not have any subordinated entities, therefore, Members of the Management Board did not receive any remuneration from the Company's subordinated entities in 2016.

In 2016 no bonuses, benefits or remuneration was paid out to Members of the Management Board based on plans for bonuses or participation in profits. Mr Artur Chabowski is entitled to an incentive bonus awarded by the Supervisory Board comprising 0.4% of the total amount of each future share issue on a stock exchange outside the territory of the Republic of Poland. Rights to the payments are acquired as at the date of the respective public offering. The payments are to be made in cash.

In 2016 no remuneration was paid to Members of the Management Board in the form of share options. The Company's corporate regulations do not provide for the Members of the Management Board to receive remuneration in the form of share options. In 2016 the Company did not grant any in-kind benefits to Members of its Management Board. In 2016 Members of the Management Board did not receive any remuneration for services provided in any other form than that described above. In 2016 Members of the Management Board were not entitled to any non-financial components of remuneration. Contracts concluded with Members of the Management Board do not include provisions relating to severance payments or any other payments to be made in the event of terminating an employment contract, short-term service contract or another similar legal transaction.

7.1.4 Contracts with management members

No contracts have been concluded with members of management which would provide for compensation in the event of their resignation of removal from the position held without a valid reason, or in the event that the removal or lay-off is the result of a merger by acquisition.

7.2 Supervisory Board

7.2.1 Composition, changes in composition and principles of appointing Members of the Supervisory Board

In 2016 the composition of the Supervisory Board was as follows:

Robert Aleksandrowicz	–	Chairman of the Supervisory Board;
Bogdan Manowski	–	Deputy Chairman of the Supervisory Board;
Grzegorz Stefański	–	Member of the Supervisory Board;
Tadeusz Pietrucha	–	Independent Member of the Supervisory Board;
Jacek Piotr Nowak	–	Member of the Supervisory Board;
Tomasz Jakub Jasny	–	Independent Member of the Supervisory Board;
Małgorzata Badowska	–	Independent Member of the Supervisory Board (from 7 June 2016).

On 16 February 2017 (post-balance-sheet event) the Extraordinary General Shareholders' Meeting passed resolutions on removing all the then-current members of the Supervisory Board and appointing the following persons to the first term joint of office on the Supervisory Board:

1. Mr Roberta Aleksandrowicza,
2. Mr Grzegorza Stefańskiego,
3. Mr Tadeusza Pietruchy,
4. Mr Jacka Nowaka,
5. Mr Macieja Wieczorka,
6. Mr Davida Johna James,
7. Mr Artura Olecha.

The above-mentioned resolutions on removing and appointing Members of the Supervisory Board became binding upon entering amendments to the Company's Articles of Association by the Registration Court in the Register of Businesses of the National Court Register on 23 March 2017, introduced by section 7 of the Resolution of the Extraordinary General Meeting No. 7/II/2017 dated 16 February 2017, i.e. upon entering the amendments to § 21 of the Company's Articles of Association.

Members of the Supervisory Board are appointed for a three-year period. Members of the Supervisory Board are appointed and removed by the General Meeting. The Supervisory Board comprises five to ten members.

7.2.2 Rights and description of operations of the Supervisory Board

In accordance with par. 22 of the Company's Articles of Association the Supervisory Board's competencies comprise actions reserved for it in the Commercial Companies Code, and moreover:

a) passing resolutions on the purchase and sale of real estate, perpetual usufruct or share in real estate;
b) appointing a registered auditor to audit the Company's financial statements;
c) appointing and removing the Management Board Members;
d) determining the amount of remuneration of Management Board Members;
e) assessing Management Board motions as to appropriation of profit or offset of loss; approval of the Regulations of the Management Board;
g) giving opinions on the Company's multi-year strategic plans;
h) passing Regulations which determine the principles of operation of the Supervisory Board;
i) granting consent for purchasing the Company's fixed assets the value of which exceeds 10% (in words: ten percent) of the Company's equity;
j) granting consent to pledging or granting usufruct in respect of registered shares.

Apart from the activities specified above from the moment of admitting the Company's shares to trading on a regulated market, the Supervisory Board should:

a) grant consent to conclude a contract with the related entity referred to in § 28.3 of the Articles of Association,
b) once a year prepare and present to the General Meeting a concise assessment of the internal control system and risk management system material to the Company;
c) investigate and give opinions on issues which are to be on the General Meeting's agenda.

In accordance with par. 25 of the Company's Articles of Association, the Supervisory Board appoints the Audit Committee responsible for supervising the Company's financial affairs. The Audit Committee comprises three Members appointed by the Supervisory Board from among its Members, where at least one of the Members of the Audit Committee should be an independent Member of the Supervisory Board within the meaning of the provisions of § 21 of the Articles of Association and have qualifications in accounting and finance.

Additionally, the Supervisory Board may appoint the Nomination and Remuneration Committee responsible for preparing assessments of candidates as Members of the Management Board and determining the remuneration principles and amounts of remuneration of Members of the Management Board. The Remuneration Committee comprises three Members appointed by the Supervisory Board from among its Members, where at least one of the Members of the Remuneration Committee should be an independent Member of the Supervisory Board within the meaning of the provisions of § 21 of the Articles of Association.

The Supervisory Board is not obliged to appoint the above Committees if it comprises five Members. If the Supervisory Board has not appointed the above Committees, their tasks shall be performed by the Supervisory Board.

7.2.3 Remuneration, bonuses and terms and conditions of employment contracts of Members of the Supervisory Board

The value of the remuneration payable for performing functions on the Company's Supervisory Board received in respect of 2016 was as follows:

Member of the Supervisory Board	Remuneration for 2016, gross
Robert Aleksandrowicz	1500,00
Grzegorz Stefański	1500,00
Tomasz Jasny	7000,00
Bogdan Manowski	7195,99
Tadeusz Pietrucha	1056,30
Jacek Nowak	6560,76
Małgorzata Badowska	500,00

In 2016 Members of the Management Board received remuneration based on the resolution of the Company's General Meeting dated 28 June 2012, pursuant to which:

» Members of the Supervisory Board are entitled to remuneration of PLN 500, gross, in respect of participating in Supervisory Board meetings;
» Members of the Supervisory Board appointed to the Audit Committee are entitled to monthly remuneration of PLN 500, gross.

None of the Members of the Management Board receives remuneration for working on an employment contract.

The Company does not have any subordinated entities, therefore, Members of the Supervisory Board did not receive any remuneration from the Company's subordinated entities in 2016.

In 2016 no bonuses, benefits or remuneration was paid out to Members of the Supervisory Board based on plans for bonuses or participation in profits. The Company's corporate regulations do not provide for the Members of the Supervisory Board to receive remuneration in the form of plans for bonuses or participation in profits.

In 2016 no remuneration was paid to Members of the Supervisory Board in the form of share options. The Company's corporate regulations do not provide for the Members of the Supervisory Board to receive remuneration in the form of share options.

In 2016 the Company did not grant any in-kind benefits to Members of its Supervisory Board.

In 2016 members of the Supervisory Board did not receive remuneration from the Company for services of any nature provided by them except for additional remuneration for membership in the Audit Committee, as shown in the schedule above.

On 16 February 2017 (post-balance-sheet event) the Extraordinary General Shareholders' Meeting passed resolutions on determining remuneration for Members of the Supervisory Board. Pursuant to Resolution No. 26/II/2017:
» Members of the Supervisory Board are entitled to remuneration of PLN 1000, gross, in respect of participating in Supervisory Board meetings;
» Members of the Supervisory Board appointed to the Audit Committee are entitled to monthly remuneration of PLN 4000, gross.

The above-mentioned resolutions on remunerating Members of the Supervisory Board became binding upon entering amendments to the Company's Articles of Association by the Registration Court in the Register of Businesses of the National Court Register on 23 March 2017, introduced by section 10 of the Resolution of the Extraordinary General Meeting No. 7/II/2017 dated 16 February 2017.

7.2.4 Appointed Committees

An Audit Committee operates in the Company, but not a Nomination and Remuneration Committee.

In 2016 functions of the Audit Committee Members were performed by:
» Mr Tomasz Jakub Jasny,
» Mr Bogdan Manowski,
» Mr Jacek Piotr Nowak.

On 16 February 2017 (post-balance-sheet event) the Extraordinary General Meeting passed resolutions on removing all the then-current members of the Supervisory Board and appointing the following persons to the first term joint of office on the Supervisory Board: The above-mentioned resolutions on removing and appointing Members of the Supervisory Board became binding upon entering amendments to the Company's Articles of Association by the Registration Court in the Register of Businesses of the National Court Register on 23 March 2017, introduced by section 7 of the Resolution of the Extraordinary General Meeting No. 7/II/2017 dated 16 February 2017, i.e. upon entering the amendments to § 21 of the Company's Articles of Association.

On 31 March 2017 the Company's Supervisory Board, acting on the basis of § 25. 1 and 3 of the Company's Articles of Association appointed the following persons to the Audit Committee of the Supervisory Board:
» Mr Jacka Piotra Nowaka,
» Mr Davida Johna James,
» Mr Artura Olecha.

The Audit Committee operates pursuant to the provisions of Article 86 of the Act on registered auditors and their self-government, registered audit companies and public supervision of 7 May 2009 (Journal of Laws No. 77, item 649, as amended), and its organizational structure and operating principles are described in the Regulations passed by the Supervisory Board.

7.3 General Meeting

7.3.1 Operating principles of the General Meeting

The General Meeting acts based on the Commercial Companies Code and the Company's Articles of Association.

7.3.2 Significant rights of the General Meeting

The competencies of the General Meeting include issues reserved for it by the Commercial Companies Code, and the purchase and sale of real estate, perpetual usufruct or share in real estate do not require the passing of a resolution by the General Meeting (par. 17 of the Company's Articles of Association).

The following, in particular, require passing a resolution by the General Meeting:
» appointing and removing Members of the Supervisory Board;
» suspending or removing Members of the Management Board;
» method of appropriating the Company's net profit;
» determining the dividend date.

To be valid, a resolution on the merger or demerger of the Company requires a majority of 3/4 (in words: three quarters) of the votes cast.

In recognition of the provisions below, to be valid, a resolution on removing issues from the General Meeting's agenda requires a majority of 3/4 (in words: three quarters) of the votes cast in the presence of shareholders representing at least 50% (in words: fifty percent) of the Company's share capital, with the consent of the shareholders filing a justified motion to abandon investigating the issue on the agenda. In the event that a motion for removing an issue from the agenda is filed by the Management Board, the resolution of the General Meeting requires an absolute majority of votes cast.

Removing issues from the General Meeting's agenda based on Article 401 of the Commercial Companies Code on the motion of a shareholder representing at least 1/20 (in words: one-twentieth) of the Company's share capital requires the consent of the shareholder who made the motion.

7.3.3 Rights of shareholders and the manner of their execution

Rights and obligations related to the Company's shares are determined in the provisions of the Commercial Companies Code, in the Articles of Association and in other legal regulations.

Property rights related to the Company's shares following from the Articles of Association

The Company's shareholders have the following property rights following from specific provisions of the Articles of Association:
1) Right of first refusal in the purchase of registered shares by the-then holders of registered shares in proportion to the shares held (par. 13 of the Company's Articles of Association).
2) Right to redeem the shares held (par. 12 of the Company's Articles of Association).

Corporate rights vested in the Company's shareholders related to participation in the Company:

1) Right to participate in the General Meeting (Article 412 of the CCC) and right to vote at the General Meeting (Article 411 § 1 of the CCC).

Voting rights from the existing Company shares are as follows:
a) two votes at the General Meeting are attached to each of the A, B, C, E, F, G-series shares;
b) one vote at the General Meeting is attached to each D, H, I, J, K, L, M, N, O- series shares;

2) The right to convene the General Meeting by shareholders representing at least one-half of the share capital or at least one-half of the votes in the Company (Article 399 § 3 of the CCC).

3) The right of shareholders with at least one-twentieth of the Company's share capital to convene the Extraordinary General Meeting and demand that certain issues be put on the agenda (Article 400 § 1 of the CCC). If within two weeks of the date of presenting the request to the Management Board the Extraordinary General Meeting is not convened, the Registration Court may authorize the shareholders who requested the Meeting to convene it (Article 400 § 3 of the CCC).

4) The right of shareholders with at least one-twentieth of the Company's share capital to put certain matters on the agenda of the Extraordinary General Meeting (Article 401 § 1 of the CCC). The demand should include at least the justification or draft resolution relating to the proposed item on the agenda (Article 401 § 1 of the CCC).

5) The right to appeal against General Meeting resolutions on the principles specified in Articles 422-427 of the CCC.

6) The right to request appointing the Supervisory Board in separate groups. Pursuant to Article 385 § 3 of the CCC, on motions from shareholders representing at least one-fifth of the share capital. The Supervisory Board should be appointed by the next General Meeting by voting in separate groups.

7) The right to demand that a specific issue related to establishing or running the affairs of a public company be audited by a registered auditor (an auditor for special issues). The respective resolution should be passed by the General Meeting upon a motion by a shareholder or shareholders holding at least 5% of the total voting rights at the General Meeting (Article 84 of the Act on Public Offering). For this purpose the shareholders may demand that the Extraordinary General Meeting be convened or that the passing of this resolution be included on the agenda of the next General Meeting. If the General Meeting dismisses the motion for appointing an auditor for special issues, the motioners may request that such an auditor be appointed by the Registration Court within 14 days of passing the resolution (Article 85 of the Act on Public Offering).

8) The right to obtain information about the Company in the scope and manner specified by the law, in particular pursuant to Article 428 of the CCC. During the General Meeting the Management Board is obliged to give information relating to the Company at the request of a shareholder, if this is justified for assessing an issue on the agenda; a shareholder who is refused such information during the General Meeting and who reports his/her opposition to the minutes of the Meeting may file a motion with the Registration Court to oblige the Management Board to provide such information (Article 429 of the CCC).

9) The right to a registered deposit certificate issued by the entity which maintains the securities account in accordance with the regulations governing trading in financial instruments (Article 328 § 6 of the CCC).

10) The right to demand copies of the Company's Directors' Report and financial statements, and the registered auditor's opinion fifteen days before the General Meeting at the latest (Article 395 § 4 of the CCC).

11) The right to review the list of shareholders entitled to participate in the General Meeting on Management Board premises and to request a copy of the list reimbursing the costs of its preparation (Article 407 § 1 of the CCC).

12) The right to demand copies of motions in cases covered by the agenda within a week of the date of the General Meeting (Article 407 § 2 of the CCC).

13) The right to file a motion for checking the list of attendees to the General Meeting by a specially appointed committee comprising at least three persons. The motion may be filed by the shareholders holding one-tenth of the share capital represented at the General Meeting. The motioners are entitled to appoint one of the members of the committee (Article 410 § 2 of the CCC).

14) The right to review the book of minutes and demand that copies of resolutions certified by the Management Board be issued (Article 421 § 2 of the CCC).

15) The right to file a claim for repairing damage caused to the Company according to the principles specified in Articles 486 and 487 of the CCC, if the Company does not claim the damages within a year of the date of disclosing the action which caused the damage.

16) The right to review documents and demand that the copies of documents referred to in Article 505 § 1 of the CCC (in the event of a merger), in Article 540 § 1 of the CCC (in the event of a demerger) and in Article 561 § 1 of the CCC (in the event of the Company's transformation) be made available on the Company's premises free of charge.

17) The right to review the share register and to request a copy of the register, reimbursing the costs of its preparation (Article 341 § 7 of the CCC).

18) The right to demand that the commercial company which is the Company's shareholder provide information whether it is the parent or subsidiary of a given commercial company or co-operative which is the Company's shareholder, or whether it ceased to be such a parent or subsidiary. A shareholder may also demand that the number of shares or votes be disclosed, or the number of shares or votes that the commercial company holds, including as a pledgee, user or based on agreements with other persons. The demand for information should be filed in writing (Article 6 § 4 and 6 of the CCC).

7.4 Principles for amending the Company's Articles of Association

The principles for amending the Company's Articles of Association are regulated by the Commercial Companies Code. Amendments to the Articles of Association require a resolution of the General Shareholders' Meeting and entry into the register. Determining consolidated wording of the Company's Articles of Association lies within the competencies of the Supervisory Board.

7.5 Main features of internal control and risk management systems

The Company does not have a formalized internal control system or financial risk management system in respect of the preparation of financial statements. Data for the purpose of financial statements and the financial statements themselves are prepared by the Company's accounting function. A Management Board Member supervises the preparation of the financial statements. After the financial statements are approved, they are presented to the Company's Management Board.

8 ADDITIONAL INFORMATION

8.1 Remuneration policy

The Company does not have a separate, formal remuneration policy and the remuneration of each member of the Management Board is each time negotiated by the Supervisory Board, and for the Supervisory Board, by a General Meeting of the Company.

The terms and conditions, and amounts of remuneration of Members of the Company's Management Board and non-financial elements of remuneration for which they are eligible are presented in section 7.1.3 of this Directors' Report. The key managers of the Company were not eligible for any non-financial elements of remuneration in 2016.

No major changes took place in 2016 as far as the lack of a remuneration policy and the Company's remuneration system in place are concerned. In the Company's opinion, the remuneration setting procedures and remuneration amounts make it possible for the Company to achieve its goals, including a long-term increase in shareholder value and stability of the Company's operation.

8.2 Liabilities for pensions and similar benefits

In 2016, the Company did not have any liabilities for pensions or similar benefits to former members of its managing or supervisory bodies, or any liabilities incurred in connection with such pensions.

8.3 Proceedings

In the year ended 31 December 2016, the Company was not a party to any proceedings before a court, an arbitration authority or a public administration authority.

8.4 Registered audit company

The financial statements were audited by PricewaterhouseCoopers Spółka z ograniczoną odpowiedzialnością, with its registered office in Warsaw, at al. Armii Ludowej 14, entered in the list of registered audit companies maintained by the National Board of Registered Auditors ("PwC"). The registered audit company was appointed by the Supervisory Board by its Resolution adopted on 7 June 2016, as authorized by the Company's Memorandum and Articles of Association. Under the audit contract (scope: an interim review for the period from 1 January 2016 to 30 June 2016 and an audit of the annual financial statements for 2016) executed on 14 July 2016, the fee for the audit of the financial statements as at and for the year ended 31 December 2016 amounted to PLN 40,000, net of value-added taxes, and the fee for the review of the financial statements amounted to PLN 25,000, net of value-added taxes. The contract was executed for 12 months.

In the prior year, PwC audited the Company's financial statements as at and for the year ended 31 December 2015 (scope: an interim review for the period from 1 January 2015 to 30 June 2015 and an audit of the annual financial statements for 2015) for a fee of PLN 17,000 , net of value-added taxes, for the review, and PLN 28,000, net of value-added taxes, for the audit.

On 21 February 2017, the Company executed a contract with PwC for the provision of services associated with the proposed issue of the Company's shares on a U.S. stock exchange. The scope of services provided by PwC under that contract is:

- Support for the Company in the preparation for the transformation of the PAS financial statements for the years 2016 and 2015 into IFRS financial statements;
- Audit of the IFRS financial statements for the years 2016 and 2015;
- Drafting of the so called Comfort Letters in connection with the proposed listing of the Company's shares on a stock exchange outside the territory of Poland (in Europe or the United States);
- Support in the drafting of issue documents necessary for the issue of the Company's shares in the territory of Europe (other than Poland) or the United States.

PwC's fee for the provision of services involved in the proposed issue of the Company's shares outside the territory of the Republic of Poland amounted to PLN 1m, plus out-of-pocket expenses of not more than four percent of the fee.
In the years 2015 and 2016, PricewaterhouseCoopers Spółka z ograniczoną odpowiedzialnością did not provide any services other than as discussed above.

8.5 Employment

As at 31 December 2016, the Company employed 120 people, whereas the average employment in full-time equivalent terms was 106.45 people in 2016.

8.6 Major research and development achievements

Mabion S.A. operations focus on research and development for the purpose of implementing new biotechnological and biosimilar medicines generated thanks to modern genetic engineering. The strategic goal of the Company is to develop, produce and sell medicines applied in the treatment of cancers, and autoimmune and metabolic diseases. In 2016, the Company conducted active research intended to develop several medicines biosimilar to original medicines existing on the market (the so called "reference medicines"), applied in the treatment of cancers, metabolic and autoimmune diseases, including:

- MabionCD20 monoclonal antibody - an oncological medicine biosimilar to MabThera/Rituxan product (including rituximab as the active substance), produced by Roche. MabThera/Rituxan is widely used in the treatment of blood cancers (lymphomas, leukemias) and rheumatoid arthritis;

- » MabionHER2 monoclonal antibody - an oncological medicine biosimilar to Herceptin (including trastuzumab as the active substance), produced by Roche. Herceptin is used in the treatment of breast cancers;
- » MabionVEGF_Fab monoclonal antibody - a medicine biosimilar to Lucenties (including Ranimizumab as the active substance). Lucentis (Novartis) is used in adults in the treatment of several visual impairment diseases;
- » MabionEGFR monoclonal antibody - an oncological medicine biosimilar to Erbitux (including Cetuximab as the active substance). Erbitux is indicated for the treatment of metastasized colon cancer.

MabionCD20 is the highest priority medicine. It is at the same time in the most advanced stage of development of all the products being developed by the Company.

Research projects conducted by Mabion S.A. in 2016.

Internal projects

Project – therapeutic proteins	Indication	Project completion stage (December 2016)
MabionCD20 (Rituximab)	non-Hodgkin lymphomas (NHL); chronic lymphoid leukaemia; rheumatoid arthritis	preclinical | Phase I | Phase III
MabionHER2 (Trastuzumab) - project strategy change since 2015	breast cancer (HER2 positive)	preclinical | Phase I | Phase IV
MabionEGFR (Cetuximab)	Colon cancer, squamous cell cancers of the head and neck	preclinical | Phase I | Phase IV

External projects

MabionVEGF_Fab (Ranimizumab)	neovascular form of age-related macular degeneration (AMD); visual impairment caused by diabetic macular oedema (DME); visual impairment caused by macular oedema after retinal vein occlusion (RVO); visual impairment caused by choroidal neovascularization (CNV)	preclinical | Phase I | Phase IV
anti-ANGPTL4	lowering of the level of triglycerides	

Project stages: preclinical | Phase I | Phase IV — In progress

Other re-combined proteins/internal projects:

Project – other re-combined proteins	Indication/application	Project completion stage (December 2016)
Protease for the double cutting technology	specific proteolysis of proteins and peptides (obtaining proteins from precursors, protein mapping)	
Cell platform for targeted and specific introduction of cDNA of re-combined proteins in the host's genome	establishing stable cell lines	

Completed In progress

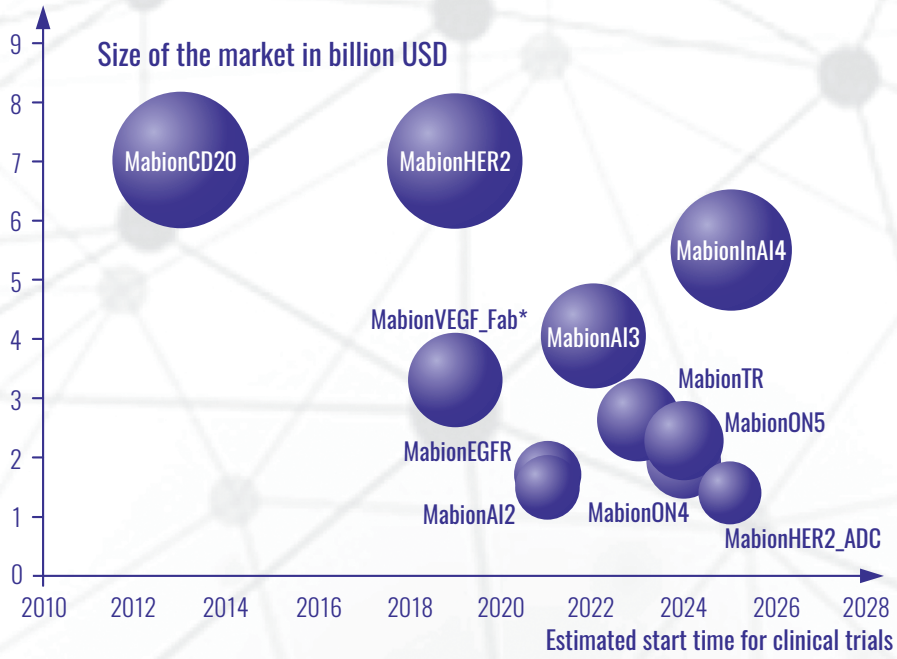
MabionCD20 project stages completed in 2016 by Research and Development

Project stage name	Task completion stage (status in December 2016)
QTTP (characteristics of the physiochemical and biological profile of a series of Mabthera reference medicine)	
Head to Head comparability/similarity* (external analyses) – part 1	
Head to Head comparability/similarity* (external analyses) – part 1	
Comparability of MabionCD20 series (2 x 250 L scale series, Łódź Production Facility)	
PK sample analysis (RA trial)	
Qualification, validation, transfer of analytical methods (comparability, PK NHL)	
Optimization of new analytical methods	
Establishment of the process space – upstream	
Establishment of the process space – downstream	
Head to Head similarity (MabionCD20 vs. Mabthera vs. Rituxan)	

* *Comparative trials: "Comparability" – involves comparisons between MabionCD20 series, "similarity" – involves comparisons between MabionCD20 medicine and the reference medicine.*

On 30 March 2017, the Company's Management Board adopted a resolution concerning the plan of a medicinal product development strategy.
A graphic representation of the strategy is presented below:

PIPELINE



Product	Therapeutic area	Comments
MabionCD20		Size of the market based on data for the year 2016
MabionHER2		Conditional development. Size of the market based on data for the year 2016
MabionEGFR		Size of the market based on data for the year 2016
MabionVEGF_Fab*		Size of the market based on data for the year 2016
MabionAI2		Size of the market based on estimations of the analysts for the year 2022
MabionAI3		Size of the market based on estimations of the analysts for the year 2022
MabionTR		Size of the market based on estimations of the analysts for the year 2022
MabionON4		Size of the market based on estimations of the analysts for the year 2022
MabionON5		Size of the market based on estimations of the analysts for the year 2022
MabionHER2_ADC		Conjugate based on MabionHER2. Size of the market based on estimations of the analysts for the year 2022
MabionInAI4		Innovative medicine, size of the market based on estimations of the analysts for the year 2022

Autoimmunology Oncology Ophthalmology Tissue metabolism

* Stage of common development with the partner.

8.7 Natural environment issues

The Company operates in compliance with the environmental protection laws and regulations. In the Company's opinion, there are no environmental protection requirements which could affect the Company's use of its property, plant and equipment.

The Company operates in compliance with the currently applicable laws and regulations in that respect. Hazardous and non-hazardous laboratory waste codes are established on the basis of the currently applicable laws and regulations, i.e.:

- *Polish Act on Microorganisms and Genetically Modified Organisms of 22 June 2001 (Journal of Laws of 2001, No. 76/811);*
- *Polish Act on Amendments to the Act on Genetically Modified Organisms and Certain Other Acts of 15 January 2015;*
- *Polish Environmental Protection Act of 27 April 2001 (Journal of Laws of 2013, item 1232);*
- *Polish Act on Waste of 14 December 2012 (Journal of Laws of 2013, item 21);*
- *Polish Water Act of 18 July 2001 (Journal of Laws of 2012, No. 145, as amended);*
- *Polish Act on Environmental Damage Prevention and Repair of 13 April 2007 (Journal of Laws of 2014, item 210, as amended);*
- *Polish Act on the Management System for Greenhouse Gas or Other Substance Emissions of 17 July 2009 (Journal of Laws No. 130/1070, as amended)*
- *Decree of the Health Minister on the Detailed Medical Waste Handling Procedures of 30 July 2010 (Journal of Laws of 2010, item 940);*
- *Decree of the Environment Minister on Waste Records Document Templates of 12 December 2014 (Journal of Laws of 2014, item 1973)';*
- *Decree of the Environment Minister on the Waste Catalogue of 15 January 2015 (Journal of Laws of 2015, item 110).*

The Company's registered office address is Konstantynów Łódzki, ul. gen. Langiewicza 60. The Company's Management Board is located there. The Company has two production sites.

The Research and Development Centre for Biotechnological Medicinal Products in Łódź, at ul. Fabryczna 17, has a valid permit for waste generation as stated in Decision No. 65/Op./15 of 28 April 2015, issued by the Mayor of Łódź.

An application for an integrated permit for the Medical Biotechnology Scientific and Industrial Centre of Mabion S.A. in Konstantynów Łódzki, ul. gen. M. Langiewicza 60, was submitted with the Marshal's Office of the Łódź Voivodship in 2015. On account of the installation type, the facility was classified as an IPCC-type (Integrated Pollution Prevention and Control) installation and, in light of the Decree of the Environment Minister on the Types of Installation Capable of Significantly Polluting Individual Nature Elements or the Environment as a *Whole of 27 August 2014 (Journal of Laws of 2014, item 1169)* (Section 4.4 of the Appendix to the above Decree: "Installations in the chemical industry for the production, using chemical or biological processes, of: medicinal products or pharmaceutical materials"), it requires an integrated permit for the operation of the installation. Before that, under administrative proceedings, the Company obtained environmental conditions dated 15 May 2015 from the Mayor of Konstantynów Łódzki.

Waste generated by the Company is consistent with the waste codes declared in the above documents. The waste handling procedure, its removal, sorting and disposal are described in detail in the Company's system documents (Good Laboratory Practice and Good Manufacturing Practice procedures and instructions). Waste record sheets are regularly updated in the form envisaged by the applicable statutory provisions.

Strict records are kept of waste collected in designated places. Prior to disposal, bags and packaging are sorted, checked for agreement with the records, and transferred for disposal to an external company at least at the statutory intervals. Transfer of waste to its recipient is documented with a waste transfer sheet which is retained for five years after the end of the calendar year in which the document is drawn up. Waste is collected by authorized companies which hold a permit for the collection and transport of waste, issued by relevant authorities.

After the end of each calendar year, not later than by 15 March, *a summary of the types and quantities of waste generated* is drawn up using the applicable forms whose templates are announced by the Ministry of the Environment. Summaries are submitted to the Marshal's Office of the Łódź Province.

The Company's operations generate gas emissions associated with the use of cars for business purposes. In order to submit a Report on the Use of the Environment to the relevant authorities, each year a summary of gas or dust emissions from fuel combustion processes taking place in the combustion engines of cars is prepared. The person responsible for that retains/marks fuel invoices issued to Mabion S.A. Fuel type and year of manufacture of the car (which makes it possible to assign the car to an appropriate category) are taken into account in the drafting of such reports. A *Summary of the Scope of Use of the Environment and Fees Due* is submitted to the Marshal's Office of the Łódź Province by 31 March of the following year.

Under Article 3.6 of the Environmental Protection Act, where only vehicles are used, it is not necessary to set up an account in the *National Greenhouse Gas and Other Substance Emission Database* (KOBIZE). Only entities which manage a facility (where 'facility' is defined as in the Act of 27 April 2001) are required to do so.

The following waste collection, disposal or recovery contracts were in place in respect of waste management at Mabion S.A. in 2016.

1. A contract with EGOLIT Sp. z o.o. dated 20 April 2011. The contract applies to hazardous or non-hazardous chemical waste having the codes agreed by both parties. The scope is determined by reference to Mabion's activities and in accordance with a valid decision of the Municipality of Łódź concerning a waste generation permit and a valid decision of the Kutno Starost concerning a permit for hazardous or non-hazardous waste transport activities for EGOLIT.
2. A contract with "EMKA" Handel – Usługi Krzysztof Rdest, in place since 29 October 2010. The contract applies to hazardous or non-hazardous medical waste having the codes agreed by both parties. The scope is determined by reference to Mabion's activities and in accordance with a valid decision of the Municipality of Łódź concerning a waste generation permit and a valid decision of the Mazowieckie Province Governor (Voivod) concerning a permit for hazardous waste disposal, including transport, for EMKA.

8.8 Social responsibility policy

EQUAL OPPORTUNITY POLICY

Mabion S.A. pursues a policy of equal opportunities for all employees, in terms of sex, race or age. Neither job descriptions nor remuneration levels are differentiated depending on any of the above factors. Employees are evaluated based on their competence by means of periodical performance appraisals. The Company actively pursues a policy of protection of pregnant women and women on maternity leave, granting them several special rights. Where that is necessary, female employees who are pregnant, have recently given birth to a child or who are breastfeeding are transferred to positions which do not pose risks to their health. We also draw attention to the fact that the Company respects parental rights of female and male employees alike, i.e. the right to additional childcare leave (Article 188 of the Labour Code).

The Company employs people of various ages. Religion does not affect employment, either, as religious issues are not discussed during the recruitment process or employment. Mabion has been pursuing an equal employment opportunity policy on the various dimensions of its operation since inception. The Company's policy is rooted in the European Union's Directives (including, among other things, Council Regulation (EC) No 1083/2006).

1. ETHICS

Each employee of the Company may learn about his/her rights and obligations and values embedded in our corporate culture, which translates into clarity and transparency of mutual expectations and rules of conduct in everyday work. Mabion S.A. aspires to creating a work environment rooted in respect and mutual trust. Each employee:

» knows his or her duties;
» may engage in an open and constructive dialogue about his or her performance;
» may count on professional development assistance;
» is recognized and rewarded based on merit (basic pay system, plus performance bonuses and motivational trips;
» may voice his or her opinion and contributes to improving his or her team's performance;

» is treated fairly and respectfully, and not discriminated against;
» feels supported in pursuing his or her personal priorities.

2. RECRUITMENT

Mabion S.A.'s recruitment policy ensures equal opportunities for all those interested in getting a job with the Company. In the first instance, the following rules apply to recruitment:
» recruitment period is sufficiently long for all interested persons to respond to a job offer;
» recruitment advertisements are published in various media (industry media, the Internet, the corporate website), which ensures that the advertisement reaches a wider audience of potentially interested persons;
» no preferred sex of applicants is stated in advertisements;
» the same criteria are laid down for all job applicants regardless of their sex or other legally protected status or general social opinions;
» no questions about marital status, family-starting or family-enlargement plans, and availability are asked.

3. WORK-LIFE BALANCE

Mabion S.A. believes that acquisition and retention of talent requires more than just competitive remuneration and a stimulating work environment. The Company also focuses on work-life balance aspects. Therefore, the Company promises to be fully open to employees' work-life balance initiatives. Projects will be managed in equal measure by men and women, depending on their qualifications and competition results.

While treating all of its employees equally, the Company promotes a culture of diversity, which should be understood as respect for values and religions, opinions, experiences and rights of each employee to his or her own opinion.

Continued efforts to train employees are yet another dimension. Relevant departments are the starting point for the training programme. Away training days and one on one training are managed by relevant business units. Each employee has equal access to the professional education programme and may decide about the type and pace of promotions on his or her own. High appraisal scores and laboratory or process work experience level predispose employees to be included in the semi-annual promotion procedure. The promotion procedure envisages professional development in terms of scientific, process or functional positions. Process and quality control position exams are held in writing and it is on their basis that employees are promoted. Whereas functional position exams are oral or written. The Company makes it possible for employees to continually improve their qualifications by supporting training initiatives and assisting employees in taking and completing PhD courses. This policy ensures that employees are fully committed to the Company and their jobs.

The above corporate policy is being continually developed as the Management Board of Mabion S.A. uses its best efforts for Mabion to remain an attractive and competitive employer.

8.9 Promotional activities

In 2016, the Company conducted its promotional activities together with On Board Public Relations Sp. z o.o. ECCO International Communications Network based on a contract signed on 1 February 2016. The Company's public relations activities involve a wide range of communication channels, including:
» information and press materials for the media, analysts and shareholders;
» experts' materials, published in leading industry media, intended for the pharmaceutical, medical, and biotechnological communities;
» expert statements and comments of the Company's officials in Polish and international media, online interviews and teleconferences involving the Company's Management Board;
» audio or video feeds of investor meetings;
» videos presenting employees and the Company's registered office;
» meetings with analysts, institutional or individual investors;

» educational activities among investors;
» participation in national and international fairs and conferences.

On 9 and 10 May 2016, the Company participated in the Bioforum Central Europe. This is one of the most important events in the pharmaceutical and biotechnological industries in Poland. The Company's officials took part in conferences and meetings with pharmaceutical and biotechnological companies and with patent spokespersons from Central and Eastern Europe at the fair.

In addition to presenting the Company at fairs and conferences, the Company's officials were regularly updating the Polish and international press on the clinical trial progress, the progress of work taking place in Konstantynów Łódzki, the progress of talks with the global distributor, and the successful progress of the scientific advice procedure. The Company drew the attention of industry and business media, which followed the Company's accomplishments in the context of its competitors.

Mabion S.A.'s name more and more often came up in comments made by analysts and, as far as its stock prices were concerned, it was mentioned as one of the companies with good returns in fund management companies' portfolios. Mabion S.A. is also mentioned as an example of a successful investment in the context of New Connect and the great success of the Company's transfer to the main floor of the WSE. It is also mentioned as one of the companies with the highest profits for investors.

8.10 Investor relations

The purpose of Mabion S.A. investor relations activities is to create value for the Company's Shareholders. The key objective is to have an effective, two-way communication channel with the Company's stakeholders, in the first instance Shareholders and prospective investors, and to ensure the Company's transparency through full compliance with disclosure obligations and corporate governance principles.

Since 1 February 2016, the Company has been working together in this respect with On Board Public Relations Sp. z o.o. ECCO International Communications Network, which has made it possible to significantly intensify investor relations.

In 2016, the Company held two meetings with individual and institutional investors (22 February 2016 and 8 December 2016) and participated in many individual meetings with market analysts. Online teleconferences were also held and the Company's Management Board officials attended various national and international conferences, for instance, on 16 May 2016, at the invitation of the Warsaw Stock Exchange, IPOPEMA Securities and Auerbach Grayson, the Company presented itself at the second run of the Polish Capital Markets Conference held in New York. The purpose of the conference was to promote Polish companies and the Polish market to the broad market of US investment institutions.

The above efforts were supported by a rearrangement of the Company's website and the form of presentation of, among other things, periodical reports. Mabion S.A.'s website contains a separate section for investors, with the materials available in Polish and English.

The following is available, among other things, on the website:
» Timeline of key events in the Company's history;
» Corporate documents;
» Ad hoc and periodical reports;
» Stock price information;
» Investor relations contact form.

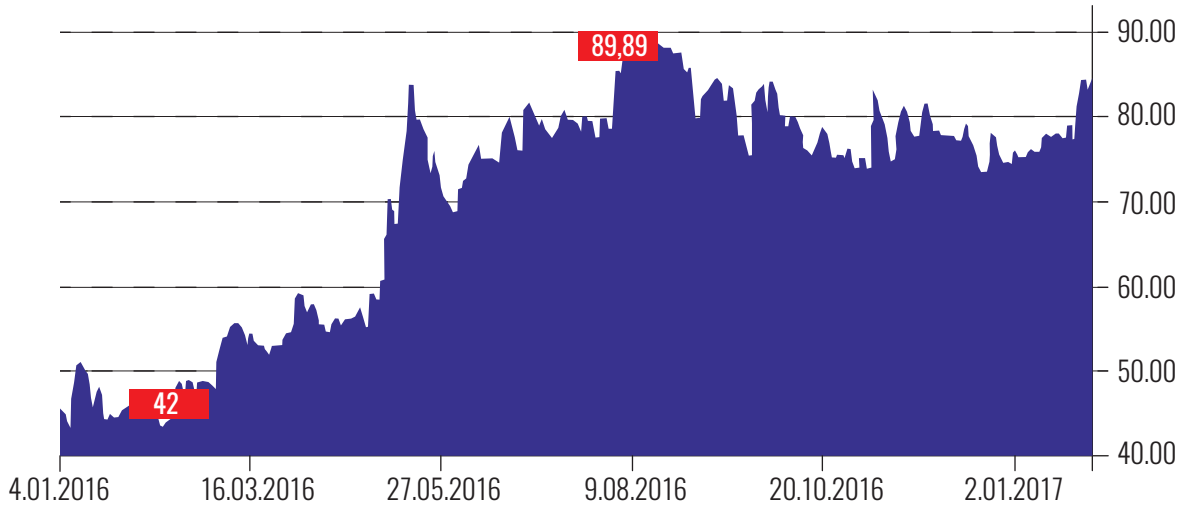
The Company regularly reported key events by means of ESPI system ad hoc reports and press releases in key dailies, on financial and business portals. The Company's Management Board officials gave interviews to key biotechnological and financial media and answered media enquiries on an ongoing basis.

The Company's public relations policy mainly involved the following areas:
» MabionCD20 medicine clinical trial process;
» assessment of the quality of the clinical trial of MabionCD20 medicine and its safety by the DSMB Committee;
» collaboration with Plexus Ventures LLC;
» agreement with the global distributor Mylan Ireland;
» the Company's growth plans.

In May 2016, ING Securities experts valued Mabion's shares at PLN 100 per share and issued a buy recommendation. Whereas, at the beginning of January 2017 IPOPEMA Securities S.A. analysis issued a recommendation for Mabion S.A., including a buy rating and a target price of PLN 101.

Contact for investors: mabion@onboard.pl

8.11 The Company's stock performance on the Warsaw Stock[20]



Reference price:	PLN 46.96 (30/12/2015)
Start date:	2016-01-04
End date:	2016-12-30
Change:	58,07%
Change:	PLN 27.27
Low:	PLN 42.00 (11/02/2016)
High:	PLN 89.89 (03/08/2016)
Average:	PLN 69.23
Volume:	2,319,982
Average volume:	9,243
Turnover:	172.354 million
Average turnover:	0.687 million

[20] https://www.gpw.pl/karta_spolki/PLMBION00016/#wykres

Management Board

Konstantynów Łódzki, 25 April 2017

Board President
Artur Chabowski

Board Member
Jarosław Walczak

Board Member
Sławomir Jaros