Mabion S.A.
Directors' Report for the year 2018

Konstantynów Łódzki, 9 April 2019

Ladies and Gentlemen, Dear Shareholders,

On behalf of the Management Board, I would like to present the report on the activities of Mabion S.A., which summarises and describes the most important events influencing the Company's operations in 2018.

Last year was primarily marked by further progress in our flagship medicine development project – MabionCD20. The company not only developed the results of the clinical trial that confirmed clinical bioequivalence of the product, but also applied, on 1 June 2018, to the European Medicines Agency (EMA) for registration of the medicine in EU countries. Less than 3 weeks later, we were informed about the positive completion of the application validation process and its acceptance into the assessment procedure. For reaching this milestone, we received a payment of USD 5 million from our partner, Mylan. We are currently at the end of Day 120 of this procedure – work is in progress to finalise the development of answers to EMA questions relating to our medicine.

At the same time, we are continuing our efforts to register MabionCD20 in the United States. The U.S. Food and Drug Administration (FDA), with which we met last June, allowed the data in possession of the Company to be used to support the application process. At the same time, it proposed an overall strategy for linking a product registered in the European Union (MabThera) to a product authorised to be placed on the market in the USA (Rituxan), which excludes the need for a completely separate development process for the US market for MabionCD20. The company has been admitted to further stages of the consultation process and remains in constant contact with the FDA, carrying out consultations with the regulator on the bridging clinical trial design.

In addition to MabionCD20, last year we continued a number of other projects, the most advanced of which is MabionMS. On 26 October 2018, we filed a second patent application with the Patent Office of the Republic of Poland concerning the use of rituximab in the treatment of multiple sclerosis (MS). This time, the scope of the notification covers the use of the drug as part of monotherapy, which is an innovative indication and offers a possibility of expanding it on a global scale. We hope that MabionMS will achieve a similar market success as ocrelizumab (Ocrevus, Roche) introduced in 2017, whose sales are growing rapidly. We trust that our efforts will allow Mabion to join the USD 20 billion drug market in the MS area.

Without a doubt, one of the key events of 2018 was the issue of shares, owing to which the Company not only leveraged nearly PLN 175 million for further development, but also – or perhaps above all – gained new investors. The fact that the European Bank for Reconstruction and Development, the Polish Development Fund and American funds specialising in the health care and biotechnology sector have joined Mabion's shareholders shows global potential of the Company.

Mabion's strong position is also evidenced by talks with potential partners from all over the world. We notice interest from the largest global players in the pharmaceutical market – both in our projects at a preliminary stage as well as advanced ones, but also in cooperation on the development of other biosimilar drugs. Contacts with Big Pharma, among others, indicate that relying on the competence and high scientific level of our research and development teams, we can compete with the largest biotechnological enterprises in the world. It is our ambition to sign several partnering agreements this year, which will provide us an impulse for even harder work and further development.

There are key quarters ahead of us. We believe that this year, we will be able to complete the whole registration process and obtain the consent of the European regulator for the commercialisation of MabionCD20. This is our most important objective, the achievement of which will confirm the rightness of the path we have chosen and will increase the Company's market value for all its Shareholders.

We would like to thank Investors for their trust and all Employees and Associates, as well as the Members of the Supervisory Board for the immense amount of their work, without which we would not be in this place right now. As the Management Board, we make every effort to ensure that our belief in Mabion's potential will result in our growing position in the global biotechnology industry. Wishing us all successes, I invite you to read the report.

Kind regards

Artur Chabowski
President
of the Management Board of Mabion S.A.

Mabion S.A. Directors' Report for the year 2018

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1 ORGANIZATION OF MABION S.A.

1.1 Basic information about the Company

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

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

The Company was also 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
Telecommunications numbers:	phone (+48 42) 207 78 90
e-mail address:	info@mabion.eu
Website address	www.mabion.eu

1.2 Branches

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

Currently, the Company has two centres (plants) – the Research and Development Centre (Centrum Badawczo-Rozwojowe - CBR)[1] in Łódź, ul. Fabryczna 17, and the Scientific-Industrial Complex of Medical Biotechnology (Kompleks Naukowo-Przemysłowy Biotechnologii Medycznej) in Konstantynów Łódzki, ul. Langiewicza 60, which is also the Company's statutory registered office.

1.3 Changes in the Company's management rules

In 2018, no significant changes were noted in the basic principles of management in the Company.

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 in the meaning of Article 4 § 1.4) of the Polish Code of Commercial Companies and Partnerships (CCCP).

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 Offering, Conditions Governing the Introduction of Financial Instruments to Organised Trading, and Public Companies (the Public Offering Act) and of the definition of the Company's parent pursuant to Article 4 § 1.4) of the Polish Code of Commercial Companies and Partnerships. In addition, according to the Company's best knowledge, the shareholders and members of the Company's bodies are not connected by the agreement referred to in Article 87.1 (5) and Article 87. 4 of the Act on Public Offering. Significant shareholders have no voting rights other than those resulting from the shares held.

[1] Proper name.

2 OPERATIONS OF MABION S.A.

2.1 Schedule

January	On 5 January 2018, the Management Board of the Company received information on the preliminary result of the assessment of two primary pharmacokinetic endpoints of the MabionCD20 clinical trial in the indication of non-Hodgkin's lymphoma (NHL). Initial results indicated that the assumed equivalence criteria were met. On 8-11 January 2018, representatives of the Company took part in the JP Morgan Annual Conference 2018 in San Francisco. On 10 January 2018, the Management Board of the Company received preliminary preparation of data on the efficacy of the treatment and the general safety profile of MabionCD20 in the indication of non-Hodgkin's lymphoma (NHL) (secondary endpoints). Based on the therapy efficacy data, the Management Board assessed patients' responses to treatment in both groups (treated with MabionCD20 and MabThera) as comparable. On 11 January 2018, the final visit of the last patient took place as part of the additional observation period of the long-term follow-up of patients recruited in the MabionCD20 NHL study. Therefore, the collection of data for all endpoints in the study was completed. On 15 January 2018, the Company's Management Board received preliminary preparation of data on the pharmacokinetic secondary endpoints as well as the pharmacodynamics of MabionCD20 in the indication of non-Hodgkin's lymphoma (NHL) (secondary endpoint). The Management Board assessed the pharmacokinetic parameters obtained in the groups treated with MabionCD20 and MabThera as equivalent.
March	On 22 March 2018, the Company obtained funds of PLN 174.8 million in the form of a loan agreement from a Company's shareholder, Twiti Investments Ltd. On 22 March 2018, the Company received confirmation that the status of the results of a clinical trial of MabionCD20 in rheumatoid arthritis (RA) patients reported by the Company earlier as "preliminary", after a thorough verification of data, changed to "final". Thus, the positive evaluation of the clinical trial result did not change.
April	On 4 April 2018, the Company received information that the Company's application for co-financing of the project entitled "Expansion of the Research and Development Centre of Mabion S.A. - research on a new generation of medicines" was selected for co-financing. On 23 April 2018, a subscription agreement on P shares with Twiti Investments Ltd. was signed.
May	On 1 May 2018, the Company became aware about the registration of the increase in the Company's share capital and the repeal of the provisions of the Articles of Association regarding the authorised capital. On 11 May 2018, the company's registered office was visited by participants of the StarShip conference. The aim of the meeting, organized by EIT Health, was to inspire young people from all over Europe to undertake business and scientific initiatives in Research and Development area and in innovative branches of the economy. On 23 May 2018, Mr. Artur Chabowski, President of the Management Board of Mabion S.A., took part in a debate devoted to the development and prospects of the biotechnology sector in Poland as part of the 17th edition of BioForum. On 25 May 2018, the Company received confirmation that the status of the results of clinical trials in the indication non-Hodgkin's lymphoma (NHL), reported in previous communications as "preliminary", after a thorough verification of data was changed to "final". Thus, the positive assessment of the clinical trial result is not changed.

June	On 1 June 2018, the Company filed a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) with regard to the market regulated by the EMA for the drug of a working name "MabionCD20". The drug was developed as a biosimilar for MabThera and its indications are in line with the list of indications MabThera. On 11 June 2018, the Company signed a contract for co-financing the "Expansion of the Research and Development Centre of Mabion S.A. - research on a new generation of medicines" project. The total cost of the Project was set at PLN 172.88 million, with the co-financing amounting to PLN 63.25 million. On 19 June 2018, the Company's representatives took part in the European Biotech Investor Day in New York – an event under the patronage of Nasdaq. On 21 June 2018, the Management Board of the Company received information about the successful completion of the validation of the marketing authorization application (MAA) for the drug with the working name "MabionCD20" by the EMA and thus its acceptance into the assessment procedure. On 27 June 2018, the Company received a summary from the US Agency for Food and Drug Administration (FDA), following a BPD (Biosimilar Biological Product Development) Type 2 meeting.
July	On 17 July 2018, the Company and Bank Zachodni WBK S.A. (currently Santander Banka Polska S.A.) entered into a revolving loan agreement to finance the operating activities of the Company for a period of two years from the date of the agreement. The amount of funding awarded under the loan agreement, upon meeting specified condition, shall be PLN 30 million. On 19 July 2018, representatives of the Management Board of Mabion S.A. took part in an international conference under the patronage of Nasdaq, among others. The purpose of the summit was to introduce the most interesting companies from the biotechnology industry in Europe to institutional investors from the United States.
August	On 6 August 2018, the Company received permission from the EMA to submit a second registration application ("Duplicate application") for the drug with the working name MabionCD20. On 27 August 2018, the Company was notified of Mylan Ireland's payment of USD 5 million for the achievement of the milestone in the form of the registration of MabionCD20 by EMA, specified in the mutual cooperation agreement.
October	On 25 October 2018, the Management Board of the Company took part in the 8th Central European Life Science Investment Conference in Cracow. The meeting was attended by representatives of the pharmaceutical and biotechnology industry from Poland and the entire world, as well as public and private funds investing in this sector. On 26 October 2018, the Company filed a patent application in the area of use of MabionCD20 for the treatment of multiple sclerosis, entitled "Low aggregate anti CD20 ligand formulation" with the Patent Office of the Republic of Poland.
November	On 14 November 2018, the Company received the decision of the Staroste of Pabianice approving the works project and granting a building permit as part of the investment called "The Science and Technology Centre for advanced medical biotechnology of Mabion S.A." together with the necessary infrastructure in Konstantynów Łódzki. On 14-15 November 2018, representatives of Mabion S.A. took part in the Jefferies Global Healthcare Conference in London. The purpose of the conference was to maintain investor relations with foreign funds and shareholders of the Company. Meetings with potential partners were also held.

December	On 5 December 2018, the Company filed a notification regarding the extension of patent protection under the PCT procedure for the patent application entitled "Combination Therapy of Multiple Sclerosis containing a CD20 Ligand" with the European Patent Office in the Hague. The subject of the patent application is an innovative therapy for patients suffering from multiple sclerosis with the use of MabionCD20 antibody as part of a combination treatment with other substances. On 4-7 December 2018, Company's representatives took part in a conference organized by WOOD & Company in Prague, where they met with industry investors and biotechnology companies from around the world.

2.2 Market environment

The activity of Mabion S.A. focuses on research and development work enabling the implementation of new biotechnological medicines, including biosimilars, obtained owing to the achievements of modern genetic engineering. The strategic goal of the Company is to develop, manufacture and sell drugs used in the treatment of neoplastic, autoimmune, metabolic and neurological diseases.

Medicines developed by the Company are targeted drugs characterized by the ability to recognize a factor, e.g. a receptor whose overexpression is associated with the development of cancer and to interact only with that factor. Appropriate engineering of the structure of such drugs and thereby, a high degree of similarity to the proteins of the patient's body, makes the immune system treat the therapeutic antibody as its own protein. This guarantees very low toxicity of the therapies developed by the Company and is a significant benefit for the patient.

Currently, the Company's most advanced product is a biosimilar medicine MabionCD20, a referential to MabThera/ Rituxan (Roche), currently in Phase III of clinical development.

Biosimilar medicines

Biosimilar medicines form a dynamically developing area in the global pharmacy. As shown in reports and analytical studies, biosimilar medicines increase their share in global sales year by year.

According to a market survey published in March 2018[2] by Infoholic Research, the global market for biosimilar medicines is expected to have, in 2018-2024, a cumulative annual growth rate (CAGR) of 57.03%, reaching a total value of USD 99.28 billion by 2024. More cautious data are presented by ResearchAndMarkets.com in the report "Global Biosimilars Market - Increasingly Lucrative Market Fueled by Constrained Payer Environment and Patent Expiries for Best-Selling Biologics", published in January 2019. The report predicts that in the years 2017-2024, the market will reach a CAGR of 45.22%.[3] The authors of the study indicate that the development of this market is driven, *inter alia*, by the expiration of patents for several best-selling biological medicines. However, they point out that issues such as the costs and complexity of the development of biosimilars may be a challenge for market development.

The market of biosimilars in Europe alone in 2017 reached over USD 2 billion. It is predicted to exceed USD 9 billion by 2023, and CAGR between 2017 and 2023 will amount to 29%.[4]

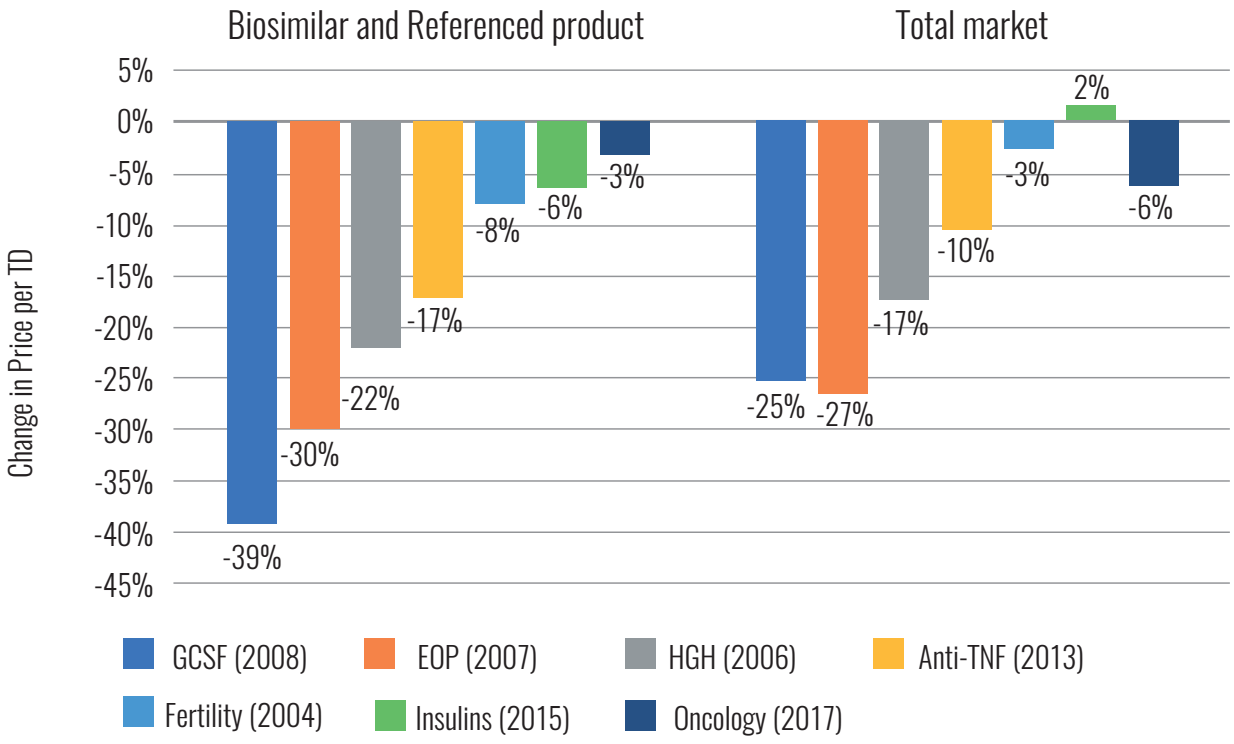
[2] Global Biosimilars Market 2018-2024 -Global Biosimilars Market - Drivers, Restraints, Opportunities, Trends, and Forecasts: 2018-2024, https://www.marketresearch.com/Infoholic-Research-v4070/Global-Biosimilars-11668804/

[3] Global Biosimilars Market - Increasingly Lucrative Market Fueled by Constrained Payer Environment and Patent Expiries for Best-Selling Biologics, ResearchAndMarkets.com, https://globenewswire.com/news-release/2019/01/22/1703176/0/en/Global-Biosimilars-Market-2017-2024-Market-by-Products-is-Projected-to-Grow-at- CAGR-and-of-45-22.html

[4] Biosimilar Market in Europe: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2018-2023, ResearchAndMarkets.com, https://www.businesswire.com/news/home/20180910005373/en/Biosimilar-Market-Europe-Industry-Trends-Share-Size

According to QuintilesIMS reports entitled "The Impact of Biosimilar Competition in Europe"[5], systematically prepared for the European Commission, one of the reasons for the introduction of biosimilars was to increase price competition, which translates into a lower price of a medicine for the patient. As shown by data collected by QuintilesIMS, in seven therapeutic areas where there is competition in the form of biosimilar medicines, there is a consistent reduction in prices. Increased competition resulting from the introduction of biosimilar medicines into the market affects not only the price of the reference medicine for a given biosimilar medicine, but also the prices of the entire product class (a biosimilar medicine and a reference medicine).

Table 1: Change of the treatment day price from the date of introduction of biosimilar medicines (the date of introduction of the biosimilar medicine provided for each treatment).



"The Impact of Biosimilar Competition in Europe", QuintilesIMS (09.2018)

According to a report by QuintilesIMS, in some countries, health systems can see savings even if the share of biosimilar medicines in the market is relatively small. Cuts in prices of biosimilar drugs may be the result of intervention in the area of price regulation or commercial decisions of producers. The introduction of biosimilar medicines contributes to the creation of a competitive environment and leads to lower prices. Price erosion after marketing biosimilar drugs stops at an average level of about 30%. For the majority of therapeutic classes, after the introduction of biosimilar medicines, a significant increase in consumption is observed, dictated by the increased availability of therapy for patients.[6]

[5] "The Impact of Biosimilar Competition in Europe", QuintilesIMS, May 2017, September 2018, https://ec.europa.eu/search/?queryText=The%20Impact%20of%20Biosimilar%20Competition%20in%20Europe&query_source=GROWTH&swlang=en

[6] Ibid.

Table 2. The countries with the largest change in the volume of therapy (summary: 2017 for data from 1 year before the entry of the biosimilar medicine).

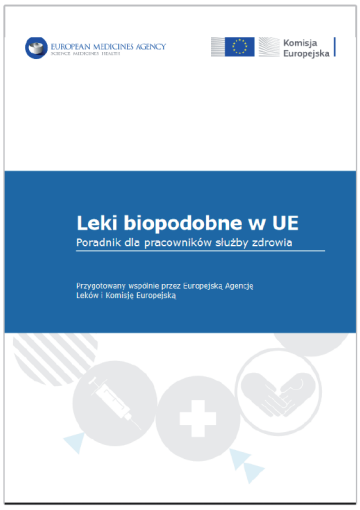
Anty-TNF	Price per TD 2017/Yr before BS entrance	Volume TD 2017/Yr before BS entrance	TD/capita (Year before Biosimilar entrance)
Austria	4%	407%	0,17
Bulgaria	-25%	242%	0,10
Portugal	-19%	82%	0,26
Norway	-1%	71%	1,07
Poland	-30%	69%	0,04
EPO			
Poland	-37%	418%	0,03
Greece	-51%	103%	0,02
Italy	-8%	41%	0,82
UK	-10%	32%	0,24
Czech	-34%	30%	0,09

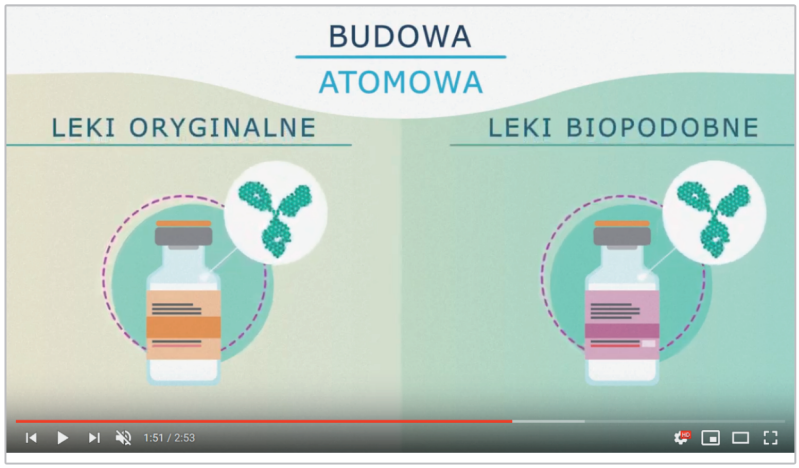
G-CSF	Price per TD 2017/Yr before BS entrance	Volume TD 2017/Yr before BS entrance	TD/capita (Year before Biosimilar entrance)
Bulgaria	-60%	1893%	0,00
Romania	-63%	489%	0,00
Slovakia	-65%	426%	0,01
Slovenia	-56%	249%	0,02
Norway	-12%	152%	0,03
HGH			
Romania	-31%	145%	0,02
Poland	-41%	102%	0,04
UK	-16%	94%	0,04
Czech	-31%	85%	0,08
Ireland	-10%	75%	0,04

"The Impact of Biosimilar Competition in Europe", QuintilesIMS (09.2018)

In therapeutic classes for which biosimilar medicines have been present on the European market for many years, in some countries reference medicines are no longer available, and biosimilar medicines have a 100% market share. Until the date of publication of this report, there are 51 biosimilar medicines on the EMA list which are admitted to trading[7]. It is worth noting that EMA builds patients' awareness of the use and safety of biosimilar medicines by publishing educational films dedicated to it[8] and guides[9]:

Table 3. Publications of the European Medicines Agency.





7 European public assessment reports https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar?sort=field_ema_med_market_auth_date&order=asc

8 https://www.youtube.com/watch?v=oNP-yvJOCoU&list=PL7K5dNgKnawb3lQri7llr5wbaWxP71jQJ&index=6

9 https://www.ema.europa.eu/en/documents/leaflet/biosimilars-eu-information-guide-healthcare-professionals_pl.pdf

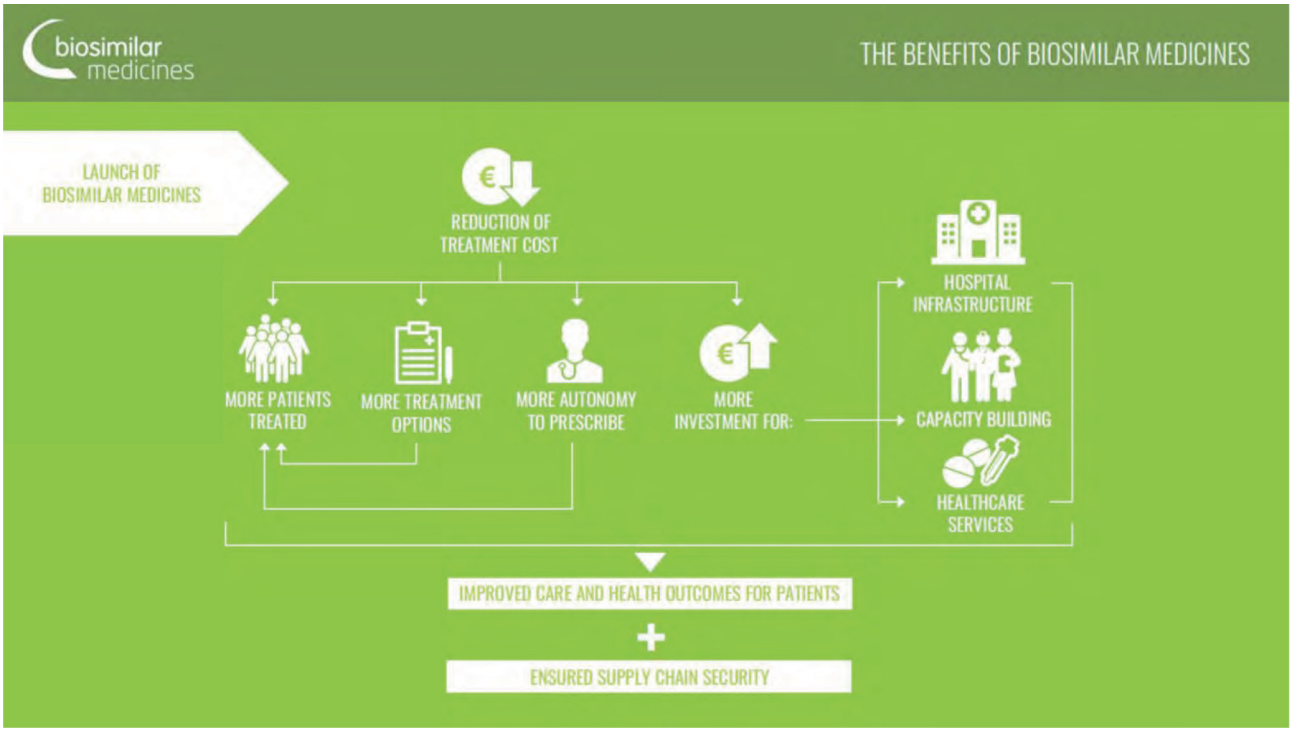
With regard to the US market, the FDA took steps in June 2018 to facilitate the development of biosimilar medicines. This included the withdrawal of the 2017 guidelines, so that the regulatory approach would be more adapted to the real possibilities of obtaining biosimilarity with respect to the original medicine. In the opinion of GlobalData experts, this is a move that can significantly reduce barriers to the development of biosimilar medicines in the US market[10].

Despite approval by the FDA of 18[11] biosimilars (data as at the date of publication of this report), some of these drugs have not yet been released to the market. GlobalData estimates that in 2017 alone, due to these delays, the health care system lost the opportunity to save nearly $ 5 billion.[12]

The impact of the new FDA guidelines and action plan to facilitate the entry of biosimilar medicines on the US market will be carefully monitored by various stakeholders. Three biological drugs generating the highest revenues (blockbusters), or Humira (AbbVie), Rituxan (Roche) and Enbrel (Pfizer / Amgen) achieved global sales of USD 18.4 billion, USD 9.2 billion and USD 7.9 billion in 2017, respectively a significant part of the revenues of these companies. Considering that the patent exclusivity period has expired for each of these drugs, as well as for other biologics that generate the highest income in the entire industry, many companies will closely scrutinize the competitive environment and probably implement preventive actions will lose profits[13].

From the point of view of patients and payers, the introduction of biosimilar medicines generates many benefits. Demand for drugs used in oncology and autoimmune diseases is limited by the financial possibilities of national health systems. The emergence of newer and cheaper solutions will bi-directionally increase the demand, both by treating patients who cannot afford treatment, and by the possibility of treating patients who react badly to less-secure treatments.

Table 4. Benefits of using biosimilar medicines.[14]:



[10] With Recent Steps by the FDA to Bolster Development, What Does the Future Hold for US Biosimilars ?, GlobalData, 07.2018
[11] FDA Biosimilar Product Information: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm580432.htm
[12] With Recent Steps by the FDA to Bolster Development, What Does the Future Hold for US Biosimilars ?, GlobalData, 07.2018
[13] Ibid.
[14] http://www.boussiasconferences.gr/files/_boussias_conferences_content/presentations/biosimilars_conference/2018/diogo_piedade_biosimilars_18.pdf

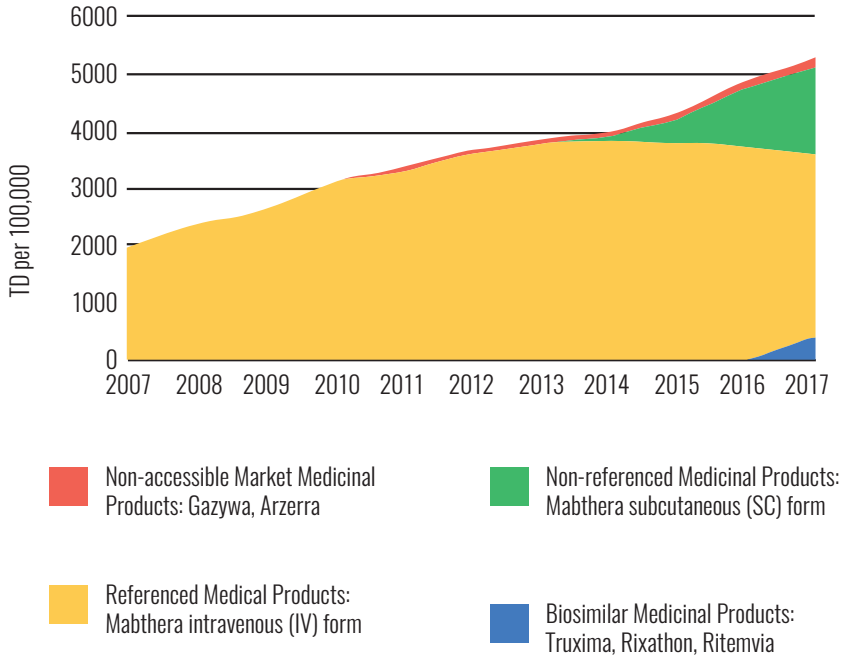
MabionCD20

A medicine with the working name MabionCD20 is the most advanced project of the Company. In 2018, the Company not only prepared the results of a clinical trial that confirmed the effectiveness of the therapy, but also applied for the registration of the drug in the European Union countries.

Conducting intensive work related to the registration of the drug, the Company constantly monitored the competitive environment of biosimilars to MabThera/Rituxan (Roche), as well as the sales results of the original medicine.

Regarding the reference medicine, it should be pointed out that Roche predicts a drop in sales of MabThera/Rituxan due to the introduction of biosimilar medicines (in 2017, the sale of the above-mentioned drug in Europe decreased by 11%[15]), took action to protect market share by changing the formulation of the drug. As the data show, this change affected the company's sales results. Roche's defense strategy consisted of introducing a subcutaneous version of the drug (subcutaneous -SC) . Previously, the medicine was only available as an intravenous (intravenous -IV) and in such a formulation, biosimilar medicines for MabThera/Rituxan are available. The sale and price of Roche in the subcutaneous version, contrary to the traditional formulation, tend to increase.[16]

Table 5. Change in the price and volume of sales before and after the introduction of biosimilars in Europe (2017).



Source: IQVIA MIDAS December 2017; Total volume development across all European countries included in the study

"The Impact of Biosimilar Competition in Europe", QuintilesIMS (09.2018)

In the financial report for 2018, Roche reports that the global sale of MabThera/Rituxan amounted to CHF 6.7 billion (approximately USD 6.7 billion), which is a decrease of 9% worldwide (use of the drug in oncological and immunological therapies).[17]

In 2017, two biosimilar molecules competitive to MabionCD20 hit the European market - Celltrion drug (operating on the market under four names: Blitzima, Ritemvia, Rituzena and Truxima) and Sandoz (sold as Riximyo and Rixathon).

[15] https://www.roche.com/dam/jcr:b70415c0-954f-4a2a-a0e2-47f94bd280e0/en/fb17e.pdf
[16] "The Impact of Biosimilar Competition in Europe", QuintilesIMS (09.2018)
[17] https://www.roche.com/dam/jcr:933329c4-4564-4b17-a29b-246ac7e617d5/en/fb18e.pdf

Table 6. EMA data in the scope of registered products in the following oncological therapies:

		Classification				Indicatios					Route	
Molecule	Product	Reference product	Biosimilar	Non-reference	Non-accessible	Chronic Lymphocic Leukemia (CLL)	Folliocular Lymphoma	Non-Hodgkin's Lymphoma	Rheumatoid Arthritis	Granuloma-tosis with Polyangiitis	Subcutaneous	Intravenous
Rituxumab	MabThera (IV)	●				●	●	●	●			●
	MabThera (SC)			●		●	●	●	●		●	
	Truxima		●			●		●	●	●		●
	Rixathon		●			●	●	●	●	●		●
	Ritemvia		●				●	●		●		●
Obinutuzumab	Gazyva				●	●	●		●			●
Ofatumumab	Arzerra				●	●						●

"The Impact of Biosimilar Competition in Europe", QuintilesIMS (09.2018)

As reported by Celltrion in October 2018, from June 2018 in 18 European countries, Truxima took 32% of the original MabThera/Rituxan market. Market share in five major countries (the United Kingdom, Germany, France, Italy and Spain), was 34%.[18] In November 2018, Celltrion obtained the approval of FDA for its rituximab for the marketing of this medicine. Celltrion is therefore entitled to sell Truxima on the US market, accounting for 56% of global rituximab sales and valued at USD 4.45 billion.[19]

Table 7. Sales of the drug MabThera/Rituxan in the world (source: Roche Finance report, 2018).

2018 (CHF million)	2017 (CHF million)	Change% (CER)	% of sales (2018)	% of sales (2017)
MabThera/Rituxan in oncology				
5,191	5,832	–10	11.8	14.1
MabThera/Rituxan in immunology				
1,561	1,556	+1	3.6	3.8

[18] https://pulsenews.co.kr/view.php?year=2018&no=641732
[19] http://www.theinvestor.co.kr/view.php?ud=20181129000720

Table 8. Sales of the drug MabThera/Rituxan by region (source: *Roche Finance report, 2018*).

Sales by regions:	2018 (CHF million)	2017 (CHF million)	Change% (CER)	% of sales (2018)	% of sales (2017)
USA	4,290	4,133	+4	63.5	55.9
Europe	916	1,690	-47	13.6	22.9
Japan	188	293	-36	2.8	4.0
International	1,358	1,272	+11	20.1	17.2
Total sales	6,752	7,388	-8	100	100

As predicted by market analysts (incl. GlobalData[20]) the sales results for MabThera/Rituxan will fall in the coming years.

Innovative biotechnology medicine - MabionMS

On December 5, 2017, the Company filed with the Patent Office of the Republic of Poland a European patent application, with the possibility of extending it in PCT mode, based on which it applies for legal protection for its invention, entitled "Combination Therapy of Multiple Sclerosis containing a CD20 Ligand". The subject of the patent application is an innovative therapy for treating patients suffering from multiple sclerosis with the use of MabionCD20 antibody combined with other substances (MabionMS combination therapy project). On December 5, 2018, the Company submitted to the European Patent Office in The Hague a notification regarding the extension of patent protection in PCT mode for the above-mentioned companies. invention.

In order to avoid a dangerous situation in which the Patent Office accuses of an attempt to double patent the same scope of protection (which is known as double patenting), in March 2019 the Company withdrew the originally filed European application in order to benefit from the protection granted on the basis of an international application (also covering the European area). This is a procedural step to optimise the process.

On October 26, 2018, the Company filed a European patent application with the Patent Office of the Republic of Poland, with the possibility of expanding in PCT mode, from the area of application of MabionCD20 in the treatment of patients suffering from multiple sclerosis (MabionMS project), entitled "Low aggregate anti CD20 ligand formulation." The application concerned the use of MabionCD20 on a monotherapy basis.

The Management Board of the Company recognized the fact of submitting the above patent applications as significant because they are the first research projects implemented by the Company on innovative therapies and in the event of their success and protection, it may have a positive effect on the future economic, property and financial situation of Mabion S.A.

At present, the Management Board of Mabion S.A. identifies the following products as the most commonly used drugs in patients with multiple sclerosis:

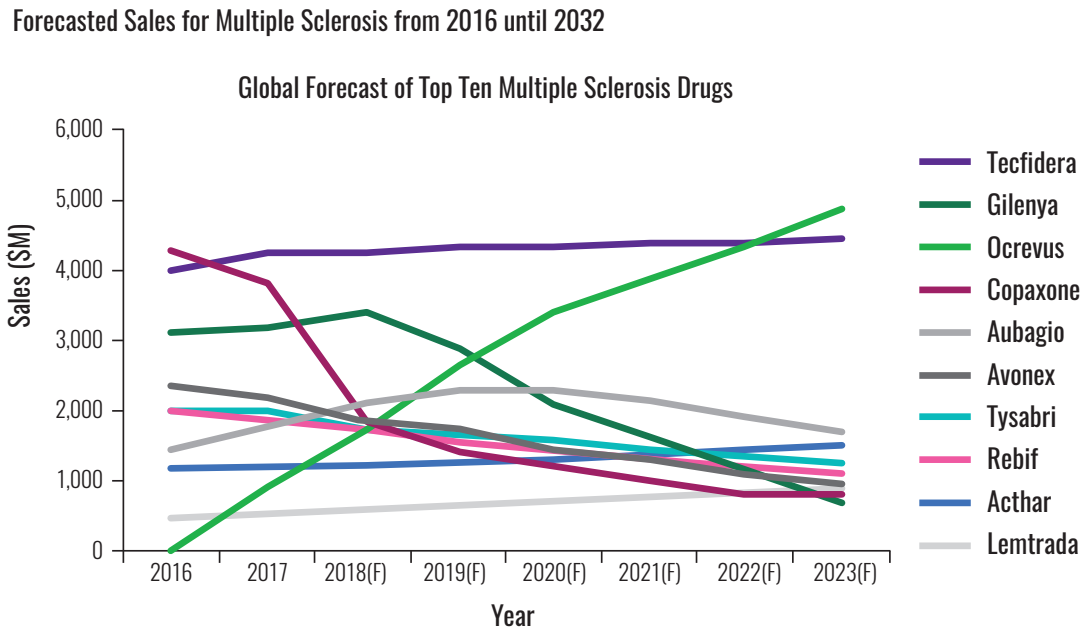
» Ocrelizumab (trade name: Ocrevus) - drug of the Roche group. Ocrevus is intended for the treatment of recurrent forms of multiple sclerosis and primary progressive multiple sclerosis, a highly disabling form of multiple sclerosis. The drug was introduced to the EU market: January 8, 2018

» Glatiramer acetate (trade name: Copaxone) - a Teva drug that is a combination of four amino acids (a protein) that affects the immune system. It is used to treat people with relapsing multiple sclerosis. Copaxone does not cure multiple sclerosis, but it can cause relapses to occur less frequently. The drug was introduced to the EU market: April 7, 2003

[20] https://www.pharmaceutical-technology.com/comment/roches-rituxan-biosimilar-woes-just-beginning/

- Fingolimod (trade name: Gilenya) - a drug from Novartis Europharm Ltd., which is used to treat relapsing multiple sclerosis with high activity in adults. The drug was introduced to the EU market: March 17, 2011.
- Teriflunomide (trade name: Aubagio) is a Sanofi-Aventis drug used in relapsing multiple sclerosis when the patient has exacerbation of symptoms (relapses) followed by periods of recovery (remissions). The drug was introduced to the EU market: August 26, 2013.
- Interferon beta-1b (e.g. Extrat-biological drug from Novartis Europharm Ltd.), which is given to patients as a solution for injection. It is used in patients who are at high risk of developing MS.
- Interferon beta-1a (e.g. Avonex from Biogen) available in many forms, including intramuscular, subcutaneous injection solutions and pegylated preparations. It is used in patients with diagnosed recurrent multiple sclerosis;
- Dimethyl fumarate (trade name: Tecfidera) - is a drug of Biogen Idec Ltd. used especially in adults with an MS type known as recurring multiple sclerosis, in which the patient has exacerbation of symptoms (relapses), followed by periods of regeneration (remissions). The drug was introduced to the EU market: 30 January 2014.
- Natalizumab (trade name: Tysabri) - a humanized monoclonal antibody from Biogen, used in the case of ineffective first-line therapy and in the aggressive form of multiple sclerosis. The drug was placed on the EU market: 27 June 2006;
- Alemtuzumab (trade name: Lemtrada) is a humanized monoclonal antibody from Sanofi. It is used in an active relapsing-remitting SM form. The drug was placed on the EU market: 12 September 2013;
- Mitoxantron (e.g. Mitoxantron-Ebewe - an EBEWE Pharma drug) used in a secondary progressive form of SM or a relapsing-remitting form as a second- or third-line drug when the first line drugs proved to be ineffective.

Table 9. Sales of selected drugs used in multiple sclerosis until 2017 and sales forecast from 2018.[21]



Source: GlobalData, Pharma Intelligence Center, Drugs Database (Accessed February 23, 2018.)

[21] https://www.pharmaceutical-technology.com/comment/moderate-growth-multiple-sclerosis-market/

MabionMS is an innovative therapy based on the active substance rituximab for use in the treatment of multiple sclerosis. Similar to ocrelizumab, rituximab binds specifically to the CD20 receptor on B lymphocytes. The mechanism of action is the same as ocrelizumab. Safety data is beneficial for this antibody. They have been used in the treatment of leukemias, lymphoma and rheumatoid arthritis for over a dozen years, and therefore there is an extensive database on the favorable safety profile of this antibody in these indications.

The company currently has a technology for the production of this antibody, it also has developed analytical tools. In addition, it already has the results of clinical trials in patients suffering from rheumatoid arthritis and lymphoma. As a result of the conducted research, the Company thoroughly learned the clinical parameters of MabionCD20, including the mechanism of action and the safety profile. Considering this knowledge, as well as analysing the above-mentioned competitive therapies of multiple sclerosis, it is likely that MabionCD20 should have great potential in treating this disease.

This will be an innovative therapy, because for the rituximab substance such an indication has not been registered so far. However, based on the available clinical data, the Company expects a favorable safety profile due to the much lower toxicity of MabionCD20 compared to the adverse effects of chemical drugs used in the treatment of MS, while at the same time being highly effective. With regard to biological medicines, e.g. Ocrevus, the price will be a benefit for patients and health systems in the European Union. Ocrevus is an expensive drug (the price for 1 vial of concentrate for preparation an infusion solution in a concentration of 30 mg/ml and volume of 10 ml amounts at average to 16,973.50 USD, i.e. 64,838.77 PLN. The recommended dose is 600 mg every 6 months, so to get the cost of annual therapy for one patient, this amount should be multiplied by four[22]. The company, knowing the prices of this drug, as well as having the MabionCD20 production technology, which makes it possible to estimate the costs of new therapy, may assume that it will be priced more attractive compared to the treatment with ocreizumab.

According to GlobalData[23], the sale of drugs used in the treatment of multiple sclerosis in 2016 reached USD 19.1 billion in seven major markets.[24] It is expected to increase to USD 25.5 billion in 2026, with an annual average growth rate of 3%. In the opinion of GlobalData experts, the market for multiple sclerosis therapy is moving towards earlier and more aggressive therapies. In the USA, research is being conducted on the introduction of monoclonal antibody-based therapies already in people who have just been diagnosed with multiple sclerosis. As the results show, the initiation of such therapy is beneficial, and monoclonal antibodies may become the first-line drugs in the majority of patients and this will be a major paradigm shift in the treatment algorithm[25].

2.3 Regulatory environment

Worldwide, standards for the registration of biological medicines, including biosimilar medicines, are complex and very demanding. In markets with a high degree of regulation (e.g. Europe, United States, Japan, Canada) regulators need to meet strict quality, safety and efficiency criteria. Companies wishing to register the drug on regulated markets must provide detailed product characteristics (physicochemical and biological analyses), toxicology (animal studies) and clinical data, including pharmacokinetic and pharmacodynamic analyses of the biosimilar and reference medicine to demonstrate no significant clinical differences. Since biosimilar medicines must mimic the effects of the original medicine, the requirements for clinical trials are different from those required for innovative biologics.

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

With the increasing globalization of drug development, it became important that data from clinical trials carried out in multiple regions of the world (MRCT) could be accepted by regulators to support and validate drug registrations. Therefore, in June 2018, a guideline for conducting multi-regional clinical trials came into force (ICH guideline E17 on general principles for

[22] https://www.drugs.com/price-guide/ocrevus
[23] GlobalData, Multiple Sclerosis: Dynamic Market Forecast is 2026, November 2018
[24] USA, France, Germany, Italy, Spain, United Kingdom and Japan (https://www.globaldata.com/multiple-sclerosis-disease-modifying-therapies-market-reach-25-billion-2026/)
[25] GlobalData, Multiple Sclerosis: Dynamic Market Forecast is 2026, November 2018

planning and design of multi-regional clinical trials, 14 June 14 2018). The purpose of the guideline is to describe the general principles of MRCT planning and design. The guideline refers to strategic program issues as well as to issues related to planning and designing MRCT research.

In July 2018, an updated guideline on clinical trials in rheumatoid arthritis entered into force (Guideline on the clinical investigation of the treatment of rheumatoid arthritis, 1 July 2018). This document is an update of the guideline adopted in November 2003. In recent decades, advanced pharmacological treatment has been introduced in this indication. Modern therapeutic strategies allow intensive therapy in the early phase of the disease, often based on a combination of traditional and biological drugs. A goal-oriented treatment strategy is currently in use, which means that the main goal of treatment is remission or at least low disease activity in patients not responding to prior treatment. Until the desired therapeutic effect is achieved, the treatment should be used for at least 3 to 6 months. In addition, new criteria for the classification of rheumatoid arthritis with ACR-EULAR have been developed and approved, allowing early treatment. These advances require modified recommendations for the development of therapy. This led to the emergence of new endpoints reflecting the remission or low disease activity targets at earlier time points instead of the previous primary endpoint of meeting the ACR20 improvement criteria over 6 months. In addition, new guidelines distinguish between trials from previously untreated patients or patients who have had an inadequate response to prior treatment. Recommendations have also been made to measure the prevention of structural bone damage. The key elements to assess safety issues that should be considered when developing new pharmacological treatments have been updated accordingly.

In October 2018, a new guideline was introduced containing an overview of the current regulatory requirements and the applicability of the 3R rule - Replacement, Reduction, Refinement (Reflection paper, which provides an overview of the 3Rs, 18 October 2018).

In November 2018, a guideline describing documentation requirements in clinical trials of biological drugs was published (Guideline on the requirements for the quality of the clinical trials in 1 November 2018). Due to the possibility of conducting research in different EU countries, the guideline sets out harmonized documentation requirements that can be used in the European Union for drug registration.

In the context of the overall development strategy, it is known that most often several clinical trials are required, using products from probably different versions of the production process, in order to generate the data necessary for registration. The purpose of the guideline is to address the quality requirements of the investigational medicinal product for a given clinical trial. For all phases of clinical development, it is the sponsor's responsibility to ensure patient safety in a clinical trial using a high-quality investigational medicinal product (IMP).

Emerging countries (pharmerging markets), such as China, Brazil, India, Russia, Mexico, Turkey or South Korea, as well as other countries of the world have developed or develop their own laws specifying the conditions for the registration of biosimilar medicines. These provisions are often not very precise, and the definition of biosimilar medicines themselves contained therein is inaccurate. In many of the emerging countries, unclear regulations and insufficient patent protection have resulted in preparations similar to those protected by the original medicines patent. An example of this may be India, where since 2007 there has been a drug on the market being a copy of rituximab, but its registration was made on the basis of a far less extensive clinical trial program than required in the European Union. Also in China, biosimilars have been registered for original oncological preparations and erythropoietin. It is likely that these medicines may not have been authorised as a result of the strict regulatory process required for the authorisation of biosimilars in the European Union. EMA regulatory requirements ensure the same high standards of quality, safety and efficacy of biosimilars as for original biological medicines, as well as rigorous comparative research with regard to the reference product[26]. However, it is worth noting that in Mexico in 2012 a drug called Kikuzubam was registered. However, it is worth noting that in Mexico in 2012 a drug called Kikuzubam was registered. However, it was quickly withdrawn from the market by the regulator due to documented anaphylactic reactions and lack of clinical data[27].

[26] http://www.gabionline.net/Biosimilars/General/Biosimilars-of-rituximab
[27] Biosimilars in rheumatology: current perspectives and lessons learnt, T Dörner, J Kay - *Nature Reviews Rheumatology*, 2015.

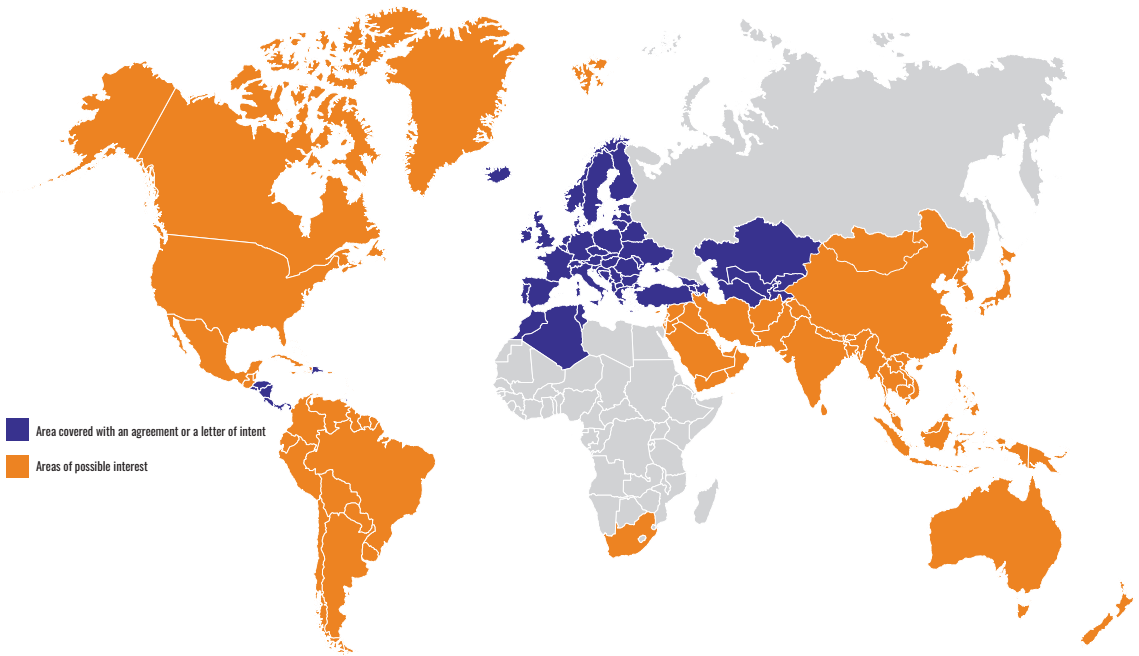
This example is a confirmation of the thesis that even in markets with a less advanced regulatory level, the regulatory agencies are more and more meticulous, which the Company believes is beneficial to it.

2.4 Listing Information

The Company's core business in the future will be the development, manufacture and sale of medicines which are currently at various stages of development. In the past, contracted research and development work in respect of technologies for obtaining various biotechnological medicines for third parties was the main source of revenue. In 2018, the Company did not generate sales revenues, focusing on the implementation of own projects and work related to the registration procedure for MabionCD20.

In 2018, Mabion S.A. continued its cooperation with Plexus Ventures LLC, which supports the Company in obtaining a partner for the sale and distribution of MabionCD20 on the global market. Advanced talks were carried out with potential partners for the non-European market. The negotiation process in this area is complex, since the offers concern both independent and several connected regions. it is also spread over time, because it is necessary to take into account the issues related to the implementation of the appropriate provisions of partnering agreements on both sides, that is elements naturally occurring in business negotiations.

Table 10. Markets for which the Company has entered into distribution agreements, signed letters of intent or which are under discussion with potential distributors.



Currently the regulators in countries with a lower degree of regulation often consider the EMA and FDA guidelines to be leading; therefore, registering MabionCD20 in any of those countries before its registration with the EMA or FDA is unlikely.

Detailed information on the agreements made and advances received is presented in Note 19 to the Financial Statements.

2.5 Procurement sources

The Company carries out development work in respect of obtaining biotechnological medicines. The degrees of development of various projects differ. In 2018, work was conducted on all possible molecular levels, from developing molecular biology techniques at the DNA level through obtaining protein in cell systems, protein purification and the analysis of its purity and quality, including its physico-chemical and biological properties. In consequence of the advanced level of technologies developed in Mabion and the much differentiated level of project topics, the Company uses an extremely wide range of products and services available on the market. The research and development work is characterized by high diversity and variability, which is reflected in the number of sources of supply used by the Company.

Producing such an advanced biotechnological product as a monoclonal antibody requires maintaining the appropriate sterility conditions and cleanliness areas, as well as certified input materials, including disposable materials. The final product is subject to quality control release procedures, which often require using appropriately characterized reagents or outsourcing analyses to appropriately certified bodies.

In 2018, the only supplier the purchases from which reached a level above 10% of the Company's annual operating expenses was:

» Sartorius group – supplying disposable materials, manufacturing equipment and analytic services (with a share in procurement of approx. 11.2%)

The entities from the Sartorius group are not related to Mabion S.A.

As regards the supplies of manufacturing equipment and disposable materials, the Company has been closely cooperating with the Sartorius group for many years. These goods are directly related to the "single use" technology applied in the Company and terminating the cooperation by the Sartorius group would involve for Mabion S.A. the need to find an alternative supplier, which could put the continuity and cost-effectiveness of the manufacturing process at risk.

Therefore, in the Company's opinion, Sartorius is its key supplier on which the Company is dependent to a significant extent. Finding suppliers alternative for Sartorius is one of the Company's priorities.

2.6 Main domestic and foreign investments

In 2018, the Company did not make any significant investments in securities, financial instruments, intangible assets (apart from the integrated IT system of the Company) or real estate.

The expenses related to the purchase and implementation of an integrated IT system were financed from the Company's own funds and from loans granted by financial institutions described in Note 20 to the Financial Statements.

2.7 Information on agreements entered into by MABION S.A.

2.7.1 Significant agreements relating to operating activities

On 8 November 2016, the Company signed a long-term agreement for the development and commercialisation of MabionCD20 with Mylan Ireland – a subsidiary of Mylan N.V. – a leading global pharma company. The agreement provides Mylan with exclusive rights to the sale of MabionCD20 in all European Union and Balkan countries. In addition, Mylan will support the Company in actions aimed at obtaining the approval of the EMA for MabionCD20.

Pursuant to the terms and conditions of the agreement, Mylan paid the Company USD 10 million in the form of an upfront payment. On 27 August 2018, Mabion received another payment of USD 5 million for the achievement of a milestone, defined by a mutual cooperation agreement, in the form of the registration of MabionCD20 by EMA. In addition, Mabion will receive payments for completing the agreement milestones in the total amount of USD 30 million, that is issuing a positive opinion by EMA for MabionCD20 medicine and launching MabionCD20 on key EU markets, as well as royalties dependent on the net revenue from sales of the medicine per annum.

2.7.2 Agreements relating to loans and borrowings received in 2018

In 2018, the Company entered into borrowing agreements with related parties and with Idea Getin Leasing S.A. Loans from related parties were incurred in order to finance current operating expenses. Loans from Idea Getin Leasing SA were taken out in order to finance the purchase of specific investments, in particular investments in computer hardware.

Table 11. Information on the loans received by the Company in 2018

Lender	Date of agreement	Loan amount	Currency	Maturity	Interest rate	Terms of repayment
Artur Chabowski	4 January 2018	200,000	PLN	30 April 2018	WIBOR3M + 2 p.p.	Repaid with own funds
Robert Aleksandrowicz	15 February 2018	1,500,000	PLN	30 April 2018	WIBOR3M + 2 p.p.	Repaid with own funds
Glatton Sp. z o.o.	23 February 2018	500,000	PLN	30 April 2018	WIBOR3M + 2 p.p.	Repaid with own funds
Glatton Sp. z o.o.	5 March 2018	200,000	PLN	31 May 2018	WIBOR3M + 2 p.p	Repaid with own funds
Glatton Sp. z o.o.	8 March 2018	300,000	PLN	31 May 2018	WIBOR3M + 2 p.p.	Repaid with own funds
Twiti Investments Ltd.	22 March 2018	174,790,252	PLN	30 June 2019	WIBOR1M + 3 p.p.	Repaid with own funds
Idea Getin Leasing S.A.	21 May 2018	92,963.40	PLN	31 May 2020	floating	Repaid with own funds
Idea Getin Leasing S.A.	2 August 2018	449,848.39	PLN	20 July 2021	floating	Repaid with own funds

The loan agreements with shareholders did not require a collateral for repayment by the borrower.

As at 31 December 2018, there are no loans from related entities which had not been repaid by the Company.

Loans from Idea Getin Leasing are secured with blank promissory notes, transfer of title agreements and registered pledges on equipment financed by loans. The lender has the right to fill in the promissory note up to the amount equivalent to all payable but unpaid receivables due to the lender under the loan agreement, in the event that the Company fails to pay any of these receivables on their due date.

As at 31 December 2018, the total value of outstanding loans secured on assets, granted by PKO Leasing S.A. and Idea Getin Leasing S.A. amounts to PLN 2,269 thousand.

On 15 January, 15 March, and 28 March 2018, the Company used the last tranches of the loan under the agreement entered into on 8 June 2017 with Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) in the amount of PLN 5,000 thousand, PLN 2,500 thousand and PLN 7,500 thousand, respectively. In this way, the Company used the full amount of credit available, i.e. PLN 75 million. The loan was repaid in full on 11 May 2018 from the funds originating from the issue of P series shares.

On 17 July 2018, the Company entered into an agreement with Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) on a revolving loan to finance the Company's operating activity for a period of two years from the date of the agreement. The amount of the loan is PLN 30 million, whereas a loan amount of PLN 15 million shall be disbursed once formal and legal conditions are met and collaterals are established, and disbursement of the loan above the amount of PLN 15 million may take place after the Company receives a positive decision of the European Medicines Agency regarding the registration of the drug MabionCD20. The loan bears interest at a variable rate based on WIBOR 1M plus the Bank's margin set at market conditions. The Loan is secured with a contractual mortgage registered on the land and mortgage register as the first entry, up to the maximum amount of PLN 45 million established on the Company's ownership right to a real property in Konstantynów Łódzki and a transfer of receivables to the Bank under an insurance agreement for buildings/structures on this property, a statement of submission to enforcement by way of a notarial deed pursuant to art. 777 § 1 (5) of the Code of Civil Procedure each time up to 150% of the loan amount, and a surety and another form of collateral provided by entities related to the Company (the main shareholders of the Company). The agreement provides for numerous obligations of the Company towards the Bank and situations which constitute a breach of the agreement resulting, among others, in the possibility of its termination by the Bank.

All collaterals for the Loan were established within the period specified in the loan agreement. As at 31 December 2018, the Company did not use the loan line granted.

2.7.3 Agreements relating to loans or borrowings terminated or dissolved in 2018

In the financial year 2018, the Company did not terminate or dissolve any loan or borrowing agreements.

2.7.4 Agreements relating to borrowings granted

In the financial year 2018, the Company did not grant any borrowings.

2.7.5 Sureties and guarantees

In the financial year 2018, the Company received a surety for a loan granted by Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) from Glatton Sp. z o.o. (see section 2.7.6). The Company did not receive any guarantees in 2018.

The Company did not grant sureties or guarantees to any third parties.

2.7.6 Transactions with related parties

In 2018, the Company did not enter into transactions with related parties on terms other than arm's length, apart from the free-of-charge surety for the loan from Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) provided by Glatton Sp. z o.o., amounting up to PLN 45 million.

2.8 Information on other significant events

2.8.1 Significant events and factors during the financial year

January

On 5 January 2018, the Company's Management Board received from an external company contracted to provide analyses of the results in a clinical trial of MabionCD20 conducted in patients treated as part of the non-Hodgkin's lymphoma (NHL) indication, information on the initial assessment of two primary pharmacokinetic endpoints of the clinical trial. The preliminary results indicated that the assumed equivalence criteria were met. This information has been published in current report No. 2/2018 dated 5 January 2018.

On 10 January 2018, the Management Board of the Company received a preliminary preparation of data from an external company regarding treatment efficacy and the general safety profile of MabionCD20 as part of the indication of non-Hodgkin's lymphoma (NHL) (secondary endpoints). Based on the efficacy data, the Management Board determined that patients' responses to treatment in both groups (treated with MabionCD20 and MabThera) are comparable. In the Company's opinion, MabionCD20 met the general safety profile requirements. The Management Board stressed that due to the relatively small population of patients participating in the study compared to the MabionCD20 RA study, the assessment in consideration was not based on statistical inference, but rather on the basis of descriptive statistics. This means that the final assessment of the reported results will be carried out by the European Medicines Agency and may differ from the assessment made by the Company. The final study reports were used in the marketing authorization application (MAA), which the Company submitted to the EMA in June 2018. The information presented here was published in current report No. 3/2018 dated 10 January 2018.

On 11 January 2018, the Management Board of the Company was informed about the last visit of the last patient as part of the additional period of observation of the so-called long-term follow-up of patients recruited in the MabionCD20 NHL study. Summing up, all patients in the MabionCD20 NHL study completed a 46-week course of treatment and follow-up consisting of a baseline treatment and follow-up period of 26 weeks and additional 20 weeks of long-term follow-up. Thus, the collection of data for all

end points in the study was completed. Based on the data collected, the Company obtained results in the scope of long-term follow-up secondary end points. The information presented here was published in current report No. 4/2018 dated 11 January 2018.

On 15 January 2018, the Company's Management Board received a preliminary preparation data from an external company regarding the pharmacokinetic secondary endpoints as well as the pharmacodynamics of MabionCD20 in the indication non-Hodgkin's lymphoma (NHL) (secondary endpoint). The Management Board determined that the pharmacokinetic parameters obtained in the groups treated with MabionCD20 and MabThera are equivalent. As regards the pharmacodynamics, both groups showed depletion (removal) of B lymphocytes, and the degree of repletion (reconstruction) of lymphocytes in both groups was similar. The Management Board emphasized that due to the relatively small population of patients participating in the study compared to the MabionCD20 RA study, the assessment in consideration was based on a simplified statistical approach. This means that the final assessment of the reported results will be carried out by the European Medicines Agency and may differ from the assessment conducted by the Company. The final reports on the study were used in the marketing authorization application (MAA), which the Company submitted to the EMA in June 2018. The information presented here was published in current report No. 6/2018 of 15 January 2018.

March

On 22 March 2018, the Company obtained financing in the amount of PLN 174.8 million in the form of a borrowing agreement from a Company's shareholder, i.e. Twiti Investments ("Shareholder"). Funds for the borrowing were obtained by the Shareholder from the sale of 1,902,772 ordinary bearer shares of the Company as part of a private offering referred to below. The borrowing from the Shareholder was originally to be repaid by 30 June 2018 through a contractual set-off of mutual claims: the Company's receivables due to the Shareholder paying for the same number of the new ordinary bearer shares of the Company as the number of shares sold under the private offering that were to be issued by the Company at the same issue price as the price obtained from the sale of shares as part of the private offering, and the claims of the Shareholder due to the repayment of the borrowing from the Shareholder. Finally, the borrowing was repaid by the Company in cash on 23 April 2018, about which the Company informed in current report No. 26/2018 dated 23 April 2018.

On 22 March 2018, Twiti Investments Ltd. Entered into sales agreements related to the sale of 1,920,772 ordinary bearer shares of the Company owned by it as part of a private offering for a limited number of selected institutional investors, including investors from the United States in accordance with the exception concerning private subscriptions according to Section 4) a) (2) of the US Securities Act of 1933 (American Securities Act), as amended, and investors from outside the United States based on the exclusion provided for in Regulation S of the American Securities Act. The private offering was carried out in a manner that did not constitute a public offering within the meaning of Article 3. 1 of the Act of 29 July 2005 on public offerings (...) and does not require preparation or approval of a prospectus or information memorandum. The shares were sold in block transactions on the WSE carried out on 23 March 2018 and settled on 27 March 2018. The price for one share sold by the Shareholder was PLN 91.00. The private offering was addressed mainly to institutional investors specializing in the health care and biotechnology sector from the United States, who strengthened and diversified the shareholding structure of the Company. The investors who purchased shares from the Shareholder and become Company's shareholders included, among others, the European Bank for Reconstruction and Development (EBRD), which acquired shares for PLN 61.4 million, and PFR Life Science sp. Z o. O. (PFR Life Science), which acquired shares for PLN 38.3 million. Pursuant to framework agreements entered into with PFR Life Science and the EBRD, as long as PFR Life Science or the EBRD hold shares representing more than 1% of the share capital of the Company, the EBRD, after consulting PFR Life Science, will have the right to nominate a candidate for the Supervisory Board of the Company, who will meet the independence criteria set out in Annex II to the Commission Recommendation of 15 February 2005 on the role of non-executive or supervisory directors of listed companies and on supervisory board committees. On the basis of a framework agreement entered into with the EBRD, the Company undertook to follow the good practices adopted by the EBRD in the field of environmental and social policy, as well as to comply with the anti-fraud policy. The information presented here was published in current report No. 12/2018 dated 23 March 2018.

On 22 March 2018, the Company received from a company contracted to analyse the results of the clinical trial of MabionCD20 in RA patients confirming that the status of the results of the clinical trial reported by the Company earlier as "preliminary", after a thorough verification of data, was changed to "final". Thus, the positive evaluation of the clinical trial result did not change. The final versions of the reports were attached to the marketing authorization application (MAA) submitted in June

2018. Positive results do not guarantee product approval by the (EMA). The information presented here was published in current report No. 13/2018 dated 23 March 2018.

April

On 4 April 2018, the Company received information that the Company's application for co-financing of the project entitled "Expansion of the Research and Development Centre of Mabion S.A. - research on a new generation of medicines" submitted as part of competition 2.1 / 2/2017 to measure 2.1 Support for investment in R&D infrastructure of enterprises, Smart Growth Programme 2014-2020, was selected for co-financing. The subject of the project is development of the company's R&D facilities by preparing the necessary infrastructure: the Research and Development Centre building, and the purchase of research equipment for research on innovative medicines. The planned Research and Development Centre will be used to develop and the latest generation of biotechnological drugs, monoclonal antibodies, and prepare them for the commercialization. The total cost of the Project was set at PLN 172.88 million, and the recommended co-financing amount is equal to the requested amount of co-financing and totals PLN 63.25 million. The information presented here was published in current report No. 22/2018 dated 4 April 2018.

On 18 April 2018, the Extraordinary General Meeting of the Company (EGM) passed a resolution to increase the Company's share capital from PLN 1,180,000 to PLN 1,372,077.20 by issuing 1,920,772 ordinary series P bearer shares, each having a par value of PLN 0.10, in a private subscription within the meaning of Article 431 § 2 (1) of the Commercial Companies Code addressed to Twiti Investments Ltd. The EGM decided to deprive current shareholders of the pre-emptive rights to all series P shares. The issue price of one P series share amounted to PLN 91 (total issue value: PLN 174.8 million). The Management Board of the Company was authorized to apply for the admission and introduction to trading on the regulated market operated by the Warsaw Stock Exchange of P-series shares and to sign an agreement with the National Depository for Securities for the registration of P-series shares in the depository of securities, as well as to take all other necessary actions related to shares dematerialisation. The information presented here was published in current report No. 23/2018 dated 18 April 2018.

On 23 April 2018, the Company sent to Twiti Investments Ltd. an offer to subscribe for shares through a private subscription within the meaning of art. 431 § 2 (1) of CCC with regard to 1,920,772 ordinary bearer shares of P series of the Company. The shareholder accepted the offer to subscribe for series P shares and on 23 April 2018, the P series share subscription agreement was made, under which the Shareholder acquired 1,920,772 ordinary bearer series P shares, each having a par value of PLN 0.10 each, at the issue price of PLN 91.00 per share (the total value of P series shares issue amounted to PLN 174.8 million). The Shareholder paid the total issue price for series P shares in cash on 23 April 2018. The funds obtained from the issue of series P shares are used by the Company for the expansion of the Research and Development Centre in Konstantynów Łódzki, covering costs and liabilities related to the development and commercialization of Mabion CD20 and the repayment of loans and other liabilities to financial institutions. Information on the acquisition of series P shares by the Shareholder was published in current report No. 26/2018 dated 23 April 2018.

May

On 25 May 2018, the Company received from a company contracted to analyse the results in the scope of responses to treatment of patients as part of the NHL indication confirming that the status of the results of clinical trials reported in earlier communications as "preliminary", after a thorough verification of data, was changed to "final". The positive assessment of the clinical trial result is not changed. The final versions of the reports have been attached to the marketing authorization application (MAA). Positive results do not guarantee product approval by the EMA. The information presented here was published in current report No. 35/2018 of 25 May 2018.

June

On 1 June 2018, the Company filed a marketing authorization application (MAA) with the European Medicines Agency for the drug of a working name "MabionCD20" with regard to the market regulated by the EMA. The drug was developed as a biosimilar drug for MabThera and its indications are in line with the list of indications for MabThera. The information presented here was published in current report No. 36/2018 dated 1 June 2018.

On 11 June 2018, the Company entered into an agreement with the Minister of Investments and Development for the co-financing of the Project "Expansion of the Research and Development Centre of Mabion S.A. - research on a new generation of medicines", under Measure 2.1 Support for investment in R&D infrastructure of the Smart Growth Operational Programme 2014-2020, co-financed by the European Regional Development Fund. The total cost of the Project was set at PLN 172.88 million, with the co-financing amounting to PLN 63.25 million. The information presented here was published in current report No. 42/2018 dated 11 June 2018.

On 21 June 2018, the Management Board of the Company received information about the successful completion of the validation of the marketing authorization application (MAA) for the drug of a working name "MabionCD20" by EMA and thus its acceptance into the assessment procedure. Confirmation of the acceptance of the application for evaluation does not guarantee product approval by the European Medicines Agency. The information presented here was published in current report No. 46/2018 dated 21 June 2018.

On 27 June 2018, the Company received a summary from the US Agency for Food and Drug Administration, following a BPD (Biosimilar Biological Product Development) Type 2 meeting. The meeting was aimed at a preliminary, general presentation of data collected by the Company on the development of MabionCD20 with reference to the MabThera reference drug, as well as at establishing basic issues regarding the possibility of cooperating with the Agency based on this data in order to obtain registration of MabionCD20 in the USA. According to the summary received, the Agency allowed the use of data held by the Company as supporting the application process. At the same time, the Agency proposed a general strategy for linking a product registered in the European Union (MabThera) with a product authorized for sale in the USA (Rituxan). The agency did not indicate the need for a completely separate development process of MabionCD20 for the US market. The company was admitted to further stages of the consultation process, within which the objective is to make the requirements of the FDA more specific. The company informs that the process of registration and admission to trading of MabionCD20 in the USA is a multi-stage process and it cannot be excluded that in the future there will be additional requirements related to product approval by the FDA. The information presented here was published in current report No. 50/2018 dated 28 June 2018.

July

On 17 July 2018, the Company and Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) entered into a revolving loan agreement to finance the operating activities of the Company for a period of two years from the agreement date. The amount of the loan is PLN 30 million, and its disbursement in the amount of PLN 15 million was possible from 18 October 2018, i.e. as of the fulfilment of formal and legal conditions and establishing a collateral, while its disbursement in an amount exceeding PLN 15 million may occur after the Company has obtained a positive decision of the European Medicines Agency regarding the registration of MabionCD20. Until the publication of this report, the Issuer did not use the Loan. The interest rate on the Loan is variable and based on the WIBOR 1M rate increased by the Bank's margin set at market terms. The Loan is secured by: a contractual mortgage entered on the first place in the land and mortgage register up to the maximum amount of PLN 45 million established on the Company's ownership right to a real estate in Konstantynów Łódzki, and transfer of receivables to the Bank under the construction / building insurance contract on this property, a declaration of submission to enforcement by way of a notarial deed in accordance with art. 777 § 1 (5) of the Code of Civil Procedure each time up to the amount constituting 150% of the loan amount, and a surety and other forms of security provided by entities related to the Company (main shareholders of the Company). The agreement contains numerous obligations of the Company towards the Bank and situations constituting a breach of the agreement resulting, among others, in the possibility of its termination by the Bank. The information presented here was published in current report No. 55/2018 dated 17 July 2018.

August

On 6 August 2018, the Company received a permission from the European Medicines Agency (EMA) to submit a second registration application ("Duplicate application") for the drug of a working name MabionCD20. With the second application, the Company intended to acquire an additional trade name, for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). This activity may accelerate the commercialization of the drug with the working name MabionCD20 in markets where RA is still covered by the patent protection for MabThera. At the same time, the Company announced that the above-mentioned EMA's consent is only a preliminary confirmation of the possibility of registering the medicine and does not guarantee any success

in the process in consideration. The Company also reserved the possibility to withdraw from submitting the second registration application depending on the final assessment of potential business benefits for the Company. Until the publication of this report, the Company did not take the final decision regarding the submission of the second registration application. The information presented here was published in current report No. 56/2018 dated 6 August 2018.

On 27 August 2018, the Company was notified of Mylan Ireland's payment of USD 5 million for the achievement of the milestone specified in the mutual cooperation agreement as registration of MabionCD20 by EMA. In addition, Mabion will receive payments for completing the agreement milestones in the total amount of USD 30 million, that is issuing a positive opinion by EMA for MabionCD20 medicine and launching MabionCD20 on key EU markets, as well as royalties dependent on the net revenue from sales of the medicine per annum. The information presented here was published in current report No. 58/2018 dated 27 August 2018.

October

On 26 October 2018, the Company filed a European patent application with the Patent Office of the Republic of Poland, with the possibility of expanding pursuant to the PCT procedure, as part of the area of application of MabionCD20 in the treatment of patients suffering from multiple sclerosis (MS), entitled "Low aggregate anti CD20 ligand formulation." This is the second patent application for using MabionCD20 in treatment of multiple sclerosis constituting an innovative indication for the molecule. It concerns the use of MabionCD20 on a monotherapy basis. The information presented here was published in current report No. 59/2018 dated 26 October 2018. The first patent application in this therapeutic area was submitted by Mabion on 5 December 2017 (current report No. 56/2017). Filing an application does not mean a guarantee of obtaining patent protection.

November

On 14 November 2018, the Company received a decision of the Staroste of Pabianice approving the works project and granting a building permit as part of the investment called "The Science and Technology Centre for advanced medical biotechnology of Mabion S.A." together with the necessary infrastructure in Konstantynów Łódzki. Obtaining a building permit enables starting the work on the extension of the existing plant of the Issuer's Scientific and Industrial Complex for Medical Biotechnology, which will result in a significant increase in the Company's production and R&D capacity. The Science and Technology Centre will be used to develop and prepare for the commercialization of the latest generation of biotechnological drugs: monoclonal antibodies. In the future, the Company's investment plans may be extended in relation to the investment covered by the currently obtained permit, therefore the Company may in the future apply for another permit. The information presented here was published in current report No. 60/2018 dated 14 November 2018.

December

On 5 December 2018, the Company filed a notification regarding the extension of patent protection pursuant to the PCT procedure for the invention called "Combination Therapy of Multiple Sclerosis containing a CD20 Ligand" with the European Patent Office in The Hague (the original application was made on 5 December 2017).

The subject of the patent application is an innovative therapy for the treatment of patients suffering from multiple sclerosis using MabionCD20 antibody as part of a combination treatment with other substances. The information presented here was published in current report No. 61/2018 dated 5 December 2018. Filing an application does not mean a guarantee of obtaining patent protection.

On 24 December 2018, the Supervisory Board of the Company adopted a resolution on appointing, as of 2 January 2019, Mr. Grzegorz Grabowicz as a member of the Management Board for the 1st joint term of office in the Company. The information presented here was published in current report No. 63/2018 dated 24 December 2018.

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

On 20 March 2019, an audit was carried out concerning the Company's compliance with the condition of permit No. 203 of 12 April 2012 for conducting business activity in the Łódź Special Economic Zone (Łódź SEZ) concerning the completion, by 31 December 2018, of the construction of a new production plant for technologically innovative biotechnological drugs used in

targeted cancer therapies, immune system disorders and metabolic diseases in the Łódź Subzone, Complex 1. On the basis of the audit, it was concluded that the said condition has been fulfilled. The Company incurred capital expenditure in the total amount of approximately PLN 74.6 million, of which PLN 45 million are eligible investment costs. The Company informed about the event in current report no. 5/2019 of 20 March 2019. The Company informed about obtaining the above mentioned permit in current report no. 10/2012 of 16 April 2012, and about fulfilling the previous conditions under this permit in current report no. 5/2017 of 11 January 2017.

On 3 April 2019, the Management Board of Mabion S.A., as a result of the annual update of the strategy for the development of medicinal products, adopted a resolution approving the changes in this strategy. In accordance with the resolution, the catalogue of projects whose implementation the Company, now or in the future, alone or with partners, is interested in has been changed. The company has also qualified scientific and research projects to three groups of projects, i.e. active projects, new projects planned for 2019, and partnership projects. Detailed information on the updated strategy can be found in 4.2. of this report.

The Company will continue to update its strategy for the development of medicinal products on an annual basis. The Company informed about the event in current report no. 8/2019 of 3 April 2019.

2.8.3 Other events

On 31 October 2018, the Company made a statement on the termination of the agreement on the lease of office, service and warehouse space at ul. Fabryczna 17 in Łódź of 17 August 2015 to Fabryczna 17 SPP Sp. z o. o. SKA, from whom it rented the said premises. The statement on the termination of the lease agreement was submitted with effect as of 1 November 2018, with a six-month notice period effective at the end of a calendar month. Mabion also expressed its will to extend the notice period in such a way so that the lease agreement would be dissolved on 31 December 2019. Then Mabion and Fabryczna 17 SPP Sp. z o.o. S. K. A. extended the aforementioned period of notice of termination of the lease agreement, by way of an agreement entered into on 20 February 2019, until 31 December 2019. As a result, the lease will expire at the end of 2019. There is a research and development laboratory for biotechnological medicinal products on the premises.

On 28 March 2019, the Company received information from the Polish Agency for Enterprise Development (PARP) regarding the adoption of the Company's report on the dissemination of industrial research results as part the project entitled "An innovative double cutting technology for obtaining modern analogues of the human insulin hormone". The report has been accepted, and the condition of granting a bonus for wide dissemination of results, in accordance with the provisions of the agreement on co-financing of the project in question, has been met thereby (agreement of 2 February 2012).

The project was implemented by the Company in the years 2011-2016. On 3 November 2015, the Company submitted an application to PARP for early completion of the project. The technology developed as part of the project was used to obtain an exemplary prototype of an insulin analogue, but it was not possible to develop an appropriate formulation, i.e. a solution in which the drug would be stable in the long term, i.e. long enough for a pharmaceutical product. In May 2016, the Company received a letter from PARP informing about the approval of the report on the implementation of industrial research and development work together with economic analysis and market research concerning the implementation of the project. At the same time, it was found that it was not advisable to implement the results obtained as part of the co-financing agreement. Therefore, the Company has been exempted from the need to implement the results of industrial research or development work in the form, scope and date specified in the application for co-financing.

During the lifetime of the project (3 years from the date of project completion, i.e. until 7 March 2019), the Company was obliged to disseminate the results of industrial research related to this project. The assumed work (dissemination of results by means of open source software) were performed by the Company and reported to PARP. A letter received on 28 March 2019 confirms the correctness of the work carried out and the final settlement of the project with regard to its substantive content.

2.8.4 Atypical factors and events

In the Company's opinion, there were no atypical factors or events in the financial year 2018, other than as discussed in point 2.8.1 .

3 ANALYSIS OF THE COMPANY'S FINANCIAL AND ASSETS POSITION

3.1 Selected financial data

Table 12. Selected financial data of Mabion S.A.

	in PLN thousand		In thousands EUR	
Selected financial data	**2018**	**2017**	**2018**	**2017**
Net sales	0	0	0	0
Operating profit (loss)	-64,625	-62,376	-15,146	-14,695
Profit (loss) before tax	-68,870	-57 887	-16,140	-13,638
Net profit (loss)	-68,870	-57,887	-16,140	-13,638
Net cash flows from operating activities	-38,938	-54,127	-9,126	-12,752
Net cash flows from investing activities	-6,767	-7,111	-1,586	-1,675
Net cash flows from financing activities	103,086	47,450	24,159	11,179
Total net cash flows	57,380	-13,788	13,448	-3,248
	31.12.2018	**31.12.2017**	**31.12.2018**	**21.12.2017**
Total assets	144,717	82,445	33,655	19,767
Liabilities and provisions for liabilities	102,578	136,603	23,855	32,751
Long-term liabilities	36,069	16,233	8,388	3,892
Current liabilities	66,509	120,370	15,467	28,859
Equity	42,139	-54,158	9,800	-12,985
Share capital	1,372	1,180	319	283
Number of shares (in pcs)	13,720,772	11,800 000	13,720,772	11,800,000
Weighted average number of shares (in pcs)	13,089,285	11,800,000	13,089,285	11,800,000
Net profit (loss) per ordinary share	-5.26	-4.91	-1.23	-1.16
Book value per share	11.06	6.99	2.57	1.68
Dividend declared or paid per share	0	0	0	0

Individual items of the balance sheet were translated into EUR at the average exchange rate for a specific balance sheet date, announced for the euro by the National Bank of Poland; (31 December 2018 - PLN 4.3000, 31 December 2017 - PLN 4.1709). Individual items of the income statement and cash flow statement have been converted into EUR at the exchange rate being the arithmetic average of the average exchange rates announced by the National Bank of Poland for the euro effective on the last day of each month of the financial year (2018 – PLN 4.269, 2017 – PLN 4.2447) .

3.2 Principles of preparing the financial statements

The separate 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 2017.

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. The separate financial statements, with the exception of the separate cash flow statement, have been prepared on an accruals basis.

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.

In the financial statements for the year 2018, the same accounting principles (policies) as in the financial statements for the year 2017 were applied. There were no changes in the rules for measuring assets and liabilities and financial result in 2018.

The scope of the annual report of the Company is consistent with the Minister of Finance Regulation of 29 March 2009 on current and periodic reporting by issuers of securities and the rules of equal treatment of the information required by the laws of non-member states (Polish Journal of Laws of 2018, item 757) and covers the annual reporting period from 1 January to 31 December 2018.

3.3 Key economic and financial figures and current and projected financial situation of the company

In 2018, the Company did not make any sales. Since its incorporation the Company has been focusing on conducting research and development activities with the aim to develop and launch its products on the commercial market. As a result, the Company suffered losses from its operational activities and generates negative cash flows from its operational activities. It is expected that this situation will recur in the foreseeable future.

In the 12 months of the year 2018, the Company's operating expenses amounted to PLN 66,687 thousand, which was mainly attributable to development costs, of PLN 44,931 thousand in 2018, and general administrative expenses which amounted to PLN 21,005 thousand. The Company's operating loss for the year 2018 was PLN 64,625 thousand and increased by PLN 2,249 thousand as compared with 2017. The Company's net loss reached PLN 68,870 thousand in the period of 12 months of 2018.

As at the end of December 2018, the Company's balance sheet total amounted to PLN 144,717 thousand and as compared to the end of December 2017, it increased by PLN 62,272 thousand. As at the end of 2018, non-current assets, of PLN 72,555 thousand, constituted a significant proportion of total assets, including property, plant and equipment (mainly fixed assets involved in the Konstantynów Łódzki investment project). As at the end of December 2018, cash and cash equivalents amounted to PLN 58,418 thousand and came from the funds obtained from the issue of P series shares.

On the other hand, on the liabilities side of the Company as at the end of 2018, there is a clear increase in equity by PLN 96,297 thousand compared to the end of December 2017, resulting mainly from the proceeds from the sale of P series shares. With respect to short-term liabilities, there is a visible decrease in loan liabilities, which results from the repayment in full of bank loans previously incurred by the Company. Significant changes in other items of short- and long-term liabilities relate to funds leveraged from Mylans, which in the repayable part are presented under current liabilities, while in the non-repayable part are

presented in long-term liabilities as deferred income. This approach results from the fact that these proceeds are related to the future sale of MabionCD20 to Mylan, which will be possible after obtaining a marketing authorisation, which, in connection with the requirements of IFRS 15, does not allow these amounts to be recognised in the present financial statements as revenues of the Company.

The Company's Management Board believes that support from shareholders (both strategic shareholders and stock market participants, as well as external financing in the form of loans, borrowings, and subsidies), and the long-term agreement with Mylan shall provide the Company with financing necessary to complete development work related to MabionCD20 and commercialisation of this drug, and justify continuing the Company's activities in line with the adopted development strategy.

As at the end of December 2018, the Company's financial position is stable and the Company has funds to carry out operating activities and repay its liabilities.

3.4 Financial and non-financial performance indicators

In 2017 and 2018, the Company did not conduct sales.

At the same time, the Company incurred costs of operating activities associated with the costs of conducted development work, capital expenditure on plant and machinery used for development and production of medicines in the future, as well as general administration costs related to leveraging funds to finance the current activities.

Therefore, both in 2017 and 2018, the Company recognized a loss on operating activities and a net loss, and therefore it is not possible to determine financial ratios for the Company related to profitability.

The Company's Management Board does not identify any non-financial performance indicators material for the assessment of the Issuer's growth, performance and position.

3.5 Product and geographical structure of revenues

In 2018, Mabion S.A. did not recognized any sales revenues.

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

3.6 Issues of securities

On 18 April 2018, the Company's Extraordinary General Meeting adopted a resolution on an increase of the Company's share capital from PLN 1,180,000 to PLN 1,372,077.20 by means of issuing 1,920,772 P-series ordinary bearer shares with a par value PLN 0.10 each as part of a private placement within the meaning of Article 431 § 2 (1) of CCCP, addressed to Twiti Investments Ltd. The issue price of one P-series share was PLN 91 (total value of the issue: PLN 174.8 million). The P-series shares were subscribed to and paid in full by Twiti Investments Ltd. on 23 April 2018. The Company intends to use funds obtained from the P-series share issue, among others, for the expansion of the Research and Development Centre in Konstantynów Łódzki, covering the costs and expenses in connection with the development and commercialization of Mabion CD20, and repayment of loans from and other liabilities towards financial institutions. Further information on the issue of P-series shares is provided in point 6.1.

3.7 Financial instruments used

In 2018, the Company did not use any financial instruments in the scope of risk related to: changes in prices, credit, significant distortions of cash flows and loss of financial liquidity.

In 2018, the Company did not use any derivative instruments.

3.8 Financial risk management objectives and methods

The Company does not have a formal financial risk management system. The Company does not apply hedging instruments. Transactions are planed based on up-to-date analyses of the Company's situation and its environment.

The Company's Management Board is responsible for financial risk management.

3.9 Assessment of financial resource management

Going concern assumption

The separate 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 report, the Management Board of Mabion S.A. is not aware of any circumstances that would indicate 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 2018

In 2018, the Company's operations were most affected by development costs, in the first instance clinical trials and costs involved in the production of the medicine MabionCD20.

As at 31 December 2018, the value of the Company's equity was positive and corresponded to approximately 29.3% of its total assets, whereas as at the end of December 2018 the Company's debt ratio involving long-term and current liabilities (trade liabilities) and loans totaled about 70.7%.

In evaluating its financing needs, the Company takes the following factors into account:

» current and budgeted level of cash generated from 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 authorisation and that its sales will generate sufficient future cash flows.

The Company assumes that the financing for its continuing in operation, including:

launch of commercial scale production at the Scientific-Industrial Complex in Konstantynów Łódzki;

» design and preparatory work for the launch of construction of another production plant 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;

» research and development work on further medicines developed by Mabion,

may be derived from:

» expected distribution fees for MabionCD20 medicine (milestone payments);

» aid from EU funds;

» loans provided by banks;

» funds obtained under operating or finance leases;

» funds obtained from the P-series share issue;

» performance of contracts for the provision of research and development services;

» borrowings from shareholders;

» future share issues.

3.10 Assessment of the feasibility of investment plans

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

On 23 April 2018, the Company obtained PLN 174.8 million from the issue of 1,920,772 P-series ordinary bearer shares as part of a private placement addressed to Twiti Investments Ltd. The issue price of one P-series share was PLN 91. The Company have allocated part of the funds thus acquired for the implementation of investment plans and repayment of its liabilities towards banks and other financial institutions, and the other part will be earmarked for further implementation of the investment plans.

The Company intends to obtain funds for the implementation of investment projects from sources indicated in point 3.9 .

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

The Company's liquidity may be affected adversely by:

» delayed payment of funds by government institutions handling the distribution of funds under EU co-financed projects;

» delayed distribution fee tranche payments due to failure to reach budgeted milestones by specified dates;

» delays in the refund of the tax on goods and services (VAT).

These negative phenomena should not significantly affect the scope of conducted activity. In such case the Management Board plans to mobilise alternative sources of financing its current operations. In particular, the Company can count on help from shareholders who support the Company with short-term loans while awaiting other external funding.

3.11 Dividend policy

In the financial year 2018, 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. Currently, the Company is in the growth stage and it does not intend to pay any dividend.

3.12 Explanations of discrepancies between the actual financial results and the previously published forecasts

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

4 PROSPECTS OF MABION S.A.

4.1 Development prospects

Since its incorporation, the Company has focused mainly on research and development work on biosimilars such as therapeutic monoclonal antibodies and insulin analogues. The products developed by the Company are highly specialist medicines 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 medicine 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 of therapeutic medicines – one of the most eminent achievements of modern biotechnology, enables the manufacture of targeted medicines 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 medicines which destroy not only tumour cells, but healthy tissue as well. The Company 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. acquired competencies to manufacture any biotechnological medicines, from the stage of designing them, through the selection of the technological path, to manufacturing the finished medicine. 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 medicines 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 go independently through the registration process of the therapeutic monoclonal antibodies according to the centralized procedure within the whole EU area, where the system for the registration of biosimilars is well regulated. The Company also has an important goal of introducing the medicines to the American market. In respect of regions with a less regulated registration system, in Asia and Africa, the Company plans to conduct the whole registration procedure and sales of

the medicines via leading local pharmaceutical companies, based on distribution agreements.

4.2 Implementation of the development strategy

The basic objective of the Company's operations is the development, manufacture and market launch of oncological medicines biosimilar to the original biotechnological medicines already present on the market (reference medicines).

On 30 March 2017, the Company's Management Board passed a resolution regarding a plan for medicinal product development. The plan was prepared as a result of completion of an internal analytic project that considered nearly 50 potential drug candidates for development in the Company, taking into account, among others, reference medicine patent expiry dates, current and predicted volume of the reference medicine market, medicine production technology applied in the Company, team competencies, experience with MabionCD20 and the competition in the area of biosimilars.

Prior to the publication of this statement, the Management Board carried out an annual revision of the medicinal product development strategy plan and on 3 April 2019 (an event after the balance-sheet date), adopted a resolution approving changes in the existing strategy for the development of medicinal products.

In accordance with the adopted resolution, the catalogue of projects whose implementation the Company, now or in the future, alone or with partners, is interested in has been changed. The Company has also qualified scientific and research projects to three groups of projects, i.e. active projects, new projects planned for 2019 and partnership projects.

Active projects

A group of projects of the greatest importance for the Company, as part of which the Company carries out work and invests funds. This group includes projects currently under way: MabionCD20, MabionMS and MabionEGFR.

New projects planned for 2019

Projects in which the Company plans to start research and development work in the second half of 2019. These will be projects concerning three biosimilar medicines in the area of autoimmunology, metabolic diseases, and oncology.

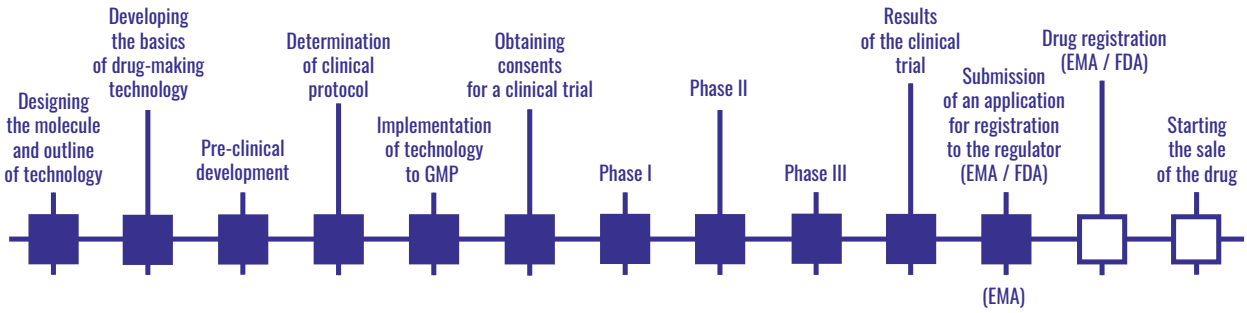
Partnership projects

Projects in which the Company considers starting implementation in the medium or long term, preferably in cooperation with a partner. These will be projects concerning, inter alia, autoimmune and oncological diseases.

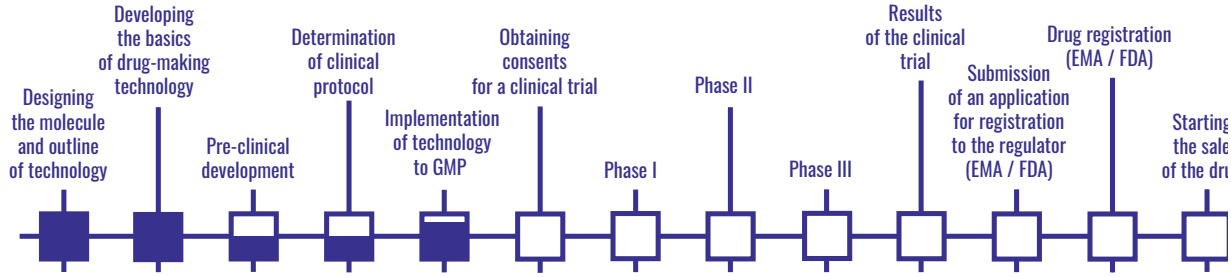
The Company will continue to update its strategy for the development of medicinal products on an annual basis. The Company informed about the event in current report no. 8/2019 of 3 April 2019.

The graphs below show in detail the already completed stages of development of ongoing projects.

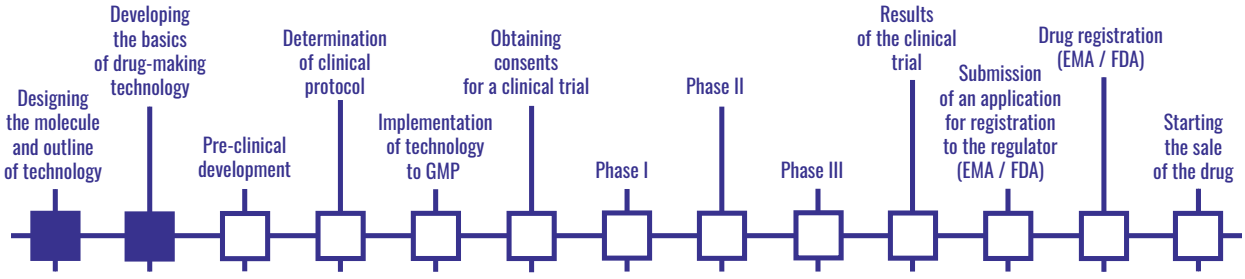
MabionCD20



MabionMS

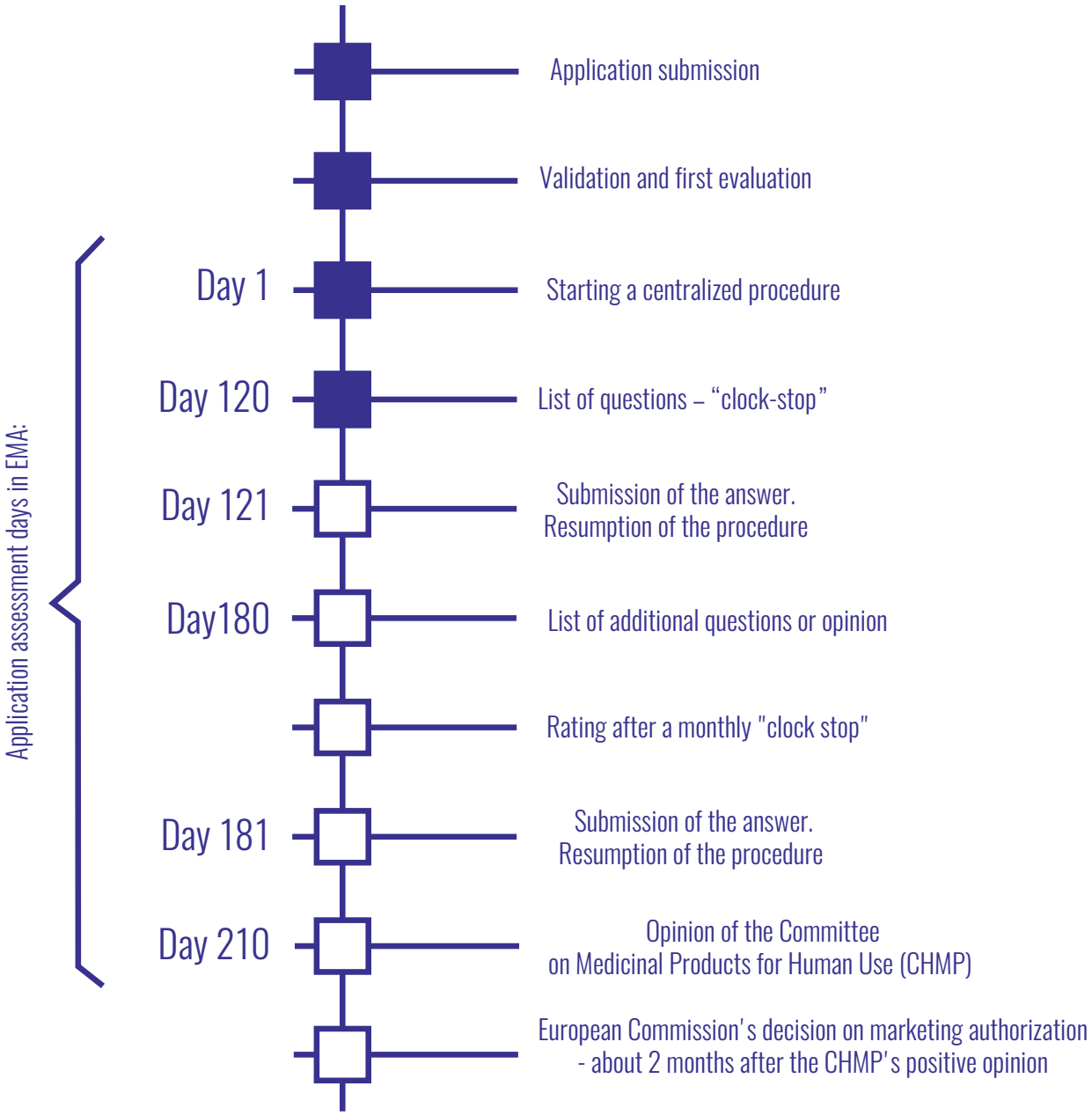


MabionEFFR



The most important and most advanced project of the Company is the admission of the drug with the working name MabionCD20 to trading. On 1 June 2018, the Company filed a marketing authorization application (MAA), with the European Medicines Agency with regard to the market regulated by the EMA, for the drug with a working name "MabionCD20" (CR No. 36/2018 of 1 June 2018). On 21 June 2018, the Management Board of the Company received information on the successful completion of the validation of this application and thus its acceptance into the assessment procedure (CR No. 46/2018 of 21 June 2018).

According to EMA regulations, the application assessment procedure is divided into the following stages:



Currently, Mabion is on the Stage of Day 120 and work is underway to develop answers to EMA's questions. After obtaining the European Commission's decision regarding the marketing authorization, the Company will submit a request for post-registration change in the form of a dossier relating to an increased manufacturing scale of up to 2x2,500 l of the bioculture volume in the reactor. The application submitted to the EMA on 1 June 2018 concerned the clinical scale of bioreactor culture, however, included the production process already after the transfer from the plant at ul. Fabryczna to the commercial plant in Konstantynów Łódzki. Post-registration changes are a typical element of cooperation with the regulator after the initial registration, they may concern changes in scale, manufacturing sites, process improvements, additional manufacturing sites, etc. This is a usual practice employed by pharmaceutical companies (e.g., the MabThera drug has undergone 44 post-registration reviews[28]).

On 27 June 2018, the Company received a summary from the US Agency for Food and Drug Administration, after a BPD (Biosimilar Biological Product Development) meeting Type 2 (CR No. 50/2018 dated 28 June 2018). The meeting was aimed at a preliminary, general presentation of data collected by the Company on the development of MabionCD20 with reference to the MabThera reference drug, as well as establishing the main issues regarding the possibility of cooperating with the Agency based on these data in order to obtain registration of MabionCD20 in the USA. According to the summary received, the Agency allowed the use of data held by the Company as supporting the application process. At the same time, the Agency proposed a general strategy for linking a product registered in the European Union (MabThera) with a product authorized for sale in the USA (Rituxan). The agency did not indicate the need for a completely separate MabionCD20 development process for the US market. It was further agreed that it was necessary to hold a Type 3 BPD meeting, for which a complete set of clinical data for the US market is required, before the submission of the dossier. This requires a bridging test and additional analytical tests. The company was admitted to parallel stages of the consultation process, within which the objective is to make the requirements of the FDA more specific, also in non-clinical areas (e.g. analytical area). The registration and marketing authorization process for MabionCD20 in the USA is a multi-stage process and it cannot be ruled out that there will be additional requirements for FDA approval in the future.

As at the date of publication of this report, the Company is in the process of drawing up a bridge clinical trial report, based on hitherto arrangements with the FDA. The report is drawn up in cooperation with Parexel, a contract research organization (CRO) with extensive experience in clinical trials of biosimilar drugs, including rituximab. This is a task is necessary for further communication and procedures with the FDA (Type 3 BPD meetings). The purpose of the study is to compare the European MabThera to the American Rituxan (bridging study), while using MabionCD20 as a bridge arm. The study will provide a kind of "bridge" to the results of the Company's MabionCD20 and MabThera comparative study.

In order to commence a bridge trial, the Company must obtain the consent of the competent authorities and the consent of the bioethics committees on the basis of the trial report. At the same time, the Company must ensure financing for the trial, which is a necessary condition for its commencement and thus determines the date of the trial. The funds for the implementation of the above assumptions may come both from a potential distribution partner and from the EU funds. With regard to the US partnering, the priority for Mabion Company is Mylan, and depending on its decision, Mabion will only be able to consider other partners that may co-finance the research and activities leading to the drug commercialization on the US market. Until Mylan makes decisions in this regard (which has to be made 30 days after the issue of the final minutes of the FDA type III meeting), the Company cannot make commitments to other partners. The company is also considering the possibility of obtaining funds for research from European Union funds, no less the potential scope of financing or the moment of concluding a possible co-financing agreement is not known as at the date of publication of this report.

On 6 August 2018, the Company received a permission from the European Medicines Agency to submit a second registration application ("Duplicate application") for a drug of a working name MabionCD20. The second application was submitted by the Company to acquire an additional trade name, for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). This activity may accelerate the commercialization of the drug of the working name MabionCD20 in markets where RA is still covered by the patent protection for MabThera. Until the publication of this statement, the Company did not take the final decision regarding the submission of the second registration application.

[28] https://www.ema.europa.eu/en/medicines/human/EPAR/mabthera#authorisation-details-section

To sum up the research and development work on MabionCD20, in 2018 the following activities were successfully carried out:

» analytical runs were prepared to supplement the product quality data provided in the registration dossier;

» bioequivalence and biosimilarity studies were carried out;

» analytical methods for determining biological activity were developed;

» system documentation for the manufacture of medicinal products was developed and, after positive verification by GIF, an extension of the authorization for manufacture of medicinal products was obtained;

» an extension of the GLP certificate for the Company's laboratory at ul. Fabryczna 17 in Łódź was obtained;

» clinical trial databases have been closed on RA and NHL patients after an annual follow-up period;

» research results were obtained for secondary endpoints related to long-term follow-up of patients;

» work related to drawing up a clinical study report which forms an essential part of the registration documentation was carried out;

» registration documentation has been submitted to EMA.

With regard to the MabionMS innovative therapy project, the Company has so far reported the submission of two patent applications in this therapeutic area. On 5 December 2017, Mabion filed a European patent application with the Patent Office of the Republic of Poland, with a possibility of extending it under the PCT procedure, based on which Mabion seeks legal protection for its invention entitled "Combination Therapy of Multiple Sclerosis containing a CD20 Ligand". The subject of the patent application is an innovative therapy for the treatment of patients suffering from multiple sclerosis with the use of MabionCD20 antibody in a combination treatment with other substances (CR No. 56/2017 dated 5 December 2017). In order to avoid a situation where the Patent Office would abandon an attempt to double patent the same scope of protection (the so-called double patenting), in March 2019 the Company withdrew the originally filed European application in order to benefit from the protection granted on the basis of an international application (also covering the European area). This is a procedural step to optimise this process.

Within the scope of the above project, in 2018 the Company conducted preparations for the pre-clinical trial, including, among others, toxicological studies in laboratory animals.

On 26 October 2018, the Company filed another patent application with the Patent Office of the Republic of Poland, with a possibility of extension pursuant to the PCT procedure, from the area of application of MabionCD20 in the treatment of patients with MS, entitled "Low aggregate anti CD20 ligand formulation." This is the second patent application relating to the use of MabionCD20 in treatment of multiple sclerosis as an innovative indication for the molecule. The application concerns the use of MabionCD20 on a monotherapy basis (CR 59/2017 dated 26 October 2018). Currently, the Company is looking for partners for the purposes of further works in the field of the development of the above mentioned therapy.

On 5 December 2018, the Company submitted a notification to the European Patent Office in The Hague regarding the extension of patent protection as part of the PCT procedure for the invention called "Combination Therapy of Multiple Sclerosis containing a CD20 Ligand" (CR No. 61/2018 dated 5 December 2018).

In terms of the MabionEGFR project, the Company is in the process of developing technological grounds and analytical tools. Part of the expenditure related to the development of the medicine is co-financed from EU funds: a project entitled "Development of a biotechnological drug through the development of an innovative monoclonal antibody of IgG1 subclass with reduced content of unfavourable glycoformes in relation to the reference medicine - directed against EGFR"). The effect of the project will be

both a product in the form of an antibody with increased pharmacological parameters, as well as its manufacturing process, significantly different from those currently used by competitors. MabionEGFR will ultimately be able to become a Polish (with a global potential) equivalent medicine, in terms of therapeutic benefits, to Erbitux, but with an improved profile in terms of the presence of glycoformes in the product adverse for the patient. The antibody developed as part of the project will feature significant improvements over the original medicine in terms of safety profile, associated with a reduced number of immunogenic factors, while maintaining all the therapeutic advantages of the original medicine. The antibody safety profile will be increased by optimizing the cell host which will be used to express cetuximab antibody. The biopharmaceutical market will see the emergence of an antibody with the potential of a very attractive and valuable medicinal product with indications for the treatment of colorectal cancer and squamous cell carcinoma in the head and neck. In 2018, as a result of the work carried out under the project, the analytical and experimentally critical functions of the technology were confirmed.

In the reporting period, the Company continued its cooperation with Plexus Ventures LLC - an experienced advisor supporting the Company in the area of business development. Plexus carries out activities aimed at the acquisition of partners that can effectively sell medicines included in the above mentioned Mabion's pipeline. The process is complex and long-lasting – it involves contacting companies, signing confidentiality agreements and presenting data of various levels of detail, depending on the level of advancement of the process. Concurrently, the companies update their offers.

The current production capacity allows the Company to partially cover the estimated demand from customers from EU countries (the supply of the drug will cover the first sale). A necessary stage in the development of the Company is to reach adequate production capacity, which involves necessary investments. A necessary stage in the Company's development is retrofitting the existing production line in order to meet the potential demand from the EU countries.

Additional equipment for the existing plant

The capital expenditure project which constitutes the subject matter of permit No. 301 in the Łódź Special Economic Zone

consists in increasing the production capacity of the current plant and covers:

» additional equipment for the existing production line 2x2500 L; and

» purchase and installation of production equipment for the second production line 2x2500 L, which will be located in the existing building.

As part of permit No. 301, the Company shall incur investment expenditure in the Zone within the meaning of § 6 of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs based on a business permit in special economic zones, amounting to at least PLN million until 31 December 2019.

With regard to permit No. 301, as at 31 December 2018 the Company made an expenditure of PLN 2.8 million.

The investment project is planned to be completed until 31 December 2021.

Extension of the existing establishment

In 2017 the Company started preparation activities connected with expansion of the existing production facility (MABION II), with an aim to increase significantly the production as well as R&D capacity of the Company. A concept of the expansion of the Scientific-Industrial Complex for Medical Biotechnology was developed and work on the selection of an architectural design studio commenced, as well as administrative actions related to the need to obtain specific official permits.

In February 2018, the Company's Management Board chose an international consortium of architectural and technological companies and entrusted them with the development of the technological and construction project. During the selection of the contractor, in addition to commercial issues, offers were evaluated for tenderer's technological know-how potential, experience in the scope of administrative procedures as well as knowledge and references in the scope of architectural and building

projects. This is one of the first elements of the implementation of the complex MABION II investment which will be eventually implemented under a project or projects co-funded with EU funds, own contribution, as well as covered with another zone permit.

In July 2018, the first stage of the project to expand the existing plant, the conceptual and technological stage, was completed. From July 2018, work is underway on a construction project and executive projects for all industries related to the investment.

In September 2018, an application for a building permit was submitted.

On 14 November 2018, the Company received a decision of the Staroste of Pabianice, approving the works project and granting a building permit under the aforementioned investments of "The Science and Technology Centre for advanced medical biotechnology of Mabion SA" together with the necessary infrastructure in Konstantynów Łódzki. Receiving a building permit enables starting work on the extension of the existing plant, however, the moment of its commencement depends on the Company's financial situation (obtaining financing, cash flow, etc.), as well as formal opportunities to enter non-European markets (signed distribution agreements, formal approvals of regulators, etc.). In the future, the Company's investment plans may be extended in relation to the investment covered by the currently obtained permit.

Table 13. Planned expansion of the existing Mabion's plant - visualization.

4.3 Factors important for the development

Standards relating to studies

The research and development work of the Company is conducted according to quality standards. The medicines 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-Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki, at ul. gen. M. Langiewicza 60.

The analyses related to samples originating from the clinical trial is carried out 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 the top quality of the research and analyses conducted. Analyses in the scope of medicine quality parameters and clinical parameters provide unbiased, reliable results acceptable by medicine registration offices throughout the world. In February 2018, the Research and Development Centre in Łódź underwent another DPL audit successfully and the validity of its certificate was extended.

The plans for the clinical development were consulted several times with experts from the European Medicine Agency in London. Obtaining scientific advice and acceptance of the scientists from the European Medicine Agency for detailed clinical trial protocols reduces the risk of rejection of the registration application for the MabionCD20 medicine.

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

Information on collective experience and knowledge of 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:

» 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);

» 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 Maciej Wieczorek (Member of the Company's Supervisory Board, previously President of the Management Board and doctor of medical sciences of the Medical University in Łódź (Medical Biology);

» 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).

The company maintains close cooperation with the academic environment, implementing the provisions of cooperation agreements entered into with the Faculty of Biology and Environmental Protection of the University of Lodz and the Faculty of Biotechnology and Food Sciences at the Lodz University of Technology. In addition, it cooperates with universities in the implementation of student internships and mentoring programmes (Medical University of Lodz, Technical University of Lodz). Owing to such programmes, students can learn about the special nature of research projects, benefit from the exceptional experience of Mabion's specialists, and work on best-in-class professional laboratory equipment.

Cooperation with Higher Education Career Offices, in particular at the Lodz University of Technology and the Medical University of Lodz, as well as the Wrocław University of Technology gives the Company an opportunity to prepare a team of young specialists for cooperation as part of scientific and commercial projects run by the Company.

The company allocates significant funds for the participation of key employees in the most prestigious conferences and foreign trainings. It also supports their development by financing employee participation in post-graduate and doctoral studies. In summary, over 300 personal training sessions took place in the reporting period.

Table 14.Thematic areas of selected trainings

1.	Advanced European Regulatory Affairs
2.	Regulatory Affairs Strategies
3.	Lean manufacturing - management system
4.	The development of biological methods for the study of immunogenicity
5.	Filing Variations
6.	Filing Variations & Validation of Analytical Procedures
7.	Validation of Analytical Procedures
8.	EU vs FDA Regulatory Affairs & Validation of Analytical procedures
9.	EU vs FDA Regulatory Affairs
10.	Project management for Regulatory Affairs Professionals
11.	Documentation in the pharmaceutical quality system
12.	Project management IPMA NCB 3.0
13.	Bioprocess scale-up and technology transfer
14.	The Validation Manager in The Pharmaceutical Industry
15.	ISO 9001 +14001/18001 FOR AUDITORS
16.	Metabolite analysis methods using CuBiAn CuBiAnHT-270 system

4.4 Risk and threat factors

4.4.1 Significant risk and threat factors

Risk related to the macroeconomic, legal and political situation

Potential unfavourable changes in the macroeconomic, legal or political environment on the markets where the Company is planning to sell its medicines, for example the slowdown in the rate of economic growth or reduced healthcare expenditure, may have a negative impact on the Company's operations and financial results. Significant economic factors that have impact on the results achieved by our Company include the level of GDP, average wages, unemployment level, inflation level, volume of healthcare expenditure.

The Management Board monitors the macroeconomic, legal and political situation on an ongoing basis, trying to adapt the Company's strategy to changes in these areas sufficiently in advance.

Risk of force majeure

In the event of unpredictable events such as war or terrorist attacks, adverse changes may occur in the economic situation and on the financial market, which may adversely affect the financial position of the Company. In addition, such random events as: fires, floods and other extraordinary action of forces of nature, may cause damage or destruction of material tangible property belonging to Mabion SA, as well as disruptions in business, which may negatively affect the financial results achieved by the Company.

Risk related to operations carried out on an international scale

Operations on an international scale involve a number of risks, including:

- multiple, conflicting and changing laws and regulations, including those relating to privacy, tax, export and import restrictions, labour law, regulatory requirements and other administrative consents, permits and licences;
- failure to obtain or to keep by co-operating entities the regulatory permits for use of the Company's products in various countries;
- additional potentially significant patent rights of third parties;
- complex and difficult aspects of obtaining protection and pursuing intellectual property rights;
- difficulties in filling positions and management of foreign operations by the Company or by entities cooperating with the Company;
- complex aspects related to the management of multiple reimbursement systems, public payers or patient payment systems by cooperating entities;
- limitations of Company's capabilities and the possibilities of cooperating entities in the scope of entering international markets;
- financial risks such as long payment cycles, debt collection difficulties, the impact of local and regional financial crises on demand and payment for products, as well as exposure to the risk of exchange rate fluctuations;
- natural disasters, political and economic instability, including war, terrorism, civil unrest, outbreak of disease, boycotts,
- restriction of freedom of trade and other business constraints;
- certain expenses, including travel, translation and insurance expenses;
- regulatory and compliance risks that relate to reliable information and control over sales and operations.

The Management Board monitors the situation on target markets on an ongoing basis, trying to adapt the Company's strategy to changes in the areas described above sufficiently in advance.

Risk related to changes in legal regulations and their interpretation

Frequent regulatory changes that are typical of the Polish legal system may expose the Company to a risk that its business forecasts will become obsolete and its financial condition will deteriorate or even totally collapse. Regulatory changes that have the greatest impact on the Company operations are those related to pharmaceutical, tax and intellectual property law. Amendments to the above regulations may significantly reshape the Company's legal environment and thus alter its financial results. Also discrepancies in interpretation of the legal order prevailing in Poland and in the EU constitute a material factor which may have impact on the development prospects, results achieved and the financial position of the Company. Disparity in legal interpretations by national courts and public agencies and Community courts can have both direct and indirect consequences for the Company.

The Management Board constantly monitors changes in laws and interpretations that are of key importance for the Company in an effort to proactively adapt the Company strategy to such developments.

Risk related to the tax policy

One of the main elements that influence the entrepreneurs' decisions is Polish tax law: frequently changed, imprecise and more often than not suffering from the lack of uniform interpretations. Indeed, practices of fiscal authorities and court decisions on tax issues are all based on vague legal regulations, which translates into an increased business risk in Poland compared to the more stable tax systems in the countries with mature economies. However, tax regulations are gradually harmonised so as to ensure their unequivocal interpretation by enterprises and tax authorities alike.

Risk related to administrative decisions

The Company is unable to ensure that it will obtain particular permits, licences and consents required to complete biotechnological or construction projects, or that no current or future permits, licences and consents will be revoked. A negative development of the state of affairs may either delay the original projects or necessitate their change and so have an adverse impact on the Company business and financial performance.

Exchange rate risk

The Company purchases laboratory equipment and reagents for its research work mainly in foreign currencies (predominantly EUR and USD). Unfavourable changes in exchange rates (weakening of PLN in relation to foreign currencies) may adversely affect the Company's investment expenditure and increase its R&D spending, which in turn may result in a poorer financial performance. Given that Mabion S.A. intends to sell its medicines in foreign markets (with sales transactions denominated mainly in EUR and USD), the future risk associated with exchange rate fluctuations will be limited.

Market risk

The Company's primary objective is the development, manufacturing and marketing of biosimilars, i.e. biological medicines that are developed to be similar to the original biotech drugs (known as reference medicines). The biotech drug market is very attractive these days, and in the coming years its value should increase even more significantly. However, there is a risk that if reference medicines are withdrawn from the market or replaced with newer generation drugs, the Company's potential revenue on its in-house developed biosimilars will be lower than originally assumed, or that its products will not find buyers at all.

The Management Board monitors the reference medicine market on an ongoing basis and is prepared to undertake work on other biosimilars in order to mitigate this risk. In addition, the Company actively develops innovative therapies.

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

Oncological diseases on which the ongoing R&D efforts are focused are the most intensively studied group of diseases in biomedical sciences. It is estimated that approx. 30% of investment on research and development in biomedical companies is in the oncology domain. In addition, we witness a rapid development in the field of genetics and molecular biology. Therefore, it is likely that within a few years the market will see some innovative medicines with better efficacy or tolerability parameters compared to drugs that are currently developed by the Company. In addition, there is a risk that other treatments will be invented, such as vaccines that would be used against the same diseases that are now treated with reference medicines for the Company's future drugs.

The emergence of new medicines and therapies could adversely affect the Company future sales revenue and profit. The Management Board constantly monitors the progress of scientific research on new therapies and medicines for the diseases at which the Company drugs are to be targeted. Furthermore, most of the oncological regimens use the sequencing of treatment (in which a new medicine with a different mechanism of action is only introduced when the potential of the first drug is depleted) and polytherapies (a concomitant use of several drugs with different mechanisms of action), which significantly reduces the risk of erosion of the medicines applied in cancer therapies.

Risk relating to competition

Medicines that the Company is developing are biosimilars of the original reference medicines that are protected by patents with a commonly known validity periods. From publicly available information it may be easily inferred that at the moment there are many entities that develop biosimilars related to the same original drugs, and works on some of them are already at a very advanced stage.

Until the date of publication of this report, two companies - Celltrion and Sandoz, have introduced biosimilars to MabThera/Rituxan on the European market. According to previously reported information, this did not affect the activities of Mabion, which in June 2018, after completing the clinical trials, started the registration procedure for MabionCD20 in the EMA. Even if the commercialization of a medicine biosimilar to MabThera/Rituxan is successful for several entities, as the analysis shows, this market has a growth potential.

It should be remembered that despite the high sales of Roche's original medicine, many patients do not currently have access to this therapy. In many countries, treatment with MabThera/Rituxan for NHL patients is not reimbursed by the public health system, and for patients with RA, access is even more limited.

The biosimilars market is a market with high entry barriers. They comprise, among other things, high requirements

relating to clinical trials, especially in the US and other developed markets, in order to prove that the drug is biosimilar to the original medicine. This is confirmed by the fact that in November 2018, Sandoz resigned from applying for admission to trading in the US of its drug biosimilar to MabThera/Rituxan , after the regulator applied for additional data[29]. As of the date of publication of this report, only Celltrion has obtained the consent from the FDA to introduce its biosimilar rituximab to the US market (November 2018)[30].

Risk related to the research and development process

The biotechnology industry, especially the production of modern biosimilars, is characterised by high labour intensity and the need to incur significant expenditure on research and development. Not only the possibility of launching the developed medicines 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. The Company uses most of the funds so far obtained for research and development.

There is a risk that some of or all of the Company's research objectives will not be achieved to the full extent planned or within the scheduled time, and so it will be unable to recover some or all of the research outlays. This can have a significant negative impact on the feasibility of the Company's strategic plans and thus its financial performance.

Outcomes of R&D to date confirm that the Company is able to manufacture its own biosimilars and, in the Management Board's opinion, significantly reduce the risk of not achieving ultimate success. In addition, the Management Board constantly monitors the progress of research and development, and implements some operational and procedural solutions to ensure a high efficiency of the process.

Risk of underestimating the costs of MabionCD20 manufacture and launch

According to assumptions very generally adopted by the biotechnological industry, the development and production of a single biosimilar which meets global standards lasts about 10 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.

[29] http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681
[30] https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm627035.htm

Therefore, the exact scope of research and development work cannot be determined and the development costs of the medicines cannot be precisely anticipated.

It cannot be precluded that the actual costs of production and launching of the developed medicines (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 medicines 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 medicine development and launch, which applies also to MabionCD20:

» amendments to the regulations concerning the production of medicines and the need to use more expensive technological solutions or creating entirely new ones;

» increase in the costs of purchase of raw materials and materials used to manufacture medicines, 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 requirements concerning registration documentation, e.g. the need to perform additional trials or studies.

In order to prevent the above risk, the Company implements the policy of developing its own research and development competences, investing in its own production capacities and carrying out ongoing consultations with regulators. In the Company's opinion, this enables a significant reduction in the cost of medicine development in relation to industry assumptions.

Risk related to the work schedule

The achievement of the Company's strategic goal, which is the registration and market launch of biosimilars as soon as possible after the expiry of patent protection of the original medicines, is connected with the need to develop a detailed work schedule for several years. The possibility of pursuing this schedule depends on 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 medicines and if necessary implements the required operating solutions to minimize the impact of unexpected events on adopted time schedules.

In 2017, the company initiated the research and development process for MabionCD20, which is a medicine directly competing with the existing market drug MabThera/Rituxan from Roche. The basic patent protection in Europe for this drug expired in the period: end of 2013 – before the end of 2014, while in the United States of America, it expired in July 2018[31].

The Company's goal is to market MabionCD20 as soon as possible after patent expiration, which would allow the Company to achieve a temporarily favorable competitive position. Any delays in the MabionCD20 registration procedure may result in the medicine being marketed later than it results from the current assumptions of the Company.

In order to prevent registration risks, the Company, since the start of work on the development of MabionCD20, has cooperated with EMA regarding compliance with guidelines and procedures related to the registration process in the European Union. It carried out numerous scientific consultations which were aimed at eliminating doubts and refining activities related to the preparation of registration documentation.

[31] Global Data

The company has also commenced a consultative process with FDA, the purpose of which is to determine and perform activities consistent with the FDA's expectations and necessary for the registration of MabionCD20 in the United States.

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 medicine production on a larger scale is very important for the process of developing and producing biotechnological medicines. 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 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. In addition, the original deposit of the biological material used by the Company for the production of medicines is stored in an independent storing place outside Poland so as to be able to continue its production in any other external facility in case of any unexpected events.

The Company also monitors the workflow of the production process and the quality of the manufactured products, introducing necessary organizational, personnel, and technological changes in the framework of improving the quality management processes.

Risk related to the production process

One of the key elements in the production of biotechnological medicines is the production process, which must be carried out in compliance with the previously planned parameters. The process of producing such medicines consists of several stages and even the smallest change in any of them may negatively affect the properties of the drug (e.g. in terms of efficacy or safety). An extremely important element of the medicine manufacturing process is the transition from a small laboratory scale to the scale of industrial production (so-called up-scaling). It is very important to ensure continuity, stability and purity of the entire production process. The Company'slaboratories are equipped with state-of-the-art equipment that ensures maximum accuracy and repeatability of the obtained results. The materials used in the production zone have appropriate certificates for use in the pharmaceutical industry. The installed production line is based on sterile materials. The managing staff of the Company's departments are high-ranking specialists with a major education background, trained and properly prepared to carry out their scope of duties, both by internal and external experts.

The Company's production also depends on key suppliers. In the case of disposable technology, the Company depends on specialist solutions (disposable bags) and this may have an impact on production. In addition, the quality of the bags may vary and in some cases may affect the product, which will make it unsuitable. The Company is also dependent on timely deliveries and the quality of all raw materials essential for the effective production of products.

Even if the Company is able to successfully produce commercial quantities at our plant, it cannot guarantee that it will not face challenges in terms of guaranteeing a stable supply to global markets in the future.

Any unfavourable events having a negative impact on the Company's production activities could significantly increase costs and reduce the supply of the Company's products.

Even small deviations from the normal production process could lead to reduced productivity, product defects and other supply disruptions. If microbial, viral or other contamination is detected in the Company's products or production plant, the plant may have to be closed for a longer period of time to investigate and handle the contamination.

Any adverse event affecting the Company's product manufacturing operations may lead to shipping delays, lack of stock, batch failures, recalls or other interruptions in the supply of products. The Company may also be forced to make inventory write-

downs and incur other fees and costs due to products not meeting the specification, costly repair work or looking for more expensive production alternatives.

The production process is monitored on a continuous basis and verified in accordance with the procedures adopted at the company, owing to which the Company systematically seeks to reduce the level of risk in this area. The company meets the requirements of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP), holds the necessary approvals and permits (including a GMP Certificate for the Complex in Konstantynów Łódzki, issued by the Main Pharmaceutical Inspector).

Risk related to a possible failure in reaching capacity/demand balance

Currently, it is difficult to estimate the precise demand for Mabion CD20, but the plans to sell the medicine on the US market and other markets are connected with the need to increase production capacity above the level possible at the present plant in Konstantynów Łódzki.

The company is aware of these needs and it took care of the possibility of erecting another building in the same location, on the same plot. This building can be used to a greater extent for the production process (the current building also has an office part).

The final date and scope of such an investment will depend on arrangements with distribution partners regarding the planned delivery of MabionCD2.

The company will implement the investment based on its own experience arising during the construction and operation of the plant in Konstantynów Łódzki, as well as cooperating with outstanding external experts. In order to eliminate the risk related to possible delays in the construction schedule, and to ensure its compliance with expectations and needs, the Company has an Investment and Qualifications Department, composed of experienced specialists in this field.

Risk related to the approvals for the laboratory and the manufacturing plant

Maintaining appropriate conditions on the premises where work is conducted on the Company's products is extremely important. Currently, Mabion is in possession of all required approvals for equipment and for laboratory and manufacturing areas in both plants.

We managed to eliminate the risk of failure to obtain or delay in obtaining pharmaceutical of the Scientific and Industrial Complex in Konstantynów Łódzki acceptance by the Main Pharmaceutical Inspectorate. Nevertheless, due to the number of stakeholders (diverse supply and service channels, human factor, etc.), the Management Board of the Company cannot guarantee that these approvals will be maintained in the future.

Risk related to clinical trials

One important preparation stage related to the registration and marketing of medicines are clinical trials involving human subjects. Clinical trials are associated with the risk of insufficient efficacy or safety of the investigational medicinal product. This risk applies to current and any subsequent trials that will be carried out by the Company.

In order to prevent this risk, the Company consults its clinical trials both with the regulator and advisory entities.

Risk related to drug registration

The primary objective of the Company is the introduction of the developed biosimilars to global markets, primarily the EU and U.S. markets, which involves the obligation to register such drugs with the EMA and Food and the FDA, respectively. The drug development and implementation efforts completed by Mabion S.A. may be considered inconsistent with the EMA/FDA guidelines/standards.

There is a risk that in the case of, for example, procedural changes or errors, or gaps in the Company's documentation, the process of registering the medicine within the European Union may not take place on the planned date or registration will not be possible. In addition, there is a risk that subsequent regulations adopted by the FDA will be more restrictive in relation to the EMA guidelines or differ from them. In this case, the Company would be exposed to the need of incurring additional costs or ceasing activity on the US market altogether, which could have a negative impact on the financial results generated by the Company.

Since the beginning of work on the development of its biosimilar medicines, Mabion has been cooperating with EMA in respect of compliance with all guidelines and procedures related to the registration process on the territory of the European Union. In June 2018, the Company presented the collected data on the development of MabionCD20 in relation to MabThera the FDA. The Agency allowed the use of data held by the Company as supporting the application process. At the same time, the FDA proposed a general strategy for linking a product registered in the European Union (MabThera) with a product admitted for sale in the US (Rituxan), without indicating the need for a completely separate MabionCD20 development process for the US market.

However, there is a risk of erroneous interpretation of guidelines or failure, in the opinion of authorities, to comply with the guidelines, as well as the risk of interpretation of the Company's activities as insufficient to register the medicine in the light of the guidelines, carried out by experts employed at the Agencies.

Risk related to launching and maintaining medicines on the market

After registering the medicines, the Company is planning to launch them on the market as quickly as possible, which requires their preparation to the market product status (production, marketing, distribution and sales) and involves some substantial outlays and organizational preparedness. As the product is unique and the target markets of Mabion are diverse, the Management Board plans to implement a multi-faceted strategy for the promotion and distribution of its medicines.

According to the adopted assumptions, marketing and distribution of medicines in Poland and selected countries of Central and Eastern Europe will be carried out independently by the Company. In other European countries and other countries of the world, marketing and distribution activities will be carried out by global and local partners.

There is a risk that launching Company's medicines 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 medicines will prove to be unsellable on a given market which could have a negative impact on the sales revenue earned by the Company and on its financial results.

Mabion has acquired a distribution partner for the EU and the Balkans and is currently, through the intermediation of Plexus Ventures LLC, actively looking for an experienced and strong partner to effectively sell Mabion S.A. medicines on markets outside the European Union. The process is complex and long-lasting – it consists in 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 stake 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 drug reimbursement

Costs associated with the development and production of the latest generation biosimilars are very high, which translates into a correspondingly high selling price afterwards. On the pharmaceutical market we have medicines the sale of which is reimbursed from the state budget or by other non-budgetary payers. It is the intention of the Management Board to ensure the reimbursement for Mabion's products in as many countries as possible – wherever its medicines will obtain marketing authorisations. There is a risk that if this objective is not achieved or is only partially achieved and at the same time the reference

medicines or their biosimilars manufactured by the competitors are covered by the reimbursement mechanism, the demand for Mabion S.A. preparations will be smaller than expected and so the Company's sales revenue and financial performance may be negatively affected.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of Mabion's products will depend in part on the medical community, patients and third-party payers accepting our product candidates as medically useful, cost-effective and safe. Any product that the Company brings to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. The risk in this respect may have a negative impact on the level of sales revenues and financial results achieved by the Company.

Even if a Company's product displays an equivalent or more favourable efficacy and safety profile in preclinical and clinical trials, market acceptance of the product will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar products. If market acceptance of MabionCD20 is lower than that of MabThera or competing biosimilars, the price of MabionCD20 may need to be reduced or the Company may need to implement additional marketing endeavours in order to accrue market share, which will negatively affect Mabion's profitability. The Company's efforts to educate the medical community and third-party payers on the benefits of the Company's products may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If the Company's products are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payers and others in the medical community, Mabion will not be able to generate sufficient revenue to become or remain profitable.

The Company anticipates that its commercialization, sales and marketing strategy will include the distribution of future therapeutic products to hospitals and other public healthcare institutions that make bulk purchases of medicines selected through a public tender process. During the tender process, hospitals will establish a committee of recognized pharmaceutical experts, which assesses bids submitted by pharmaceutical suppliers. Winning bids result in contracts with hospitals for the procurement of medicines. The interest of a hospital in a medicine is determined by the inclusion of this medicine on the hospital's formulary, which establishes the scope of drugs physicians at a hospital may prescribe to their patients, and the willingness of physicians at a hospital to prescribe a certain drug to their patients. The Company believes that effective marketing efforts are critical to making and keeping hospitals interested in purchasing the Company's products. As a tenderer, the Company will be obligated to provide detailed specifications and accurate quotes regarding its products, which will be compared to other suppliers. Any large or expensive tender is likely to attract a majority of the Company's competitors. A competitive bidding process may result in competitors reducing the price of their products to a level that the Company cannot compete with. If competitors are able to offer lower prices, Mabion's ability to win tender bids will be materially harmed. This may result in loss of market share and could reduce Mabion's total revenue or decrease its profitability.

Risk of withdrawal of marketing authorisations or manufacturing certificates for the Company products and the risk of product liability

Any regulatory approvals that the Company or its collaboration partners receive may be subject to limitations regarding the approved indicated uses for which the product may be marketed or to the conditions of approval, or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product. The Company will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to ensure compliance.

The Company's collaboration partners will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, the Company's collaboration partners are not allowed to promote Mabion products for indications or uses for which they have not been approved. The Company could also be required to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing authorisation is obtained via an accelerated biosimilar approval

pathway, the Company could be required to conduct a successful post-marketing clinical study to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing authorisation.

If a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities, or disagrees with the promotion, marketing or labelling of a product, such regulatory agency may impose restrictions on that product, the Company's collaboration partners or the Company, including the requirement to withdraw the product from the market.

If the Company receives marketing authorisation, regulatory agencies including the FDA, EMA and other foreign regulatory agency regulations require that it reports certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of the Company's obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. The Company may fail to report adverse events it becomes aware of within the prescribed timeframe. The Company may also fail to recognise that it has become aware of a reportable adverse event, especially if it is not reported to it as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the Company's products. If the Company fails to comply with its reporting obligations, the FDA, EMA or other foreign regulatory agencies could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

If product liability lawsuits are brought against the Company, it may incur substantial liabilities and may be required to limit commercialisation of its current or future products, and the Company's existing insurance coverage may not be sufficient to satisfy any liability that may arise.

Under Polish law, the Minister of Health withdraws a marketing authorisation for a medicinal product in case of a sudden, severe and adverse reaction to the product that is threatening to human life or health, in case of lack of a declared therapeutic efficacy, an inadequate therapeutic effect compared to the risk involved, or finding that the medicinal product is marketed in violation of the authorisation or law. The withdrawal of authorisation for Mabion S.A. medicinal products would have a significant unfavourable impact on the Company's development perspectives and on the financial results achieved.

Notwithstanding the foregoing, in certain circumstances (for instance, whenever a justified suspicion occurs that medicinal products do not comply with the applicable requirements), the voivodship pharmaceutical inspector issues a decision to cease the marketing of certain batches of the product within the area of the inspector's authority.

If this is the case, as well as in other situations where the use of the Company's medicinal products could be harmful to specific entities, Mabion may be liable for damages, which is associated with the risk that relevant claims will be lodged in civil proceedings. The Company may also be held liable if its medicinal products turn out to be hazardous. For example, according to Polish law, a hazardous product is any product that does not offer the safety which can be reasonably expected during its normal use. Whether the product is considered safe depends on the circumstances at the time of its marketing, especially the way in which it is presented on the market, as well as consumer information on the product characteristics. If any claims for damages are lodged against the Company in connection with the above, this could also have a material adverse effect on its business and financial condition.

Risk of losing of key employees

Mabion's business is based on the knowledge and experience of its highly skilled managers and scientific and research personnel.

However, there is a risk that key employees may leave the Company in the future, which could adversely affect the quality of its products. The Company may also be unable to attract or retain qualified personnel due to strong competition for such personnel among biotechnology, pharmaceutical and other companies. If the Company is unable to attract, retain and motivate the necessary staff to achieve its business objectives, it may face constraints that will make it significantly more difficult to achieve its growth objectives, as well as limit its ability to raise capital and pursue the Company's business strategy.

The Company's future performance will also depend, in part, on its ability to successfully integrate newly hired executive officers into its management team and the Company's ability to develop an effective working relationship among senior management. If it is not possible to integrate these people and establish good employee relations between them and other members of management, this may have a negative impact on the Company's performance.

In order to counteract the above risk, the Company's Management Board pursues an active HR policy aimed at retaining the most valuable specialists in the company and supporting their development. The success of the Company depends, among other things, on the continuous ability to attract, maintain and motivate highly qualified management and scientific staff. Since September 2017, the Mabion team has been using support in the area of human resources development. With the help of an employee development specialist, professional development projects for all employees are carried out. The Company's employees can also count on the possibility of comprehensive professional development ("Mabion Academy" Project), including participation in internal and external training, support in undertaking doctoral studies, as well as the promotion procedure - the rules of obtaining the above mentioned benefits are formalized, open and objective (e.g. promotion procedures, implementation of bonus programmes for employees with long work experience, implementation of loyalty programmes and bonus programmes).

Risk related to disclosure of trade secrets

The actual implementation of the Company's plans may depend on the confidentiality of the Company's confidential information, in particular on research and technological processes. It cannot be ruled out that such information will be disclosed and used by Company business partners or, in particular, its employees, and so it will become available to and used by competitors. If this is the case, the remedies, defences and claims of the Company may prove to be inadequate to protect it against negative consequences of the disclosure.

The Company has taken a number of legal steps to eliminate this risk.

Risks related to patent protection

The company is aware that it is entering to a very competitive pharmaceutical market. Successful competitors on the pharmaceutical market have demonstrated the ability to successfully discover, patent, develop, test and obtain approvals of regulators for products, and to effectively commercialise, market and promote the approved products. Numerous companies, universities and research institutions are involved in the development, patenting, manufacturing and marketing of products that may compete with the Company's products.

The Company's objective is to effectively secure its intellectual and industrial property by providing the widest possible patent protection for the inventions made in the Company. However, it cannot be ruled out that there is a risk that patent offices will undermine the legitimacy of patent protection in applied for by the Company, and the arguments presented by the Company will be insufficient to grant this protection.

In order to prevent this and other risks associated with the granting of patent protection, the Company's Management Board cooperates with professional advisors and experts in the field in question.

Risk related to industrial and intellectual property disputes

The Company operates in the area where industrial and intellectual property rights and their protection are issues of key importance. There are no pending proceedings regarding infringement of intellectual and industrial property. Also, the Company intends to operate in such a way so as to avoid any infringements of such third party rights. However, It cannot be ruled out that third party claims for infringement of the industrial and intellectual property rights are brought against the Company, especially at the research stage and when the Company is trying to obtain marketing authorisations for its medicinal products. Such claims, even if they prove unfounded, may adversely affect the time required to obtain the said authorisation, and the defence against such claims may require considerable spending, which in turn could negatively affect the Company's financial performance.

Risk related to the funding obtained

In the reporting period, Mabion was a party to the following funding agreements in connection with its R&D and implementation projects:

» " Development and scaling of the innovative process for manufacturing the therapeutic recombined monoclonal antibody to enable the industrial implementation of the first Polish biotechnological medicine for oncological and autoimmune therapies ".
  – Value of the project: PLN 54,188,035.17
  – Value of co-financing (contribution from the EU Funds): PLN 27,094,017.84
  – Project implementation period: 01.11.2016 - 31.12.2019.

» " Development of a biotechnological medicine through the development of an innovative monoclonal IgG1 subclass antibody with reduced content of unfavourable glycoforms compared with the reference medicine – targeted against EGFR."
  – Value of the project: PLN 39,965,267.64
  – Value of co-financing (contribution from the EU Funds): PLN 28,354,422.06
  – Project implementation period: 01.08.2017 - 30.07.2022.

» " The clinical development and registration of a humanized monoclonal antibody that binds to HER2 receptor, used in breast cancer treatment."
  – Value of the project: PLN 23,949,430
  – Value of co-financing (contribution from the EU Funds): PLN 10,000,000
  – Project implementation period: 01.06.2014 - 31.05.2019.

On 15 November 2017, the Management Board of Mabion decided to complete the aforementioned project at its current stage of development. The Company's decision resulted from the high scientific risk related to the implementation of research on a Herceptin biosimilar and was made after analysis of the competitive environment. So far, the Company has used the funds of PLN 177 thousand from the received co-financing. As at the date of publication of this report, the Company has not received a final assessment of the submitted final project report from the NCRD.

» *"Expansion of the Research and Development Centre of Mabion S.A. - research on the new generation of medicines'*.
  – Value of the project: PLN 172,876,340.70
  – Value of eligible costs: PLN 140,549,870.50
  – Value of ERDF co-financing: 63,247,441.60
  – Project implementation period: 20.01.2018 – 31.12.2021

The agreements made stipulate in detail the dates and scope of tasks which may be subsidized.

With reference to the project entitled "Development and scaling up of an innovative therapeutic manufacturing process, recombinant monoclonal antibody...", on 28 September 2018, the Company submitted an application to extend the first stage of the project (from the planned 31 October 2018 to 31 October 2019). The application was related to the need to adapt to the guidelines of the regulator and to the duration of experiments in the course (additional analytical series). The Intermediate Body – the National Centre for Research and Development (NCBR) agreed to extending this stage of work on 19 December 2018.

As part the project entitled "Development of a biotechnological drug through the development of an innovative monoclonal antibody of IgG1 subclass...", there was also a need to adapt the material progress schedule to the ongoing research work. The Company applied for an extension of the first stage of project implementation on 21 December 2018 (from the planned 31 December 2018 to 31 October 2019). As at the date of publication of this report, the NCRD has not issued a decision on this issue.

There is a risk that if the Company fails to carry out the assumed work in the timeframes set by the Intermediate Body, uses all or part of the co-financing improperly or without following the applicable procedures, collects all or part of the co-financing unduly or in an excessive amount, it will be obliged to return part or the full amount of the grant plus interest. There is also a risk that the Intermediate Body does not grant consent in the event of further problems related to substantive or financial progress, which may be related to the termination of co-financing agreement(s) and the necessity to return the funds collected together with interest.

As a result, if the conditions giving rise to the liability are met, the Company's financial position may deteriorate significantly, which in the long run may jeopardise the achievement of the Company's strategic objectives.

In order to counteract the above risk, the Company has put in place internal procedures for the ongoing monitoring of project expenditures – the spending methods used and the schedule of spending implementation, as well as closely cooperates with intermediary institutions, informing on the ongoing basis on any possible risks.

Liquidity risk

At the moment, the Company does not earn any revenue from sales of market products, and its activities to date have been financed with funds obtained from the share issue, public funding and, to some extent, proceeds from distribution partners and the sale of R&D services. The Management Board obtains funds to finance the Company's ongoing operations from credits and loans.

The issue of series P shares adopted by the Extraordinary General Meeting on 18 April 2018 made it possible to obtain significant funds to cover the costs of further operations of the Company. Moreover, pursuant to the terms of the agreement with Mylan, on 27 August 2018 the Company received a payment of USD 5 million for reaching the milestone specified in the mutual cooperation agreement in the form of acceptance by the EMA of registration documents for a drug with the working name MabionCD20.

Mabion is expected to receive further payments from Mylan for the remaining stages of the agreement, that is issuing a positive opinion by EMA for MabionCD20 medicine and launching MabionCD20 on key EU markets, as well as royalties dependent on the net revenue from sales of the medicine per annum. Any delays in meeting the schedule may delay Mabion's receipt of subsequent payment tranches from the distributor.

Failure to apply for new EU aid funds may also expose Mabion to problems related to financial liquidity and the need to obtain an alternative source of financing.

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-Industrial Complex in the Łódź Special Economic Zone (ŁSEZ). In accordance with the Act on Special Economic Zones,

the income earned on business activities in a 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 of changes in law provisions concerning the operation of special economic zones or in tax advantages applicable in those zones. There is also a risk that the Company will cease meeting the conditions specified in the permit which entitles it to avail itself of these advantages. Upon the expiry of the permit or if the Company loses the permit before its expiry Mabion's further operations in the ŁSEZ may become unfavourable and increase tax burden.

4.5 Risk management system

The Management Board of the Company 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 an ongoing basis, through:

- 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 a potential risk occurrence;
- maintaining risk within predetermined limits or implementing plans to minimize the risks;
- reporting on the risks identified and their nature.

5 CORPORATE GOVERNANCE STATEMENT

5.1 The set of corporate principles applied

In 2018, the Company was governed by corporate governance principles specified in the document "Best Practices for GPW Listed Companies 2016" adopted by the Board of the GPW 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 GPW Main Market, at the address: https://www.gpw.pl/dobre-praktyki).

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 not applied

In 2018, the Company did not apply two DPSN 2016 recommendations: VI.R.1., VI.R.2.

In 2018, 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 2018, three recommendations did not apply to the Company: I.R.2., IV.R.2., IV.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 not applied or not applicable:

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 has no separate sponsorship, charity or other similar policies. The Company may engage to a limited extent in thematic biotechnology conferences as a partner or sponsor after having analysed the compliance with the adopted communication strategy and the adequacy of the costs incurred. In 2018, the Company participated in one conference as a partner of the event.

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 website is available in English in the vast majority of the scope indicated in principle I.Z.1. At the same time, the Company makes every effort to make the website available in English to the widest extent possible.

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 in the Company's structure. Therefore, currently there is no person responsible for managing those areas, reporting directly to the President or another Management Board Member and also provided with the possibility of reporting directly 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 there is no one managing 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 its own assessment of the efficiency of the systems and functions referred to in principle III.Z.1 and submits 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 structure of shareholders, the Company does not enable its 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 structure of shareholders, the Company does not enable the shareholders to participate in publicly available 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 rules of conduct where a conflict of interest has arisen or may arise, apart from indicating in the Supervisory Board Rules of Procedure the obligation of a member

of the Supervisory Board to inform other members of the Supervisory Board and to refrain 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 remuneration policy, and remuneration of particular Members of the Management Board is 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 any 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.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 incentive scheme for Members of the Management Board of the Company and its key employees does not make the right to take up and exercise the rights from A and B series subscription warrants dependent on the parameters indicated in principle VI.Z.1. The rights to take up subscription warrants may be granted to eligible persons, i.e. persons of key importance for the Company indicated by the Supervisory Board, in the quantity indicated in a resolution of the Supervisory Board. The right to take up and exercise the rights attached to A series subscription warrants shall arise on condition that, among other things, the market objective of increasing the Company's share price on the Warsaw Stock Exchange is achieved, and for B series subscription warrants – regardless of whether the above objective is achieved.

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: In 2018, no instruments linked to the Company's shares in respect of which the period between their awarding and the possibility of exercising would be shorter than indicated in principle VI.Z.2 were awarded as part of the Incentive Scheme.

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

6.1 The Company's share capital

As at 31 December 2018 and as at the date of approval of this report, the Company's share capital amounts to PLN 1,372,077.20 and is divided into 13,720,772 shares with a nominal value of PLN 0.10 each, including

- 450,000 A-series registered preferred shares;
- 450,000 B-series registered preferred shares;
- 450,000 C-series registered preferred shares;
- 450,000 D-series ordinary bearer shares;
- 100,000 E-series registered preferred shares;
- 100,000 F-series registered preferred shares;
- 20,000 G-series registered preferred shares;
- 2,980,000 H-series ordinary bearer shares;
- 1,900,000 I-series ordinary bearer shares;
- 2,600,000 J-series ordinary bearer shares;
- 790,000 K-series ordinary bearer shares;
- 510,000 L-series ordinary bearer shares;
- 360,000 M-series ordinary bearer shares;
- 340,000 N-series ordinary bearer shares;
- 300,000 O-series ordinary bearer shares.
- 1,405,999 ordinary bearer shares and 514,773 registered ordinary shares, of series P.

The registered shares of A, B, C, E, F and G series are privileged in such a way that each of them entitles to two votes at the General Meeting. The total number of votes resulting from all issued shares amounts to 15,290,772 votes.

On 13 March 2018, Krajowy Depozyt Papierów Wartościowych S.A.("KDPW") made a conditional registration in the securities depository under the code ISIN PLMBION00016 of 340,000 ordinary bearer shares of N series of the Company and 300,000 ordinary bearer shares of O series of the Company, with a nominal value of PLN 0.10 each. The condition for registration of the above mentioned shares was their introduction to trading on a regulated market, which in accordance with the resolution of 14 March 2018 of the Management Board of the Warsaw Stock Exchange (WSE) concerning the admission and the introduction of the above mentioned shares to exchange trading on the WSE Main Market took place on 19 March 2018. In accordance with the KDPW's operational announcement of 15 March 2018, the above shares were registered in the depository for securities on 19 March 2018.

On 30 April 2018, the District Court for Łódź-Śródmieście in Łódź, 20th Division of the National Court Register, registered an increase in the Company's share capital. The Company's share capital was increased from PLN 1,180,000.00 to PLN 1,372,077.20 as a result of issuing 1,920,772 P series ordinary bearer shares with a nominal value of PLN 0.10 each. After the registration of the share capital increase, the total number of votes resulting from all issued shares amounts to 15,290,772 votes.

On 18 May 2018, the Management Board of the Company, in connection with a motion filed by a shareholder, Twiti Investments Limited, pursuant to Article 334.2 of the Commercial Companies Code, adopted a resolution to convert, in accordance with the submitted motion, 514,773 P series ordinary bearer shares into P series ordinary registered series and to issue a collective share certificate representing 514,773 ordinary registered shares and deposit the collective share certificate with the Company. The shares subject to conversion constitute 3.75% of the share capital and 3.37% of the total number of votes in the Company. The remaining 1,405,999 P series shares remain ordinary bearer shares.

On 8 June 2018, KDPW conditionally registered 1,405,999 P series ordinary bearer shares with a nominal value of PLN 0.10 each in the depository for securities. The registration of the above mentioned shares was conditional on their introduction to trading on a regulated market, which, in accordance with the resolution of the WSE Management Board of 8 June 2018 concerning the admission and introduction of the above mentioned shares to exchange trading on the WSE Main Market, took place on 12 June 2018. In accordance with the KDPW's operational announcement of 11 June 2018, the above shares were registered in the depository for securities on 12 June 2018.

On 2 April 2019 (an event after the balance-sheet date), the Management Board of the Company, based on a request of Twiti Investments Limited submitted pursuant to Article 334 § 2 of the Code of Commercial Companies and Partnerships, adopted

a resolution to convert 514,773 P-series registered ordinary shares into P-series ordinary bearer shares (Shares), issue a collective share certificate and deposit it with a brokerage house, and to enter into an agreement with the Krajowy Depozyt Papierów Wartościowych S.A. for registration in the depository for securities of the Shares and applying for their admission and introduction to trading on the official stock exchange quotation market operated by the Warsaw Stock Exchange. The shares subject to conversion constitute 3.75% of the share capital and 3.37% of the total number of votes in the Company. P series shares are not privileged. After the conversion, all P series shares of the Company, i.e. 1,920,772 shares are ordinary bearer shares, including 1,405,999 P series shares admitted to trading on the official quotation market of the WSE, and the remaining 514,773 shares in accordance with the above-mentioned resolution of the Management Board of the Company will be covered by an application for admission to trading. The amount of the share capital and the total number of votes in the Company have not changed: the share capital of the Company amounts to PLN 1,372,077.20 and is divided into 13,720,772 shares with a nominal value of PLN 0.10 each, and the number of votes resulting from all issued shares of the Company amounts to 15,290,772. This information was published in current report no. 7/2019 dated 2 April 2019.

6.2 Shareholders of the Company holding significant blocks of shares

To the knowledge of the Management Board of the Company, as at the date of approval of this report, i.e. 9 April 2019, the following shareholders held at least 5% of votes at the General Meeting of the Company.

Table 15: Shareholding structure.

Lp.	Shareholder	Number of shares	Number of votes	Participation in the share capital	Share in the total number of votes
1.	Twiti Investments Limited	2,380,072	2,974,372	17.35%	19.45%
2.	Maciej Wieczorek*:	1,626,576	2,119,426	11.85%	13.86%
	Glatton Sp. z o.o.	1,006,226	1,006,226	7.33%	6.58%
	Celon Pharma S.A.	620,350	1,113,200	4.52%	7.28%
3.	Polfarmex S.A.	1,437,983	1,920,833	10.48%	12.56%
4.	Funds managed by Generali PTE S.A.	1,490,545	1,490,545	10.86%	9.75%
5.	Funds managed by Investors TFI S.A.**	1,068,007	1,068,007	7.78%	6.98%
6.	Nationale Nederlanden PTE S.A. Funds**	938,031	938,031	6.84%	6.13%
7.	Other	4,779,558	4,779,558	34.83%	31.26%
	Total	13,720,772	15,290,772	100%	100%

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

** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 28.06.2018*

6.3 Ownership of the Company' s shares and shares and stocks in related entities by managing and supervising persons

As at the date of approval of this report, i.e. 9 April 2019, members of the Management Board and Supervisory Board of the Company hold the following shares in the Company:

Table 16: Shares held by managing and supervising persons.

Shares held as at the date of approving the report for 2018 (as at 9 April 2019)	
Management Board	
Artur Chabowski	directly holds 13,718 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.10% of the share capital of the Company and giving 0.09% of votes at the General Meeting.
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which it holds 100% of the share capital) and Celon Pharma S.A. (in which it holds indirectly through Glatton Sp. z o.o. 66.67% of the share capital) holds a total of 1,626,576 shares of the Company with a nominal value of PLN 0.10 each, constituting 11.85% of the share capital of the Company and giving 13.86% of votes at the General Meeting.

As at the date of approval of this report, i.e. 9 April 2019, other members of the management and supervisory bodies did not hold any shares in the Company. Members of the Management Board and Supervisory Board of Mabion S.A. do not hold any shares or stocks in related entities of the Company.

6.4 Employee share ownership plan

In 2018, the Incentive Scheme for the years 2018-2021 was adopted. As part of the Incentive Scheme, the persons participating in it - the Eligible Persons, i.e. the key persons in the Company - will be able to obtain the right to take up Subscription Warrants. The Company does not have a separate control system for employee share programs. The decision on the form of exercising the rights is taken by the Supervisory Board of the Company after verification of the fulfilment of the criteria specified in the Incentive Scheme and on the basis of the recommendation of the Management Board.

In February 2019, the Supervisory Board, acting on the basis of the authorisation granted by the Ordinary General Meeting in resolution no. 24/VI/2018 of 28 June 2018, determined, by way of resolutions, the lists of persons entitled to take up subscription warrants of A and B series for 2018 and 2019 together with the maximum number of warrants that may be taken up by each of these persons, provided that the criteria specified in the Incentive Scheme are met. According to the resolutions, the entitled persons will have the right to take up, for 2018 , a maximum of 28,500 A series warrants and 9,500 B series warrants in total, and for 2019, a maximum of 28,500 A series warrants and 500 B series warrants in total. At the same time, after verifying whether the criteria specified in the Incentive Scheme are met, the Supervisory Board stated that in 2018, with respect to A series subscription warrants, the market objective specified in the above-mentioned resolution of the Ordinary General Meeting, constituting one of the two conditions for the right to take up and exercise the rights attached to A series warrants to become applicable was not met, while with respect to B series subscription warrants, the condition for the right to take up and exercise the rights attached to B series warrants specified in the above-mentioned resolution of the Ordinary General Meeting was met. Thus, the Supervisory Board granted the entitled persons the right to take up a total of 9,500 B series subscription warrants for 2018. As at the date of approval of these financial statements, no agreements to take up series B warrants have been made.

According to the rules and regulations of the Incentive Scheme, if the market goal is not met in a given year, subscription warrants of A series not granted for this reason may be granted together with warrants of series A for the year in which the market goal was met.

Each subscription warrant of A and B series shall entitle to take up 1 share (R series and S series, respectively). The share issue price for holders of A series warrants will be PLN 91 per each R series share, whereas for holders of B series warrants it will be PLN 0.10 per each S series share. The Incentive Scheme also allows for settlement in the form of an offer made by the Company to persons who have taken up the warrants, to purchase them against payment for the purpose of redemption.

For details, see paragraph 8.1 of this Report.

6.5 Purchase of own shares

In 2018, the Company did not acquire or dispose of its own shares.

6.6 Holders of securities with special control rights

Registered shares of series A, B, C, E, F and G are privileged in such a way that each of them entitles to two votes at the General Meeting. In addition, the Company's share capital includes 514,773 ordinary registered shares of series P. Shareholders entitled under registered shares have the pre-emptive right and the pre-emptive right to acquire registered shares for sale. The Company does not have any other securities with special control rights.

Table 17 Registered shares.

Series	Number of shares	Shareholder	Number of series shares held by a shareholder as at 9 April 2019
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	32,850	Celon Pharma S.A.	32,850
		Polfarmex S.A.	32,850
		Twiti Investments Limited	34,300
F	10,000	Celon Pharma S.A.	10,000
		Twiti Investments Limited	90,000
G	20,000	Twiti Investments Limited	20,000
P	514,773	Twiti Investments Limited	514,773

6.7 Restrictions on the exercise of voting rights

The Company's Articles of Association do not provide for any restrictions as to the exercise of voting rights or any provisions according to which, in cooperation with the Company, capital rights attached to securities would be separated from the possession of securities. Restrictions on the exercise of voting rights may result, in the case of the Company, only from the generally applicable provisions of law.

6.8 Restrictions on the transfer of ownership of securities

The Company's Articles of Association do not provide for restrictions on trading in the Company's series D, H, I, J, K, L, M, N and O shares. The Company's series A, B, C, E, F, G shares and 514,773 series P shares are registered shares. Shareholders entitled under registered shares have the pre-emptive right and the pre-emptive right to acquire registered shares for sale.

6.9 Agreements which may result in changes in the proportions of shares held by existing shareholders and bondholders

To the best knowledge of the Company's Management Board, there are no arrangements, the implementation of which in the future may result in changes in the manner of controlling the Company. The Company's Articles of Association contain provisions concerning the rules of disposal of registered preference shares of series A, B, C, E, F and G and 514,773 ordinary registered shares of series P of the Company (pre-emptive right and pre-emptive right to acquire registered shares for other owners of registered shares of the Company), pursuant to which a registered share may be sold to persons other than the shareholders entitled under registered shares only on condition that those entitled under the pre-emptive right and the pre-emptive right to acquire do not exercise this right.

7 COMPANY'S GOVERNING BODIES

7.1 Management Board

7.1.1 Members of the Management Board, its changes and rules of appointing Members of the Management Board

In 2018, the composition of the Management Board was as follows:

Mr. Artur Chabowski	–	President of the Management Board
Mr. Sławomir Jaros	–	Member of the Management Board
Mr. Jarosław Walczak	–	Member of the Management Board

On 24 December 2018, the Supervisory Board of the Company adopted a resolution on the appointment as of 2 January 2019 of Mr. Grzegorz Grabowicz as Member of the Management Board of the first joint term of office of the Company.

From 2 January 2019 until the date of preparation of this report, the composition of the Management Board is as follows:

Mr. Artur Chabowski	–	President of the Management Board
Mr. Sławomir Jaros	–	Member of the Management Board
Mr. Jarosław Walczak	–	Member of the Management Board
Mr. Grzegorz Grabowicz	–	Member of the Management Board

Members of the Management Board are appointed by the Supervisory Board for a joint term of office of 5 years. The first joint term of office of Members of the Management Board expires on the date of the Company's General Meeting approving the financial statements for the financial year 2021. Each Member of the Management Board may be suspended or dismissed by the Supervisory Board or the General Meeting.

7.1.2 Powers and description of the Management Board' s activities

The Management Board shall exercise all rights in the area of management of the Company, with the exception of rights reserved by law or the Company's Articles of Association for decisions of the General Meeting and the Supervisory Board (§ 26 of the Company's Articles of Association). The right to make a decision on the issue or redemption of shares is vested in the General Meeting (§ 17 of the Company's Articles of Association). The President of the Management Board is authorised to make declarations of will and sign on behalf of the Company, subject to the provisions of § 27 or two Members of the Management Board acting jointly or one Member of the Management Board together with a proxy. Pursuant to § 27, two Members of the Management Board acting jointly or one Member of the Management Board acting jointly or one Member of the Management Board acting jointly with a commercial proxy are authorised to make declarations of will and sign on behalf of the Company with respect to activities whose subject matter is the assumption of liabilities or regulation with a value exceeding PLN 200,000.

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

The table below presents the value of remuneration due and paid in 2018 to the Management Board Members for serving on the Company's Management Board.

Table 18. Remuneration of the Management Board Members.

Member of the Management Board	Gross remuneration due for 2018	Gross remuneration paid in 2018
Artur Chabowski	1,301,220.83	1,200,508.83
Jarosław Walczak	48,000.00	48,000.00
Sławomir Jaros*	609,222.42*	608,111.42**

* *including PLN 438,178.01 gross under employment contract (base salary plus other components);*
** *including PLN 437,067.01 under employment contract (base salary plus other components).*

The Company does not have any subsidiaries, therefore the Members of the Management Board did not receive any remuneration from the Company's subsidiaries in 2018.

Pursuant a resolution of the Supervisory Board, Mr. Artur Chabowski received a bonus in connection with the issue of P series shares on the main market of the WSE in the amount of 0.4% of the net issue value (PLN 656,236.83 gross). This amount has been included in the above statement.

Mr. Sławomir Jaros, pursuant to a resolution of the Supervisory Board, received a bonus in connection with the issue of P series shares on the main market of the WSE in the amount of 0.075% of the net issue value (PLN 123,044.41 gross) was paid. This amount has been included in the above statement.

The aforementioned resolutions replaced resolutions concerning issuances on a foreign market, in connection with the issue of shares on the Polish market.

In 2018, no remuneration in the form of share options was paid to the Management Board Members. The Company's corporate regulations do not provide for the right for Management Board Members to receive remuneration in the form of share options. In 2018, the Company introduced an Incentive Scheme for persons of key importance to the Company, the principles of which are described in points 6.4. and 8.1. of this Report. In accordance with the resolution of the Supervisory Board of the Company of February 2019, the persons entitled to take up subscription warrants for 2018 include Members of the Management Board of the Company: Mr. Artur Chabowski - the right to take up a maximum of 8,465 A series warrants, Mr. Jarosław Walczak - the right to take up a maximum of 1,411 A series warrants, Mr. Sławomir Jaros - granted 4,043 B series warrants (not taken

up until the date of approval of this Report) and the right to take up a maximum of 5,644 A series warrants. While A series subscription warrants for 2018 were not granted due to the failure to meet the market objective in 2018, nevertheless, in accordance with the rules and regulations of the Incentive Scheme, these warrants may be granted to the entitled persons during the period of the Incentive Scheme together with A series warrants for a year in which the market objective will be met.

In 2018, the members of the Management Board did not receive any remuneration for services rendered in any capacity other than those described above. The agreements concluded with members of the Management Board do not contain any provisions concerning the payment of severance payments or other payments due to termination of employment, mandate or any other legal relationship of a similar nature.

Since July 2018, all Members of the Management Board have been entitled to use the medical package purchased by the Company on the basis of an agreement concluded with a provider of medical services.

Since October 2018 Mr. Artur Chabowski and Mr. Sławomir Jaros can also use company cars for private purposes.

7.1.4 Contracts with management members

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

As at 1 January 2018, the composition of the Supervisory Board was as follows:

» Robert Aleksandrowicz - Chairman of the Supervisory Board;
» Maciej Wieczorek - Deputy Chairman of the Supervisory Board;
» Grzegorz Stefański - Independent Member of the Supervisory Board;
» Tadeusz Pietrucha - Independent Member of the Supervisory Board;
» Jacek Piotr Nowak - Member of the Supervisory Board;
» David John James - Independent Member of the Supervisory Board;
» Robert Koński - Independent Member of the Supervisory Board;
» Artur Olech - Independent Member of the Supervisory Board.

On 27 June 2018, the Company received resignations from the Supervisory Board from Mr Robert Aleksandrowicz and Mr Grzegorz Stefański, and on 28 June 2018 from Mr Artur Olech (letter dated 27 June 2018).

On 28 June 2018, the Ordinary General Meeting of the Company adopted resolutions on appointing the following Members of the Supervisory Board:

» Krzysztof Kaczmarczyk;
» Dirk Kreder;
» Józef Banach.

After the aforementioned changes, until the date of approval of this report, the composition of the Company's Supervisory Board is as follows:

» Maciej Wieczorek - Chairman of the Supervisory Board;
» Józef Banach - Deputy Chairman of the Supervisory Board, Independent Member of the Supervisory Board;

- Tadeusz Pietrucha - Independent Member of the Supervisory Board;
- Jacek Piotr Nowak - Member of the Supervisory Board;
- David John James - Independent Member of the Supervisory Board;
- Robert Koński - Independent Member of the Supervisory Board;
- Krzysztof Kaczmarczyk - Independent Member of the Supervisory Board;
- Dirk Kreder - Independent Member of the Supervisory Board.

Members of the Supervisory Board are elected for a joint term of office, which lasts 3 years. The first joint term of office of Members of the Supervisory Board expires on the date of the General Meeting of the Company approving the financial statements for the financial year 2019. Members of the Supervisory Board are appointed and dismissed by the General Meeting. The Supervisory Board is composed of five to nine members.

7.2.2 Rights of the Supervisory Board and description of its operations

Pursuant to § 22 of the Company's Articles of Association, the Supervisory Board's competencies comprise actions reserved for it in the Code of Commercial Companies and Partnerships, and moreover:

a) passing resolutions on the purchase and sale of real estate, perpetual usufruct or share in real estate;
b) appointing a statutory auditor to audit the Company's financial statements;
c) appointing and dismissing the Company's Management Board Members;
d) determining the amount of remuneration of Management Board Members;
e) assessing Management Board motions as to distribution of profit or loss coverage;
f) approval of the Rules of Procedure of the Management Board;
g) giving opinions on the Company's multi-year strategic plans;
h) passing the Rules of Procedure which determine the procedures of operation of the Supervisory Board;
i) granting consent for the sale of Company's fixed assets the value of which exceeds 10% 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 introducing the Company's shares to trading on a regulated market, the Supervisory Board should:

a) grant consent for the Company to enter into a contract with a 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) examine and give opinions on issues that are to be subject General Meeting's resolutions

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. The majority of the Members of the Audit Committee, including its Chairman, should be independent from the Company within the meaning of the Act of 11 May 2017 on statutory auditors, audit firms and public oversight. At least one member of the Audit Committee should have knowledge and skills in accounting or auditing of financial statements. At least one member of the Audit Committee should have knowledge and skills in the industry in which the Company operates.

Moreover, the Supervisory Board may appoint the Nomination and Remuneration Committee responsible for preparing assessments of candidates for 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.

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

The value of the remuneration due for performing functions on the Company's Supervisory Board and paid in respect of the year 2018 was as follows:

Table 19 Remuneration of the members of the Supervisory Board.

Member of the Supervisory Board	Remuneration due for the year 2018, gross*	Remuneration paid for the year 2018, gross**
Robert Aleksandrowicz	PLN 1,000.00	PLN 2,000.00
Józef Banach	PLN 16,666.67	PLN 12,666.67
David James	PLN 100,000.00	PLN 100,563.00
Krzysztof Kaczmarczyk	PLN 32,333.34	PLN 23,333.24
Robert Koński	PLN 52,000.00	PLN 52,843.47
Dirk Kreder	PLN 16,666.67	PLN 0.00
Jacek Nowak	PLN 50,000.00	PLN 51,000.00
Artur Olech	PLN 24,733.33	PLN 31,044.44
Tadeusz Pietrucha	PLN 4,000.00	PLN 3,079.88
Grzegorz Stefański	PLN 24,600.00	PLN 29,600.00
Maciej Wieczorek	PLN 18,666.67	PLN 14,666.67

* *The amount stated above is inclusive of the remuneration due in respect of the year 2018 for performing the function of a Member of the Supervisory Board.*

** *The amount stated above is inclusive of the remuneration paid in the year 2018, including amounts due for 2017.*

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 2018.

In 2018, no bonuses, benefits or remuneration were paid out to Members of the Supervisory Board based on plans for bonus schemes 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 bonus schemes or participation in profits.

In 2018, 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 2018, the Company did not grant any in-kind benefits to Members of its Supervisory Board.

In accordance with the Resolution of the Ordinary General Meeting of the Company dated 16 February (no. 26/II/2017), remunerations of the Supervisory Board Members were as follows:

» Members of the Supervisory Board are entitled to remuneration of PLN 1,000 gross for participating in a Supervisory Board meeting;

» Members of the Supervisory Board appointed to Supervisory Board Committees are entitled to monthly remuneration of PLN 4,000 gross.

The above-mentioned resolution 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 Entrepreneurs of the National Court Register on 23 March 2017, introduced by paragraph 10 of Resolution of the Extraordinary General Meeting No. 7/II/2017 dated 16 February 2017.

In 2018, Members of the Supervisory Board did not receive any remuneration for services provided in any capacity except for additional remuneration for membership of the Audit Committee and the Nomination and Remuneration Committee, which was shown in the table above.

7.2.4 Appointed Committees

The Company has an Audit Committee and an Appointment and Remuneration Committee of the Supervisory Board.

1. Audit Committee

From 31 March 2017 to 28 June 2018, the Audit Committee was composed of the following members:

» Mr. David John James - Chairman of the Audit Committee;
» Mr. Jacek Piotr Nowak - Member of the Audit Committee;
» Mr. Artur Olech - Member of the Audit Committee.

On 28 June 2018, the Company received the resignation of Mr Artur Olech from the position of Member of the Supervisory Board of the Company dated 27 June 2018 and on that day, the Ordinary General Meeting of the Company adopted a resolution on the appointment of Mr. Krzysztof Kaczmarczyk, Mr. Dirk Kreder and Mr. Józef Banach to the Supervisory Board.

In connection with the aforementioned changes in the composition of the Supervisory Board, on 11 September 2018 the Supervisory Board of the Company, acting pursuant to § 25.1 and § 25.3 of the Company's Articles of Association, appointed new members of the Supervisory Board to the Audit Committee.

The composition of the Audit Committee from 11 September 2018 until the date of publication of this report has been as follows:

» Mr. David John James - Chairman of the Audit Committee;
» Mr. Jacek Piotr Nowak - Member of the Audit Committee;
» Mr. Krzysztof Kaczmarczyk - Member of the Audit Committee;
» Mr. Dirk Kreder - Member of the Audit Committee;
» Mr. Józef Banach - Member of the Audit Committee.

The Audit Committee operates pursuant to the provisions of the Act of 11 May 2017 r on statutory auditors, audit firms and public oversight (Polish Journal of Laws of 2017, item 1089), and its organizational structure and operating principles are described in the Rules of Procedure adopted by the Supervisory Board.

In 2018, the Audit Committee held 4 meetings.

The independence criteria within the meaning of the Act of 11 May 2017 r on statutory auditors, audit firms and public oversight were met by in 2018 by Mr. David James, Mr. Artur Olech, Mr. Dirk Kreder, Mr. Krzysztof Kaczmarczyk and Mr. Józef Banach, respectively, for the period of holding their functions in the Audit Committee. These persons also meet the independence criteria within the meaning of Best Practice of GPW Listed Companies 2016, as appropriate for the period in which they performed their functions in the Audit Committee.

The members of the Audit Committee declared that they have knowledge and skills in the field of:	
accounting or audit of financial statements:	The industry in which Mabion operates:
David John James	Krzysztof Kaczmarczyk
Krzysztof Kaczmarczyk	Dirk Kreder
Dirk Kreder	Jacek Nowak
Jacek Nowak	Józef Banach
Józef Banach	

» **David John James – Chairman of the Audit Committee**

Graduate of Cambridge University, certified auditor, Institute of Chartered Accountants in England and Wales (ICAEW). Currently Director for International Business Development, Mazars Poland. He has 28 years of experience in audit and internal control. Member of the management boards of many companies and advisor on setting up business in Central and Eastern Europe for nearly fifty companies. Partner responsible for auditing the financial statements of more than 100 companies and groups of companies from a wide range of economic sectors, including companies listed on the Warsaw Stock Exchange, private equity funds, and family businesses. He has conducted more than 80 due diligence analyses, dealt with financial forensic audits and provided internal audit advisory services to many clients. He worked in Poland, the United Kingdom, Germany, Czech Republic, Slovakia and Russia. He is fluent in eight languages and speaks twelve others. David James spent four years mentoring about 100 teams of young entrepreneurs participating in the Cambridge Python Project. As part of this project, organised under the aegis of the British Embassy and the University of Cambridge, David James trained students from all over Poland in creating modern business plans and budgeting. David James is the creator of his own method of learning foreign languages.

» **Krzysztof Kaczmarczyk**

Graduate of the Warsaw School of Economics with specialization in finance and accounting. He is also a former student of the University of Warsaw, faculty of International Relations. In 1999-2008, he worked for Deutsche Bank in Poland, where he held a position, among others, of Deputy Director of the Stock Market Analysis Department and Stock Market Analyst for Central and Eastern Europe. In the period of 2008-2010, he held various managerial positions in the TP S.A. Group, including Director of the Strategy and Development Division. In 2010-2011, he worked for a Swiss investment bank, Credit Suisse, in Poland. In 2012-2015, he held a position of Vice-President of the Management Board for Strategy and Development at Emitel, a leading operator of the terrestrial radio and television network in Poland. Currently a professionally independent member of supervisory boards of companies listed on the Warsaw Stock Exchange and Advisor to the Management Board of KGHM Polska Miedź S.A. He gained over 10 years of supervisory experience sitting on Supervisory Boards, including companies listed on the WSE - LC Corp, WSE, KGHM, Arteria, Braster, BSC Drukarnia Opakowań, Action, Work Service, TIM, Best, Integer, SARE, Magellan, Robyg, InPost, Polimex-Mostostal, Duon, Polish Energy Partners, Graal, Wirtualna Polska, 4fun Media.

Krzysztof Kaczmarczyk has knowledge and skills in the industry in which the Company operates, acquired owing to 11 years of work at Deutsche Bank and Credit Suisse, where he held managerial positions, and was responsible for market analyses of many market sectors, including the market segment in which the Company operates. At the same time, prior to his appointment to the Supervisory Board of the Company, he previously held the position of Member of the Supervisory Boards of Braster S.A. and Celon Pharma S.A., owing to which he acquired knowledge in the area in which the Company operates.

» Dirk Kreder

A graduate of the University of Stuttgart and the University of Kiel, he holds a PhD degree in biotechnology and immunology. He also completed the International Executive MBA, AMA's Mini-MBA and Project Management programme - the curriculum covered finance, accounting, strategy building, marketing, management, and project management. Dirk Kreder has extensive experience and a broad network of contacts in the pharmaceutical and biotechnology industry, strong business awareness and experience in managing small and large pharmaceutical companies in Europe and the United States. He has contributed to the development and registration of biosimilar and generic drugs in the United States, the European Union, Canada, Australia, Japan and on other markets; he has over 10 years of experience in the development and commercialization of more than 20 drugs.

» Jacek Nowak

Graduate of Accounting and Financial Management at the University of Łódź. Additionally, he completed postgraduate studies at the French Institute of Management in Warsaw and postgraduate studies in Pharmacoeconomics, Marketing and Pharmaceutical Law at the Warsaw University of Technology Business School. Member of the ACCA since 2012. Since 2001 he has been working for the pharmaceutical company Polfarmex S.A. and since 2005, he has been holding the position of CFO at Biofana.

» Józef Banach

Graduate of the Faculty of Law at the Jagiellonian University in Cracow. Legal Counsel. Managing Partner in InCorpore Banach Szczypiński Partnerzy and Chairman of the Supervisory Board of Zarząd PKiN. He started his career in the Ministry of Finance, and then for a number of years worked at PricewaterhouseCoopers sp. z o.o., most recently as a leader of the Proceedings and International Tax Law team. Member of a number of supervisory boards of capital companies, including the position of Chairman of the Supervisory Board of Poczta Polska SA and Chairman of the Supervisory Board and Chairman of the Audit Committee of PHN SA. A long-term expert of the Tax Council at PKPP Lewiatan, including the acting head of the Tax Council. He has many years of experience in advising companies from the pharmaceutical industry, including Genexo Sp. z o.o. since its inception. Author of numerous publications in the field of law, including the commentary "Polish Agreements on Avoidance of Double Taxation" by CH Beck. Repeated proxy of the parties in proceedings before administrative authorities and administrative and common courts which ended with a success of the client.

Audit firm selection policy and policy for the provision of permitted non-audit services

Pursuant to § 22.1 (b) of the Company's Articles of Association, the Company's Supervisory Board selects a statutory auditor to audit the Company's financial statements. When selecting an audit firm, the Supervisory Board acts on the basis of the indicated criteria and the recommendation of the Audit Committee.

The policy and procedure for selecting an audit firm to conduct the audit and the Policy for the provision of permitted non-audit services were adopted by resolutions of the Audit Committee on 20 October 2017.

The main assumptions of the implemented policy for the selection of an audit firm and the policy for the provision of permitted non-audit services are as follows:

The audit firm is selected in appropriate advance so that the contract for statutory audit of financial statements can be signed in time to allow the audit firm to participate in the stocktaking of significant assets.

The selection is made taking into account the principles of impartiality and independence of the audit firm and taking into account the principle of rotation of the audit firm and the key statutory auditor. The first audit agreement is entered into with an audit firm for a period of not less than two years with the possibility of extension for further periods of at least two years. The costs of auditing the financial statements are borne by the Company.

It is forbidden to introduce contractual clauses in agreements entered into by the Company, as invalid by virtue law, which would limit the possibility of selecting an audit firm by the Supervisory Board of the Company, for the purpose of carrying out the statutory audit of the Company's financial statements, to certain categories or lists of audit firms. The Audit Committee, acting as part of the Supervisory Board of the Company, takes a decision on a recommendation to extend or not to extend the agreement with an audit firm, of which it informs the Supervisory Board of the Company.

If the Supervisory Board of the Company decides not to extend the agreement with the audit firm for a subsequent period and if the extension of the agreement for a subsequent period is not permissible in line with the rotation principle, the procedure for the selection of the audit firm shall apply.

The Tender Committee appointed by the Company's Management Board is responsible for organizing the selection procedure for the statutory audit of the Company's financial statements, including for drawing up tender documentation.

The request for proposals for the selection of an audit firm for the purposes of the statutory audit of the Company's financial statements is prepared by the Tender Committee in consultation with the Audit Committee and is subject to publication on the website www.mabion.eu and is sent to selected audit firms within a specified period of time.

Collected offers of audit firms together with a report containing conclusions from the selection procedure are submitted to the Audit Committee for approval.

The Audit Committee decides on the approval of the report containing the conclusions of the selection procedure and submits a recommendation to the Supervisory Board, which includes at least two options for selecting an audit firm with a justification and an indication of the Audit Committee's reasonable preference for one of them.

If the Supervisory Board's decision to appoint an audit firm deviates from the recommendations of the Audit Committee, the Supervisory Board justifies the reasons for non-compliance with the recommendations of the Audit Committee and communicates such justification to the General Meeting.

In accordance with Article 5(1) of Regulation (EU) No 537/14 of the European Parliament and of the Council of 16 April 2014, neither the statutory auditor nor the audit firm carrying out statutory audit of the financial statements of the Company nor any member of the network to which the statutory auditor or the audit firm belongs shall provide directly or indirectly to the Company, its parent undertaking or undertakings controlled by it within the European Union any prohibited non-audit services in:

a) the period between the beginning of the period audited and the issuing of the audit report; and

b) the financial year immediately preceding the period referred to in point (a) in relation to the services listed in point (g) of the second subparagraph of Article 5(1) of that Regulation.

Services prohibited under Article 136.1 of the Act of 11 May 2017 on statutory auditors, audit firms and public oversight (Polish Journal of Laws 2017, item 1089; hereinafter: " Act") include also other services which are not financial audit activities. Where a statutory auditor or an audit firm provides the said services to the Company, its parent undertaking or entities controlled by it for a period of at least three consecutive financial years, the total remuneration for such services shall be limited to a maximum of 70 % of the average remuneration paid in the last three consecutive financial years for the statutory audit(s) of the Company and, where applicable, its parent undertaking, entities controlled by it, and the consolidated financial statements of that group of undertakings. For the purposes of the limitations set out in the first sentence, non-audit services other than those referred to in the preceding paragraph and in this paragraph which are required to be provided under EU or national legislation shall be excluded.

The services indicated in Article 136.2 of the Act are not Prohibited services. The provision of these services is possible only to the extent not related to the tax policy of the audited entity, after the Audit Committee has carried out an assessment of threats to and safeguards of independence referred to in Articles 69-73 of the Act and after the Audit Committee has given its consent.

Audit firm

The Company's financial statements for 2018 was audited by PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k. (formerly PricewaterhouseCoopers sp. z o.o.) with its registered office in Warsaw ("PwC"). PwC also performed a review of the financial statements for the semi-annual period ended on 30 June 2018. The audit firm was selected by the Supervisory Board by resolution no. 8/V/2018 dated 25 May 2018 on the basis of the authorisation provided for in the Company's Articles of Association. The audit firm was selected on the basis of recommendations of the Audit Committee. The recommendation of the Audit Committee met the applicable conditions and was drawn up as a result of the procedure for selecting an audit firm meeting the applicable criteria, organised by the Company.

In 2018, PwC provided permitted non-audit certification services to the Company in the form of a review of the condensed semi-annual financial statements of the Company for the period from 1 January 2018 to 30 June 2018. For more information on the audit firm, please refer to point 8.4.

2. Appointment and Remuneration Committee

The Supervisory Board of the Company, acting pursuant to § 25.2 and § 25.3 of the Company's Articles of Association, appointed, on 28 July 2017, the Appointment and Remuneration Committee of the Supervisory Board in the following composition:

» Mr. Robert Koński - Chairman of the Appointment and Remuneration Committee;
» Mr. Grzegorz Stefański - Member of the Appointment and Remuneration Committee;
» Mr. David John James - Member of the Appointment and Remuneration Committee.

On 22 September 2017, the Supervisory Board of the Company, acting pursuant to § 25.5 of the Company's Articles of Association, adopted the Rules of Procedure of the Appointment and Remuneration Committee. The Committee is an advisory body to the Supervisory Board, and its Members exercise the competences specified in the adopted rules of procedure, pursuant to Article 390 of the Code of Commercial Companies and Partnerships.

As of 11 September 2018, the composition of the Appointment and Remuneration Committee until the date of publication of this report is as follows:

» Mr Maciej Wieczorek - Chairman of the Appointment and Remuneration Committee;
» Mr. Robert Koński - Member of the Appointment and Remuneration Committee;
» Mr. Krzysztof Kaczmarczyk - Member of the Appointment and Remuneration Committee;
» Mr. David John James - Member of the Appointment and Remuneration Committee.

7.3 General Meeting

7.3.1 Operating principles of the General Meeting

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

7.3.2 Essential powers of the General Meeting

The competencies of the General Meeting include issues reserved for it by the Code of Commercial Companies and Partnerships, while the purchase and sale of real estate, perpetual usufruct or share in real estate do not require the adoption of a resolution by the General Meeting (§ 17.2 of the Company's Articles of Association).

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

To be valid, a resolution on the merger or division of the Company requires a majority of 3/4 of the votes cast.

Subject to the provisions below, to be valid, a resolution on removing items included in the General Meeting's agenda requires a majority of 3/4 of the votes cast in the presence of shareholders representing at least 50% of the Company's share capital, with the consent of the shareholders filing a justified motion to abandon investigating an item included on the agenda. In the event that a motion for removing an item from the agenda is filed by the Management Board, the resolution of the General Meeting requires an absolute majority of votes cast.

Removing items included in the General Meeting's agenda on the motion filed, based on Article 401 of the Code of Commercial Companies and Partnerships, by a shareholder representing at least 1/20 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 Code of Commercial Companies and Partnerships (CCCP), in the Articles of Association, and in other legal regulations.

Property rights attached to the Company's shares resulting 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 (§ 13 of the Company's Articles of Association)

2) Right to redeem the shares held (§ 12 of the Company's Articles of Association)

Corporate rights vested in the Company's shareholders in connection with participation in the Company:

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

   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-, D-,F-, G-series shares,

   b) one vote at the General Meeting is attached to each of the D-, H-, I-, J-, K-, L-, M-, N-, O-, P-series shares,

2) The right to convene the Extraordinary 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 CCCP).

3) The right of shareholders with at least one-twentieth of the Company's share capital to request that the Extraordinary General Meeting be convened and to request that certain items be put on the agenda (Article 400 § 1 of the CCCP). 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 CCCP).

4) The right of shareholders with at least one-twentieth of the Company's share capital to request that certain matters be put on the agenda of the next General Meeting (Article 401 § 1 of the CCCP). The request should contain at least a justification or draft resolution relating to the proposed item on the agenda (Article 401 § 1 of the CCCP).

5) The right to appeal against General Meeting resolutions pursuant to the rules specified in Articles 422-427 of the CCCP.

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

7) The right to request that a specific item related to the incorporation of a public company or running it be audited by a statutory auditor (an auditor for special issues). The respective resolution should be adopted 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 request that the Extraordinary General Meeting be convened or that the passing of such a resolution be included in 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 CCCP. During a General Meeting, at the request of a shareholder the Management Board has to provide information relating to the Company, if this is justified for assessing an item on the agenda; a shareholder who is refused such information during a General Meeting and who reports his/her objection 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 CCCP).

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 CCCP).

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

11) The right to inspect, on the premises of the Management Board, the list of shareholders entitled to participate in the General Meeting and to request a copy of such a list, subject to payment of the costs of its preparation (Article 407 § 1 of the CCCP).

12) The right to request copies of motions regarding items on the agenda, within a week preceding the date of the General Meeting (Article 407 § 2 of the CCCP).

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 shareholders holding one-tenth of the share capital represented at such a General Meeting. The motioners are entitled to appoint one of the members of the committee. (Article 410 § 2 of the CCCP).

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

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

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

17) The right to inspect the share register and to request a copy of the register, subject to payment of the costs of its preparation (Article 341 § 7 of the CCCP).

18) The right to request that a commercial company which is a Company's shareholder provide information whether it is the parent or subsidiary of a given commercial company or co-operative which is a Company's shareholder, or whether it ceased to be such a parent or subsidiary. A shareholder may also request 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 CCCP).

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 Code of Commercial Companies and Partnerships. 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 a financial risk management system in respect of the process of drawing up the 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 for Financial Matters supervises the preparation of the financial statements.. He is responsible for overseeing and managing the Company's financial policy. He is also responsible for, among other things, obtaining financing, negotiating significant financial operations and commercial transactions of the Company.

8 SUPPLEMENTARY 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 on the basis of a recommendation of the Appointment and Remuneration Committee, and in relation to the Supervisory Board - by the 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 Report.

By Resolution of the Ordinary General Meeting of the Company No. 24/VI/2018 of 28 June 2018, an Incentive Scheme for the years 2018-2021 was adopted, addressed to persons of key importance for the Company indicated by the Supervisory Board, in the form of subscription warrants incorporating the right to acquire Company's shares within a conditional share capital increase up to the amount not higher than PLN 12,500. The objective of the Scheme is to ensure optimal conditions for the growth of the Company's financial results and long-term growth of the Company's value through continuous association of the persons participating in the Incentive Scheme with the Company and its objectives.

The Incentive Scheme shall be implemented through the issue and allotment of up to 114,000 A series registered subscription warrants and up to 11,000 B series registered subscription warrants entitling the holders to acquire separately issued, within a conditional share capital increase, up to 125,000 shares of the Company, excluding pre-emptive rights of the existing shareholders of the Company.

As an alternative to taking up the issued R series shares and S series shares as part of a conditional share capital increase, the Incentive Scheme also allows the Company to settle by offering to eligible persons who have taken up subscription warrants issued under the Incentive Scheme, the purchase of such warrants against payment for the purpose of redemption.

Detailed conditions for the implementation of the Incentive Scheme are set out in the Incentive Scheme Regulations adopted by resolution No. 3/XII/2018 of the Supervisory Board of the Company.

By Resolution No. 25/VI/2018 of 28 June 2018, the Ordinary General Meeting of the Company conditionally increased the share capital of the Company by an amount not higher than PLN 12,500 by way of an issue of: not more than 114,000 R series ordinary bearer shares with a nominal value of PLN 0.10 each and not more than 11,000 S series ordinary bearer shares with a nominal value of PLN 0.10 each.

The purpose of the conditional share capital increase is to grant the right to subscribe for R series shares to holders of A series subscription warrants and to grant the right to subscribe for S series shares to holders of B series subscription warrants.

By Resolution No. 25/VI/2018 of 28 June 2018, the Ordinary General Meeting of the Company resolved to issue: from 1 to 114,000 A series registered subscription warrants carrying the right to subscribe for R series shares of the Company with the exclusion of the pre-emptive rights of the existing shareholders of the Company and from 1 to 11,000 B series registered subscription warrants carrying the right to subscribe for S series shares of the Company with the exclusion of the pre-emptive rights of the existing shareholders of the Company.

The subscription warrants shall be issued free of charge, in material form, as registered securities. The subscription warrants shall be taken up by entitled persons in the number indicated in the resolution of the Supervisory Board.

Each A series subscription warrant shall entitle to subscribe for 1 R series share with the exclusion of the pre-emptive rights of the existing shareholders of the Company, while each B series subscription warrant shall entitle to subscribe for 1 S series share with the exclusion of the pre-emptive rights of the existing shareholders of the Company.

The issue price of shares for holders of A series subscription warrants will be PLN 91 per each R series share, and the issue price for holders of B series subscription warrants will be PLN 0.10 (ten grosz) per each S series share. R series shares and S series shares shall be acquired only for cash contributions made in full before the shares are dispensed.

The rights resulting from subscription warrants may be exercised until 31 July 2022. Detailed information is contained in Notes 4 t and 17 c of the Financial Statements of the Company.

Apart from the above, in 2018 there were no other significant changes in the Company's remuneration system. In the Company's opinion, the method of determining remunerations and their amount allow to achieve the Company's objectives, including long-term growth in value for shareholders and stability of the Company's operations.

8.2 Liabilities from pensions and similar obligations

In 2018, the Company did not have any liabilities for pensions or similar benefits towards former members of its managing or supervisory bodies, or any liabilities incurred in connection with such pensions.

8.3 Proceedings

In 2018, the Company was not a party to any proceedings before a court, an arbitration authority or a public administration authority which in the opinion of the Management Board of the Company could have a material adverse effect on the financial situation, operations or cash flows of the Company.

8.4 Information about the audit firm

The financial statements were audited by PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k. (formerly: PricewaterhouseCoopers sp. z o.o.) with its registered office in Warsaw, ul. Lecha Kaczyńskiego 14, entered on the list of audit firms maintained by the National Council of Statutory Auditors ("PwC"). The audit firm was selected by the

Supervisory Board by resolution no. 8/V/2018 dated 25 May 2018 on the basis of the authorisation provided for in the Company's Articles of Association. The agreement with PwC was entered into on 6 August 2018 for a period of 2 years and includes the audit of interim financial statements and the audit of annual financial statements for 2018 and 2019. The total remuneration for the performance of the aforementioned services covered by the agreement was set at PLN 490,000 net.

The Parties allow for the possibility of entering into a separate agreement for the performance of audit and review of the financial statements for 2018 and 2019 in accordance with the provisions of the PCAOB. The remuneration for the performance of the aforementioned services was measured at PLN 1,530,000.00 net.

In 2017, audit services for the Company were also provided by PwC.

The agreement entered into on 12 February 2018 included the audit by PwC of the annual financial statements for 2017. The remuneration for the performance of the aforementioned services covered by the agreement amounted to PLN 280,000 net. The agreement was entered into for a period of 1 year.

On 21 February 2017, the Company entered into an agreement with PwC for the provision of services associated with the proposed issue of the Company's shares outside the territory of the Republic of Poland (in Europe or in the United States). The scope of services provided by PwC under that agreement included:

» Support for the Company in the preparation for the transformation of the financial statements for the years 2016 and 2015, drawn up in accordance with Polish Accounting Standards into financial statements compliant with IFRS;

» Audit of the financial statements for the years 2016 and 2015, prepared by Mabion S.A. in compliance with IFRS;

» Drafting of the Comfort Letters in connection with the proposed listing of the Company's shares on the stock exchange referred to above;

» Support in the drafting of issuance 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 as above amounted to PLN 700 thousand net (of which PLN 500 thousand in respect of the audit of the financial statements for the years 2016 and 2015).

On 28 July 2017, the Company entered into an agreement with PwC for reviewing the interim condensed financial statements for the period from 1 January 2017 to 30 June 2017 drawn up by Mabion S.A. in accordance with IFRS, for a fee of PLN 180 thousand net.

On 5 November 2017, the Company has commissioned PwC to provide additional services related to the preparation of issuance documents necessary for the implementation of the issue of Mabion shares in the territory of Europe (outside the Republic of Poland) or the United States, for a fee of PLN 160 thousand net.

In addition, in accordance with the agreements made, PwC received reimbursement of expenses incurred in connection with service provision in the amount not exceeding 4 % of its fee (the limit is exclusive of the cost of the English translation of the financial statements).

Table 20: Remuneration due to PwC for the provision of services in 2017 and 2018.

	2018	2017
Examination of the annual accounts	185,000 PLN	280,000 PLN *
Other assurance services, including review of the financial statements	PLN 60,000	340,000**
Tax advisory services	PLN 0	PLN 0
Other services	PLN 0	PLN 360,000
Reimbursement of expenditure	PLN 9,800***	PLN 70,649

* *The amount includes fees to PwC in London and the USA for the verification of the transformation of PSR-compliant financial statements into IFRS-compliant financial statements.*

** *The amount includes PLN 180,000 and PLN 160,000 for reviews of interim condensed financial statements of the Company for the periods from 1 January 2017 to 30 June 2017 and from 1 January 2017 to 30 September 2017, respectively.*

*** *The maximum amount of reimbursement of expenses according to the agreement with PwC*

In 2017 and 2018, PwC did not provide any services to the Company other than those described above. Prior to 2017, the Company used the services of PwC in the following scope:

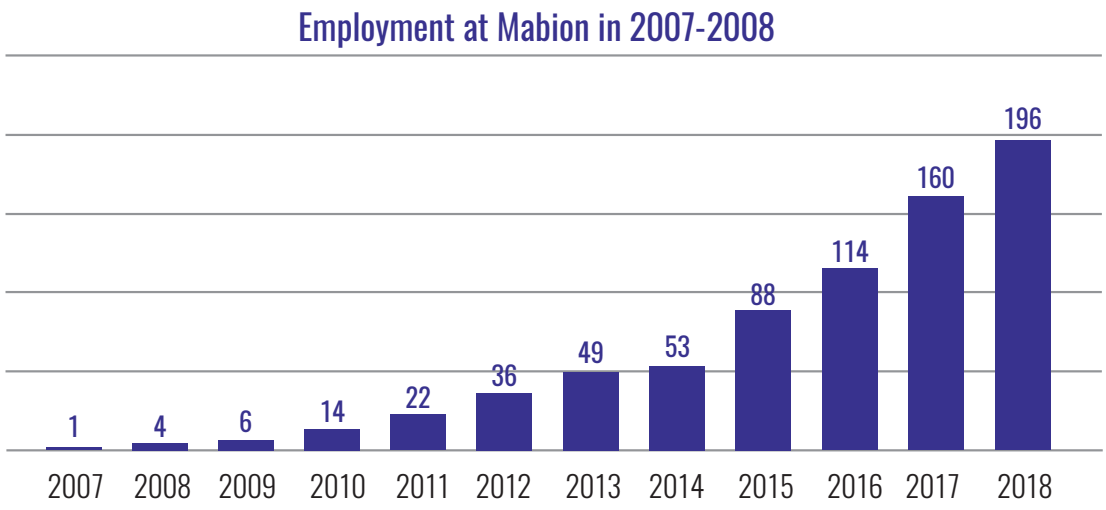
» review of the interim condensed financial statements for the periods from 1 January 2015 to 30 June 2015 and from 1 January 2016 to 30 June 2016;

» audit of the annual financial statements for the years 2015 and 2016.

8.5 Employment

As at 31 December 2018, the Company employed 196 persons, whereas the average employment in 2018 converted into full-time equivalents was 136.57 persons.

Table 21. Employment at Mabion S.A. in the years 2007 - 2018.



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 2018, the Company conducted active research on the achievement of the key objectives of the main project of the Company – development of a medicine biosimilar to MabThera. In 2018, works were carried out as part of the development of further products biosimilar to the original medicines available on the market (so-called reference medicines), applied in the treatment of cancer, 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;

» MabionMS monoclonal antibody - a madicine based on the active substance rituximab for use in the treatment of multiple sclerosis;

» MabionVEGF_Fab monoclonal antibody - a medicine biosimilar to Lucentis (with Ranimizumab as the active substance). Lucentis (Novartis) is used in adult patients in the treatment of several conditions causing visual impairment [the project is implemented for a third party];

» MabionEGFR monoclonal antibody - an oncological medicine biosimilar to Erbitux (including Cetuximab as the active substance). Erbitux is indicated for the treatment of colon cancer with metastases.

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

A milestone, achieved in 2018 as part of the development of the MabThera biosimilar, was the submission of registration documentation to the European Medicines Agency.

Tabela 23. Projekty badawcze realizowane w Mabion S.A. w 2018 roku.

Therapeutic proteins:		
Monoclonal antibodies:		
Project - therapeutic proteins	Indication	Project completion stage (December 2018)
Internal projects		
MabionCD20 (Rituximab)	Non-Hodgkin lymphomas (NHL); chronic lymphocytic leukemia; rheumatoid arthritis	preclinical / Phase I / Phase III
MabionMS (Rituximab)	Multiple sclerosis	preclinical / Phase I / Phase III
MabionEGFR (Cetuximab)	Colon cancer, squamous cell cancer in the head and neck	preclinical / Phase I / Phase III

Therapeutic proteins:		
Monoclonal antibodies:		
Project - therapeutic proteins	**Indication**	**Project completion stage (December 2018)**
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). The package of works covered by the agreement was completed and the results were handed over to the Employer.	**preclinical** **Phase I** **Phase III**

Etapy projektu: **preclinical** **Phase I** **Phase III** In progress

8.7 Natural environmental issues

Issues related to environmental protection are a very important aspect of the Company's operations. The Company, acting on the basis of applicable laws and regulations in the field of environmental protection, implements the Company's strategic objectives while following the principle of sustainable development.

The Company makes every effort to apply the best practices and solutions in the scope of the applicable Mabion's Environmental Policy. The main objective of the Company is to raise environmental awareness among all employees, which translates into effective implementation of the Environmental Policy adopted and building a sense of responsibility for its implementation, with regard to:

- rational management of raw materials and materials;
- rational use of water, electricity and heat to protect natural resources;
- observance of the Company's internal waste management system in accordance with the law, administrative decisions and internal procedures;
- reduction of air pollutant emissions, including gas and dust emissions, and noise;
- elimination, through ongoing technological and environmental monitoring, of the risk of environmental accidents or uncontrolled release of hazardous substances into the environment.

In addition, the Company makes every effort to reduce water consumption by implementing optimal production processes. Our long-term goal is also to reduce electricity consumption by optimising lighting, ventilation, and air conditioning systems.

The company has two business locations. The Company's registered office is located in Konstantynów Łódzki, at ul. Gen. Mariana Langiewicza 60. The office of the Management Board is also located at this address.

The Research and Development Centre for Biotechnological Medicinal Products is located at ul. Fabryczna 17 in Łódź.

The Company has complied with the formal regulations for obtaining administrative decisions and holds the permits and notifications listed below:

1. Decision of the Marshal of the Łódź Region of 29.07.2016 on the integrated permit (reference: RŚVI.7222.190.2015.KK) - for the location of the Company in Konstantynów Łódzki.

2. Decision of the Marshal of the Łódź Region of 02.02.2015 on the discharge of industrial wastewater containing substances particularly harmful to the aquatic environment into the sewage system of another entity (reference: RŚVI.7322.1.127.2014.PŁ) - for the location of the Company in Konstantynów Łódzki.

3. Notification of the fuel combustion installation to the District Office in Pabianice (reference: OŚ.6221.2.2018) - for the Company's location in Konstantynów Łódzki.

4. Decision No. 65/Op/15 of the Mayor of Łódź of 28.04.2015 on the award of a waste generation permit (reference: DSS-OŚR-IV.6221.5.2015) - for the Company's location in Łódź.

The Company also has internal system documents (procedures and instructions of a Good Laboratory Practice and a Good Manufacturing Practice system), regulating issues related to the conduct of rational, environmentally safe waste management at the plant, in accordance with the provisions of law.

In 2018, the following agreements were in force in Mabion S.A. as part of waste management:

1. With EGOLIT Sp. z o. o. o. of 21.08.2015 along with Annex No. 2 to the Agreement entered into on 25.09.2018. The agreement concerns the collection, disposal or recovery of hazardous and non-hazardous production waste.

2. With EMKA S.A. dated 01.02.2016, No. 390/16/MW for transport and disposal of medical waste. The agreement was terminated due to the failure to comply with the so-called proximity principle, i.e. the ban on export outside the voivodship of infectious medical waste generated outside that voivodship (Art. 20.4 of the Act on Waste).

3. With ECO-ABC dated 15.05.2018, No. 37/JN/2018. The agreement concerns the collection and disposal of medical waste.

4. With SAWO Recycling Sp. J. of 01.09.2016 concerning the collection of mixed packaging waste and of 01.10.2016 concerning the collection of secondary raw materials.

5. REMONDIS Sp. z o. o. o. deals with the collection of municipal waste, due to a successful tender for municipal waste management in the municipality of Konstantynów Łódzki (in accordance with the provisions of the Act on Maintaining Cleanliness and Order in Municipalities).

The Company has complied with all obligations relating to environmental reporting, which includes the collection and processing of data and information and the production of reports reflecting the environmental performance of the plant. Reports have been submitted to the relevant environmental authorities, on official forms in force. The Company have submitted the following reports:

» List containing a summary of information on the use of the environment and the amount of fees due for the introduction of gases and dusts into the air. The emission sources are: HCl dosing and disinfection of equipment and surfaces, both for basic installation (installation for the production of medicinal products or pharmaceutical raw materials) and auxiliary installation (research and development laboratories, quality control laboratories); fuel combustion installations; combustion of fuels in internal combustion engines.

» The report of the National Centre for Pollution Control and Balancing (KOBiZE) containing information on the amount of greenhouse gas emissions to the atmosphere, the source of which is: HCl dosing in the basic and auxiliary installation; fuel combustion installations; combustion of fuels in internal combustion engines.

» Summary data on the types and quantities of waste, the ways in which it is managed and the facilities and installations for its recovery and disposal.

» Annual report containing information necessary for the establishment of the National Pollutant Release and Transfer Register (PRTR) for the transfer of hazardous waste accross the country.

Pursuant to Article 28 of the Environmental Protection Law, entities using the environment are obliged by law and by virtue of decisions held by them to measure the level of substances or energy in the environment and the amount of emissions. Such measurements shall be carried out in a periodically repeatable manner. The results of the monitoring shall be recorded and reported or made available for inspection to the relevant environmental protection authorities. The Company fulfils this obligation by carrying out:

» measurements of noise emissions from installations and forwarding test results to the relevant environmental authorities;

» quality tests of industrial wastewater and mixed industrial and household wastewater. The results of the tests have been forwarded to the relevant environmental protection authorities;

» quantitative monitoring of: water intake, industrial wastewater discharge, electricity consumption, network heat consumption, fuel use;

» control of the technical condition and operational inspection of the oil-derivative separator.

In order to monitor the amount of waste generated, the Company keeps full records of generated waste using documents specified in waste management regulations for that purpose. The Company has also fulfilled the obligation to register in the online database on products and packaging and waste management (register maintained by the Marshal's Office competent for the place of business) with respect to the generation of both installation and non-installation waste (for which there is no obligation to hold an administrative decision).

Fulfilling the obligations specified in the Integrated Permit, the Company also carries out ongoing technological monitoring, which includes measurements of parameters characterising specific technological processes, i.e. consumption of materials, substances, products, and production volume.

8.8 Social responsibility policy

EQUAL OPPORTUNITIES POLICY

Mabion 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 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 its incorporation. 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 aspires to creating a work environment based on 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;

» is treated fairly and respectfully, and not discriminated against;

» feels supported in pursuing his or her personal priorities.

2. RECRUITMENT

Mabion's recruitment policy ensures equal opportunities for all those interested in getting a job with the Company. In

particular, 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. PERSONAL AND PROFESSIONAL DEVELOPMENT

Mabion builds a culture based on values common to everybody. Key values supporting the vision, mission and strategy of the company include: orientation on quality and effect of work, work culture, responsibility, communication and cooperation. The performance management model takes into account not only the achievement of business goals, but also the development of competencies based on these values.

The summary of work results is a manifestation of caring for the smooth functioning of the organization and contributes to shaping good interpersonal relations. Mutual feedback serves to build the organisational culture and cooperation of all employees. The development summary and planning have a far-reaching influence on the personal and professional development of

employees and on the functioning of the organization as a whole. The Company's activities in the aspect of human capital development are visible in the increasing amounts of training investments dedicated to our employees.

Mabion offers prestigious specialist training and a series of development training for the managerial staff under the name Akademia Mabion [Mabion Academy].

In addition to professional competence development, the company provides employees with access to meetings and development workshops in the areas of personal development, personal resources management, and building own brand.

Owing to cooperation with a professional coach, employees have access to professional assistance in crisis and support situations.

4. WORK-LIFE BALANCE

Mabion believes that acquisition and retention of good employees 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.

In order to ensure good relations and commitment in Mabion, starting from 2018, the employee motivation survey will be conducted.

Motivated work and work-life balance of employees in a constantly evolving organization is one of the most important investments in the future. From September 2017, the team of Mabion uses support in the area of staff development. Professional development projects for all employees are implemented with the help of the Professional Development Specialist.

Continued efforts to train employees are yet another dimension. Relevant departments are a 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, while functional position exams are oral and 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 uses its best efforts for Mabion to remain an attractive and competitive employer.

8.9 Promotional activities

In 2018, the Company implemented its communication policy in many different dimensions, thus ensuring a broad channel for reaching recipients.

The Company carried out promotional activities through:

» participation in national and international fairs and conferences;

» audio or video feeds of investor meetings;

» meetings with analysts, institutional or individual investors;

» educational activities among investors;

» 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;

On 22-23 May 2018, the Company participated in Bioforum Central Europe. It is one of the most important events in the pharmaceutical and biotechnological industry in Poland. Artur Chabowski, President of the Management Board, took part in an expert debate on the condition of the Polish biotechnology industry. On 25-26 October 2018, a case study on clinical development of MabionCD20 was presented by the Company's Management Board during the 8th Central European Life Science Investment Conference in Krakow. The guests of the meeting included representatives of Polish and foreign industry institutions.

Additionally, Company's representatives contributed to the press dedicated to the financial sector and investors (e.g. Parkiet), as well as in specialist industry titles (e.g. biotechnologia.pl) or news (PAP).

The leading communication themes in 2018 were:

» development and strategy of patent protection for MabionMS;

» results of the clinical trial and the submission of a registration application for MabionCD20 to the EMA;

» issue of shares;

» presence of Company's representatives at industry events and conferences;

» HR materials - aimed at supporting employer branding activities of the Company.

8.10 Investor relations

The purpose of Mabion's 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.

The Company organised two meetings with individual and institutional investors (9 May 2018 and 21 November 2018) and participated in many individual meetings with market analysts. In addition, it organized a total of three video conferences with investors related to current affairs (27 March 2018, 3 July 2018, and 17 September 2018).

In connection with the implementation of the strategy of increasing the international visibility of the Company, its representatives

took part, among others, in:

» JP Morgan Annual Conference 2018 in San Francisco (8-11 January 2018);

» European Biotech Investor Day in New York under the patronage of Nasdaq (19 June 2018);

» Jefferies Global Healthcare Conference in London (14-15 November 2018);

» Winter Wood Conference in Prague (4-7 December 2018).

Furthermore, the Company also communicates with investors via its website which contains a separate section for investors, with the materials available in Polish and English.

The following is available, among other things, on the website:

» Information about the Company and its authorities;

» Timeline of key events in the Company's history;

» Corporate documents;

» Current and interim reports;

» Company's stock price details;

» Investor relations contact form;

» Q&A;

» Materials for investors.

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

The information policy mainly involved the following areas:

» submission of the registration application for MabionCD20 to the EMA;

» share issue;

» increasing production capacity and Mabion II investment;

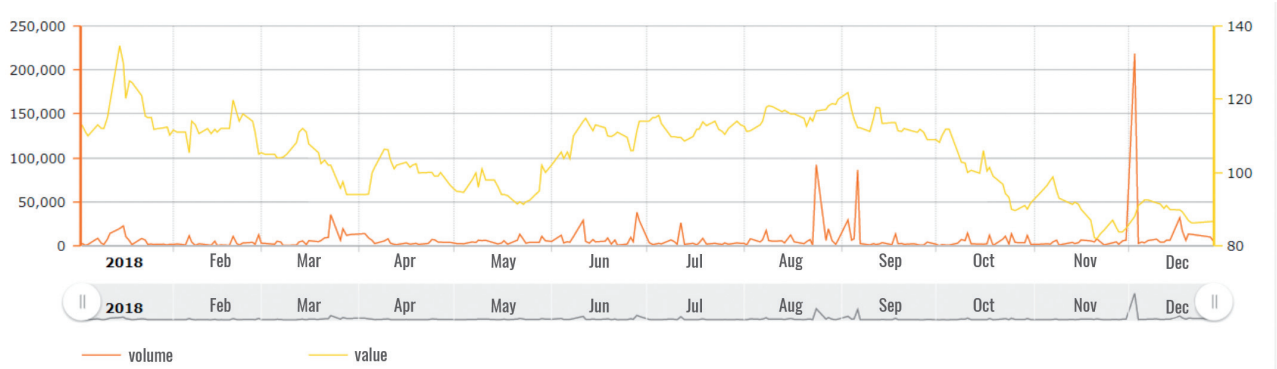
» preparations to enter into agreements with further MabionCD20 distributors;

» the Company's growth plans.

Contact for investors: relacjeinwestorskie@mabion.eu

8.11 The Company's stock performance on the Warsaw Stock Exchange

Table 23: Mabion S.A. stock quotes on the Warsaw Stock Exchange (03.01.2018 - 28.12.2018) - chart.



Source: https://www.gpw.pl/spolka?isin=PLMBION00016

Table 24: Mabion S.A. stock quotes on the Warsaw Stock Exchange (03.01.2018 - 28.12.2018) - summary.

Reference price:	PLN 112.80 (29.12.2017)
Start date:	03.01.2018
End date:	28.12.2018
Change:	-23.23%
Change:	-PLN 26.20
Low:	PLN 78.10 (21.11.2018)
High:	PLN 139.00 (15.01.2018)
Average:	PLN 105.23
Volume:	1,764,869 pcs.
Average volume:	7,145 pcs.
Turnover:	182,860 million
Average turnover:	0.740 million

The Management Board

Artur Chabowski	Jarosław Walczak	Sławomir Jaros	Grzegorz Grabowicz
President of the Management Board	Member of the Management Board	Member of the Management Board	Member of the Management Board

Konstantynów Łódzki, 9 April 2019