Mabion S.A.
Directors' Report for the year 2019

Konstantynów Łódzki, 8 April 2020

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Contents:

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.

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 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 within the meaning of the Accounting Act.

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

1.3 Changes in the Company's management rules

In 2019, no significant changes were noted in the basic principles of management in the Company.

1.4 Organisational or equity relationships

Mabion S.A. does not own any shares in any entities; there are no circumstances which could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1.4) of the Polish Code of Commercial Companies (CCC).
The Company is not owned directly or indirectly by any other entity. 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 (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. In addition, to the Company's best knowledge, the shareholders and members of the Company's bodies are not bound by an 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 by them.

[1] Proper name.

2 OPERATIONS OF MABION S.A.

2.1 Schedule

January	On 7–10 January 2019, the Company's Management Board took part in the JP Morgan Healthcare Conference in San Francisco. The JP Morgan Conference is one of the largest events bringing together leaders of the pharmaceutical industry and investors.
March	On 20 March 2019, an inspection took place concerning the Company's implementation of the condition of permit no. 203 of 12 April 2012 to conduct business activity within the Łódź Special Economic Zone. On the basis of the control activities, it was concluded that the condition has been fulfilled. On 27–28 March 2019, the then President of the Company, Mr. Artur Chabowski, attended the IFC Global Private Health Conference in Miami, which brings together leaders of private health care from around the world.
April	On 1 April 2019, the Company received a letter from the Turkish Ministry of Health concerning the issue of compliance of the Company's Scientific and Industrial Complex for Medical Biotechnology in Konstantynów Łódzki with the requirements of Good Manufacturing Practice (GMP) recognised in Turkey. On 3 April 2019, after an annual review and update of the Company's development strategy for medicinal products, the Management Board of the Company adopted a resolution approving the changes in the existing development strategy of the Company. On 24 April 2019, the Company submitted answers to questions received from the European Medicines Agency (EMA) as part of Day 120 of the EMA registration procedure for MabionCD20. On 25 April 2019, the Management Board of the Company took part in the Innovation Conference 2019 Erste Group in Warsaw, whose aim was to network European innovative companies with institutional investors from Central and Eastern Europe. On 25 April 2019, Mr. Artur Chabowski resigned from the position of President of the Management Board of the Company. The resignation came into force on 30 June 2019. On 30 April 2019, the Board of the Warsaw Stock Exchange decided to qualify Mabion S.A. for the Pilot Analytical Coverage Support Programme.
May	On 6 May 2019, the Company received confirmation from a partner that the duplicate application for a drug under the working name of MabionCD20 was correctly submitted to the EMA. On 27 May 2019, the Company was informed that the validation of the above application by the EMA has been successfully completed and thus accepted for the assessment procedure.

June	On 3–6 June 2019, representatives of the Company took part in the BIO International Convention in Philadelphia. The Convention is a series of events dedicated to the biotech and pharmaceutical industry. On 4–7 June 2019, the Company's Management Board attended the Jefferies Healthcare conference in New York, which brings together a wide range of public and private biopharmaceutical and biotech companies as well as representatives of global institutional investors. On 12 June 2019, an inspection was held regarding the Company's implementation of the condition of permit no. 203 of 12 April 2012 to operate in the Łódź Special Economic Zone (LSEZ). This was the last condition necessary for the Company to meet in order to obtain the right to take advantage of the tax exemption for conducting business activity within the Łódź Special Economic Zone. On the basis of the control activities, it was concluded that the condition has been fulfilled. On 28 June 2019, an Open Day was held at the registered office of Mabion S.A., during which a study visit of participants of the "Młodzi w Łodzi" project took place. The event was attended by students of pharmacy, biology and biotechnology from the Medical University of Łódź, University of Łódź and Łódź University of Technology.
July	On 1 July 2019, the Management Board of the Company received from the EMA a second round of questions as part of the registration procedure for the drug under the working name of MabionCD20 (Day 180). On 23 July 2019, the Company was informed that as a result of an inspection carried out by the Main Pharmaceutical Inspectorate, the Company obtained a GMP (Good Manufacturing Practice) certificate for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki for the production of an active substance (Rituximab). On 25 July 2019, the Company received a letter from the EMA informing that on the basis of an inspection carried out by the Main Pharmaceutical Inspectorate on behalf of the EMA, classified as a pre-authorisation inspection concerning a drug under the working name of MabionCD20, the EMA decided that the manufacturing processes conducted in the Company comply with the principles and guidelines of Good Manufacturing Practice (GMP) specified in Directive 2003/94/EC.
August	On 14 August 2019, the Company was informed by Mylan's legal department that they do not anticipate any impact of the planned merger with Upjohn, a spin-off entity of the Pfizer group, on the binding development and commercialization agreement in the context of cooperation between Mabion and Mylan teams in registering MabionCD20 on the European market. On 19 August 2019, the Company was informed that as a result of an inspection carried out by the Main Pharmaceutical Inspectorate, the Company obtained a GMP (Good Manufacturing Practice) certificate for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki in the following manufacturing operations: production of sterile forms of biotechnological products, quality control tests, batch release and packaging of medicinal products.

October	On 21 October 2019, the Company's Management Board agreed on the terms and conditions and decided to conclude the financing documentation with the European Investment Bank ('EIB'), including the financing agreement ('Loan Agreement') and the agreement on the issuance of subscription warrants to the EIB ('Warrant Agreement'). The Loan Agreement was entered into on 24 October 2019, and the Warrant Agreement – on 30 October 2019. The funds raised under the loan will be used to finance investment and R&D projects, including those related to the development of biosimilar and innovative biological drugs in Poland, and the expansion of the Company's R&D infrastructure and production capacity. On 23 October 2019, the Management Board of the Company was informed by an agent representing the Company before the US Food and Drug Administration (FDA) that the Company has been granted the opportunity to hold a Type 3 BPD (Biosimilar Biological Product Development) meeting with the FDA on 22 January 2020.
November	On 4–7 November 2019, the Management Board of the Company took part in the CPhI fair in Frankfurt. It is the largest trade fair in the biopharmaceutical industry, gathering each time around 2,500 exhibitors. On 10 November 2019, the Company obtained, from a company contracted to deposit the answers to the second round of questions (Day 180) as part of the MabionCD20 registration procedure, a confirmation of their successful entry to the EMA electronic system. On 11 November 2019, the Company received, from the company contracted to deposit answers, a confirmation of their successful entry to the EMA electronic system as part of the duplicate application registration procedure for MabionCD20. On 20–22 November 2019, the Company's Management Board participated in the Jefferies Healthcare Conference in London, the largest healthcare event in Europe. Every year, the conference is attended by leading public and private companies from the pharmaceutical, biotech, medical technology and healthcare services industries.
December	On 9 December 2019, the Company was informed that the National Centre for Research and Development (NCBR) granted the Company a permission to extend by 9 months, i.e. until 30 September 2020, the deadline for the implementation of the project entitled "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". On 12 December 2019, a meeting of the Committee for Medicinal Products for Human Use (CHMP) was completed, at which the Company's registration applications for the marketing authorisation of the drug under the working name of MabionCD20 were processed. On 13 December 2019, the Company received a summary of the CHMP meeting containing a list of issues highlighted by the EMA, to which the Company was required to respond in order to continue the registration procedure.

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 characterised by the ability to recognise 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).

Biosimilar medicines

Biosimilar medicines form a dynamically developing area in the global pharmacy. As shown in reports and analytical studies, the share of biosimilars in global sales increases year by year.

Numerous studies and analytical reports evaluate the potential of this market for the coming years, indicating a continuing global upward trend. Depending on the source and time frame, the cumulative annual growth rate (CAGR) ranges from 30.8% to as much as 57.03%[2] , with an estimated market value between USD 71.97 billion and USD 99.28 billion. Among the drivers of the market for biosimilar drugs, the authors of the studies mention such factors as the global increase in the incidence of oncological and immunological diseases, the introduction of biosimilar drugs by various players (both pharmaceutical giants and young companies with a global reach), a favourable environment for this type of investment, as well as the expiry of patents for best-selling biological drugs. By 2023, competition for biosimilars in the biobased market is expected to be almost three times greater than at present[3]. At the same time, it is pointed out that the costs and complexity of developing biosimilar medicines may challenge the growth of this market. According to the head of the US Food and Drug Administration (FDA), Scott Gottlieb, the cost range for the development of a biosimilar drug is between USD 100 million and USD 300 million[4].

The European Medicines Agency (EMA), which coordinates the evaluation and supervision of medicinal products for human and veterinary use throughout the European Union (EU), is at the forefront of the development of regulations for biosimilar products. In 2004, the EMA established a legal framework for the review and development of biosimilar medicines and in subsequent years, developed and refined a comprehensive set of regulatory guidelines. By the date of publication of this report, 54 biosimilar medicines have received marketing authorisation in the EU, and in 2020 other two were admitted to the market by CHMP[5].

[2] Market analyses:
- Market analyses:
- "Biosimilars Market Analysis, By Type (Recombinant Non-Glycosylated Proteins, G-CSF, Monoclonal Antibodies, Recombinant Glycosylated Proteins, Recombinant Peptides) By Disease Type (Oncology, Blood Disorders, Chronic, Infectious) Forecasts to 2026" (March 2019), https://www.globenewswire.com/news-release/2019/03/19/1757249/0/en/Biosimilars-Market-To-Reach-USD-44-56-Billion-By-Year-2026-Reports-And-Data.html
- "Biosimilars Market" (June 2019), https://www.marketsandmarkets.com/PressReleases/global-biosimilars-product-market-worth-19.4-billion-by-2014.asp
- "Global Biosimilars Market - Increasingly Lucrative Market Fueled by Constrained Payer Environment and Patent Expiries for Best-Selling Biologics" (March 2018), 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-a-CAGR-of-45-22.html
- "Global Biosimilars Market 2018-2024 -Global Biosimilars Market – Drivers, Restraints, Opportunities, Trends, and Forecasts: 2018–2024" (January 2019), https://www.marketresearch.com/Infoholic-Research-v4070/Global-Biosimilars-11668804/

[3] "The Global Use of Medicine in 2019 and Outlook to 2023" (January 2019), IQVIA, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023.pdf?_=1582121041466

[4] "The Impact of Biosimilar Competition in Europe", IQVIA (October 2019), https://ec.europa.eu/search/?queryText=The%20Impact%20of%20Biosimilar%20Competition%20in%20Europe&query_source=GROWTH&swlang=en

[5] https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar

In 2018, the share of biosimilar drugs in Europe stood at 29% (compared to 9% in 2013)[6] and according to the "Biosimilar Market in Europe" report, the value of the market reached USD 2.9 billion[7] (compared to approximately USD 2 billion in 2017[8]). It is expected that by 2024, the market will be worth USD 11.6 billion, with a 24.9% CAGR growth in 2019–2024[9]. Due to its global leadership in the regulation and approval of biosimilar products, the European biosimilar market has been the largest to date, representing about 60 % of the global market for biosimilar products and growing steadily from year to year[10].

In accordance with reports prepared systematically on behalf of the European Commission, entitled "The Impact of Biosimilar Competition in Europe"[11], one of the premises for introducing biosimilar medicines was to increase price competition, which would press down the medicine prices for health systems and patients. As the data show, in seven therapeutic areas where there has been competition in the form of biosimilar drugs, there is a consistent reduction in prices. Prescribing biosimilar medicines has reduced expenditure on biological medicines in Europe by 20% to 40%, which can bring cumulative savings to the European health systems of around EUR 15 billion over the next years[12]. Increased competition resulting from the marketing of biosimilars affects not only the price of the reference medicine for a particular biosimilar, but also the price of the whole class of products (biosimilar and reference medicine). For most therapeutic classes, there is a significant increase in consumption following the introduction of biosimilars, due to the increased availability of therapies to patients.

According to the authors of the report titled "The Impact of Biosimilar Competition in Europe", for the sustainable development of the market for biosimilar medicines it is necessary for more manufacturers to emerge. Some EU countries still have low access to biosimilar oncological therapies, almost 2 years after their market launch. The implications for Europe's healthcare systems are that if fewer companies invest in growth, without fierce competition the level of savings that is expected today will not be achieved. In order to achieve savings in the long term, many biosimilar products are necessary so as to enable reaching the full effect of competition.

With regard to the US market, in June 2018 the US regulator took steps to facilitate the development of biosimilar drugs. The actions primarily concerned changes in the regulatory approach so as to adapt it to the real possibilities of manufacturers to obtain biosimilarity to an original medicine. In the opinion of GlobalData experts, this was a move that could significantly reduce barriers to the development of biosimilar drugs in the US market[13].

Hundreds of billions of dollars were expected to be saved by introducing biosimilar drugs. Such assumptions have so far proved to be unrealistic. A report titled "Incenting Competition to Reduce Drug Spending: The Biosimilar Opportunity", issued in July 2019, indicates that the US healthcare system is not delivering the expected savings. According to the report's author, depending on its market share the system could generate the following annual savings: 50% market share – potential health care savings of USD 4.8 billion; 75% market share – potential health care savings of USD 7.2 billion. Within ten years, the savings could be equal to, depending on the size of the market share: USD 47.95 billion for 50% market share; USD 71.71 billion for 75% market share[14].

6 "Biosimilars market and opportunities in Europe" (May 2019), http://www.gabionline.net/Reports/Biosimilars-market-and-opportunities-in-Europe

7 "Biosimilar Market in Europe: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024" (February 2019), https://www.prnewswire.com/news-releases/european-biosimilar-market-report-2019-market-represents-the-most-mature-in-the-world-and-continues-to-rally-momentum-300798722.html

8 "Biosimilar Market in Europe: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2018-2023" (September 2018), https://www.businesswire.com/news/home/20180910005373/en/Biosimilar-Market-Europe-Industry-Trends-Share-Size

9 "Biosimilar Market in Europe.." (February 2019)

10 "Biosimilars market and opportunities in Europe" (May 2019), http://www.gabionline.net/Reports/Biosimilars-market-and-opportunities-in-Europe

11 "The Impact of Biosimilar Competition in Europe", QuintilesIMS (May 2017, September 2018), IQVIA (October 2019) https://ec.europa.eu/search/?queryText=The%20Impact%20of%20Biosimilar%20Competition%20in%20Europe&query_source=GROWTH&swlang=en

12 "Delivering on the Potential of Biosimilar Medicines" (March 2016), https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS-Institute-Biosimilar-Report-March-2016-FINAL.pdf

13 "With Recent Steps by the FDA to Bolster Development, What Does the Future Hold for US Biosimilars?", GlobalData, (July 2018)

14 "Incenting Competition to Reduce Drug Spending: The Biosimilar Opportunity" (July 2019), Wayne Winegarden

Table 1: Total annual savings on biologicals compared to all original medicines. The summary includes: current situation, 25% market share for a biosimilar, 50% market share for a biosimilar, and 75% market share for a biosimilar (source: "Incenting Competition to Reduce Drug Spending: The Biosimilar Opportunity", Wayne Winegarden)

Drug Class	Originator	Current	TOTAL SAVINGS (IN MILLIONS USD)		
			25% Biosimilar Share	50% Biosimilae Share	75% Biosimilae Share
Infliksymab	Remicade	79.4	318.2	636.5	954.7
Pegfilgrastym	Neulasta	21.8	121.9	243.8	365.7
FIlgrastym	Neupogen	152.1	152.1	152.1	206.8
Epoetyna alfa	Epogen & Procrit	0.5	8.4	16.9	25.3
Bewacyzumab	Avastin	0.0	199.2	398.5	597.7
Trastuzumab	Herceptin	0.0	208.0	415.9	623.9
Rytuksymab	Rituxan	0.0	280.6	561.2	841.8
Etanercept	Enbrel	0.0	324.0	648.0	972.1
Adalimumab	Humira	0.0	861.1	1,722.1	2,583.2
GRAND TOTAL		253.8	2,473.6	4,795.0	7,171.2

In the opinion of the author of the "Incenting Competition to Reduce Second Spending..." report, both the regulatory policy and the adverse market incentives have impact on this situation. In order to strengthen price competition, it is necessary to remove the obstacles preventing wider use of biosimilar drugs. This requires, inter alia, further regulatory changes at the FDA, funding arrangements and education for both patients and physicians to address concerns about the use of biosimilar medicines.

As of the date of publication of this report, the FDA had authorised 26[15] biosimilar medicines, but several of these medicines are still not present on the market. According to the authors of the Fortune Business Insights[16] report, the US market for biosimilars is expected to have a CAGR of 54.7% and reach approximately USD 17 billion by 2026.[17]

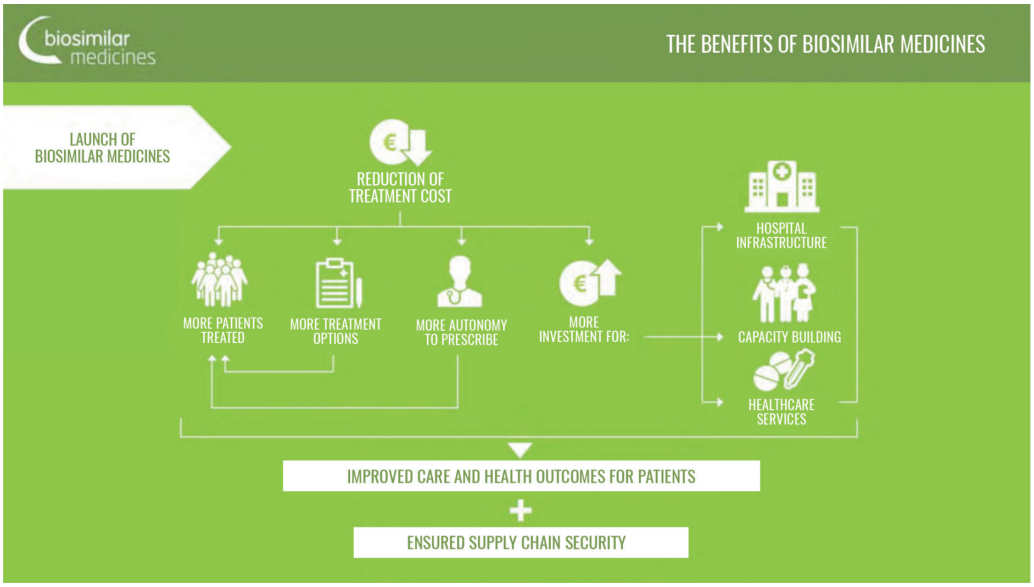
In conclusion, from the point of view of patients and payers, the introduction of biosimilar drugs generates many benefits. The demand for drugs used in oncology and autoimmune diseases is limited by the financial possibilities of the national health care systems. The emergence of newer and cheaper solutions will increase demand bidirectionally, both by covering patients who now cannot afford treatment and by making it possible to treat patients who do not respond well to less safe treatment options.

[15] FDA Biosimilar Product Information: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

[16] "Biosimilars Market 2020 Share, Size, Growth, Trends, Business Analysis, and Regional Forecast to 2026" (July 2019), https://www.fortunebusinessinsights.com/industry-reports/u-s-biosimilars-market-100990

[17] "Biosimilars Market 2020 Share, Size, Growth, Trends, Business Analysis, and Regional Forecast to 2026" (July 2019), https://www.fortunebusinessinsights.com/industry-reports/u-s-biosimilars-market-100990

Table 2: Benefits of biosimilar medicines.[18]



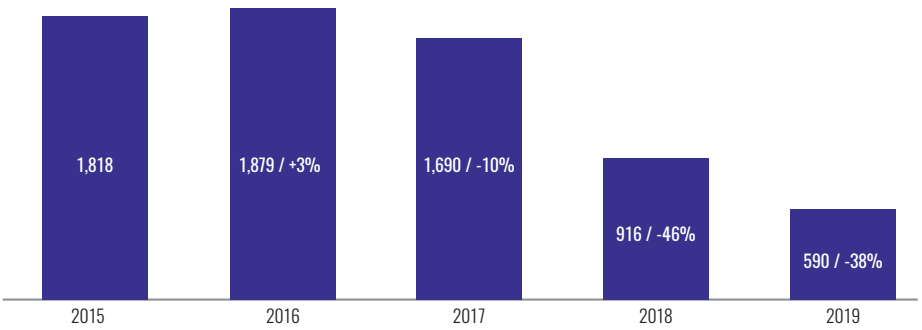
MabionCD20

The drug under the working name of MabionCD20 is the Company's most advanced project. In 2018, the Company elaborated the results of a clinical trial which confirmed the efficacy of the therapy, and submitted applications for registration of the drug in European Union countries. In 2019, the registration procedure for the drug before the EMA was continued, as part of which the Company prepared and presented to the regulator the data requested by the latter concerning the drug and the conducted studies. The Company also acted before the US FDA to confirm the drug's registration strategy in the United States. In 2020, the Company took a decision to change the regulatory strategy for the drug at the EMA by withdrawing the registration applications submitted for the product manufactured in small production scale and obtaining, on the basis of new applications, marketing authorisation directly for the drug produced on a large commercial scale.

While carrying out intensive registration work, the Company continuously monitored the competitive environment for biosimilars of MabThera/Rituxan (Roche) as well as the sales performance of the original medicine.

With regard to Roche's MabThera/Rituxan, since the introduction of the first biosimilar in Europe in 2017, sales of the drug have started to fall. This trend has continued in the following years, with the biggest falls in Europe and Japan. At the same time, it is worth highlighting that a dynamic growth in sales was shown by rituximab biosimilar drugs released on the European and US markets.

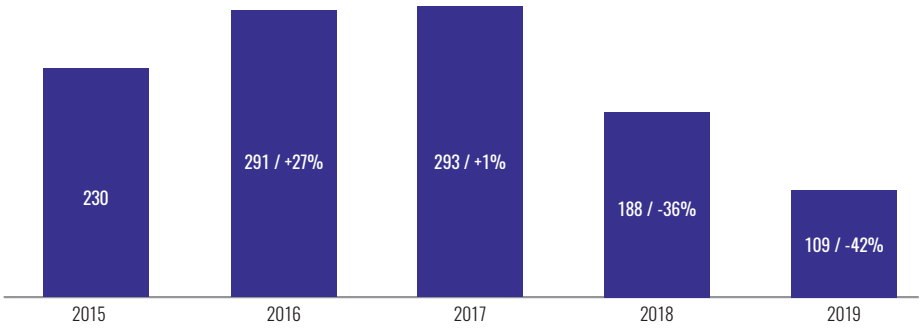
Table 3: Sales of MabThera/Rituxan in Europe 2015–2019



(source: https://www.roche.com/investors/rofis.htm)

[18] http://www.boussiasconferences.gr/files/_boussias_conferences_content/presentations/biosimilars_conference/2018/diogo_piedade_biosimilars_18.pdf

Table 4: Sales of MabThera/Rituxan in Japan 2015–2019



(source: https://www.roche.com/investors/rofis.htm)

In its financial statements for 2019, Roche reports that global sales of MabThera/Rituxan amounted to CHF 6.4 billion (approximately USD 6.5 billion), a drop of 4% YoY (use of the drug in oncological and immunological therapies).[19]

Table 5: Sales of MabThera/Rituxan globally (source: *Roche Finance report*, 2019).

2019 (CHF m)	2018 (CHF m)	% change (CER)	% of sales (2019)	% of sales (2018)
MabThera/Rituxan in oncology				
4,890	5,191	- 6	10.1	11.8
MabThera/Rituxan in immunology				
1,587	1,561	+1	3.3	3.6

Table 6: Sales of MabThera/ Rituxan by region (source: *Roche Finance report*, 2019).

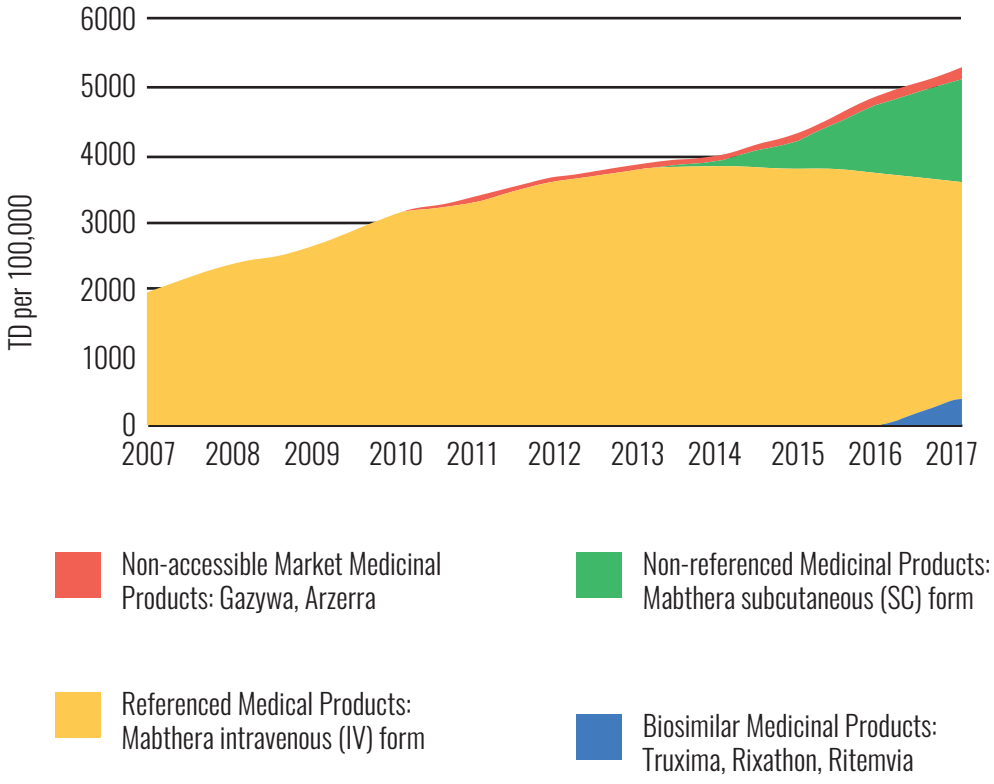
Sales by regions	2019 (CHF m)	2018 (CHF m)	% change (CER)	% of sales (2019)	% of sales (2018)
USA	4,488	4,290	+3	69.3	63.5
Europe	590	916	-33	9.1	13.6
Japan	109	188	-44	1.7	2.8
International sales	1,290	1,358	-1	19.9	20.1
Total sales	6,477	6,752	-4	100	100

As predicted by market analysts (e.g. GlobalData in "Drug Sales and Consensus Forecast View"), sales results for MabThera/Rituxan in the following years will fall.

Anticipating a decline in sales of MabThera/Rituxan due to the introduction of biosimilars, Roche took steps to protect its market share by reformulating the drug. As the data show, this change has had influence on the company's sales results. Roche's defence strategy was to introduce a subcutaneous (SC) version of the drug. Previously, the drug was only available in the intravenous (IV) version, and MabThera/Rituxan biosimilars are available in this very formulation. The sales and price of Roche's subcutaneous version, unlike the traditional formulation, tend to increase[20]. In the USA, the subcutaneous version of the medicine contributed to an increase in sales by 3% in 2019[21].

[19] https://www.roche.com/dam/jcr:1e6cfce4-2333-4ed6-b98a-f6b62809221d/en/fb19e.pdf
[20] "The Impact of Biosimilar Competition in Europe", IQVIA (09.2018)
[21] https://www.roche.com/dam/jcr:1e6cfce4-2333-4ed6-b98a-f6b62809221d/en/fb19e.pdf

Table 7: Sales volume changes before and after the introduction of biosimilar medicines in Europe (source: The Impact of Biosimilar Competition in Europe, IQVIA, September 2018).



In 2017, two biosimilar molecules competing with MabionCD20 entered the European market – the Celltrion's medicine (present on the market under four names: Blitzima, Ritemvia, Rituzena and Truxima) and the Sandoz's medicine (trade names: Riximyo and Rixathon). In November 2018, Celltrion obtained the FDA marketing authorisation for its biosimilar rituximab. Celltrion is thus entitled to sell Truxima in the US market. In January 2020, Pfizer's Ruxience was given a positive opinion by the European CHMP. The drug has already been approved by the US regulator (July 2019).

According to Celltrion, as early as the beginning of 2019, Truxima won 35% of the original MabThera/Rituxan market in Europe in 2018. The market share in the five main countries (United Kingdom, Germany, France, Italy and Spain) was 36%, and this market represents 70% of the European rituximab market[22]. By mid-2019, the Truxima's European market share was already at 38% and continued to grow[23]. In November 2019, Truxima appeared on the American market, which accounts for 56% of global rituximab sales and is valued at USD 4.3 billion[24]. Sandoz is not publishing its sales results for the MabThera/Rituxan biosimilar. In its 2019 summary of results, it reported a global increase in biopharmaceutical sales to USD 1.6 billion (+ 16% cc), through a double-digit growth in European sales of drugs such as Hyrimoz (adalimumab), Rixathon (rituximab) and Erelzi (etanercept).[25]

Currently, the demand for drugs used in oncology and autoimmune diseases exceeds the production capacity of suppliers and is limited by the financial capacity of the national health care systems. According to the independent analytical report by DM PKO BP (19.02.2020), MabionCD20 by Mabion has a chance to gain a 8% share in the European market and 10% in the American market. Taking into account the global market value of USD 8 billion, the authors of the report expect income per 1% of the market share at a level of about PLN 200 million.

22 http://www.koreabiomed.com/news/articleView.html?idxno=4873
23 https://pulsenews.co.kr/view.php?year=2019&no=923004
24 https://pulsenews.co.kr/view.php?year=2019&no=923004
25 https://www.globenewswire.com/news-release/2020/01/29/1976523/0/en/Novartis-delivered-strong-sales-growth-margin-expansion-and-breakthrough-innovation-launching-five-NMEs-in-2019.html

Innovative biotech drug - MabionMS

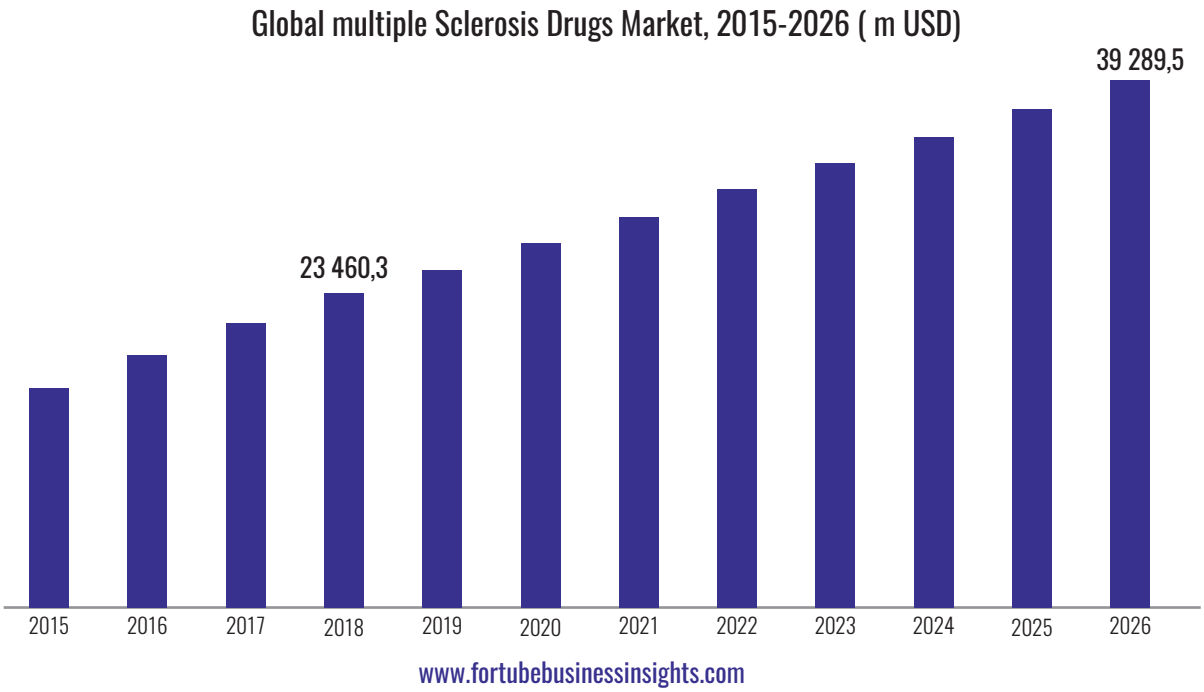
In 2017, the Company filed a European patent application with the Patent Office of the Republic of Poland, with the possibility of extension under the PCT procedure, on the basis of which it intended to apply for legal protection for its invention called "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand". The subject of the patent application was an innovative therapy for the treatment of multiple sclerosis patients using the MabionCD20 antibody combined with other substances (MabionMS combination therapy project). In 2018, the Company filed an application with the European Patent Office in the Hague to extend, under the PCT procedure, the patent protection for the above mentioned invention. In order to avoid a dangerous situation in which the Patent Office would accuse the Company of an attempt at double patenting the same scope of protection, in 2019 the Company withdrew its original European application in order to benefit from the protection granted on the basis of the international application (also covering the European area). This was a procedural measure aimed at optimising the process.

In 2018, the Company filed a European patent application with the Patent Office of the Republic of Poland, with the possibility of extension under the PCT procedure, for the area of application of MabionCD20 in the treatment of patients suffering from multiple sclerosis (MS), titled "Low aggregate anti CD20 ligand formulation" (MabionMS project). The application concerned the use of MabionCD20 on a monotherapy basis.

Submitting the above patent applications is important as these are the first research projects carried out by the Company on innovative therapies and in the case of their success and obtaining protection, it may have a positive impact on the future economic, property and financial situation of Mabion S.A.

According to the "Multiple Sclerosis Drugs Market" report (May 2019) published by Fortune Business Insights, the multiple sclerosis medicine market will feature a CAGR of 6.7% and will be worth USD 39 billion by 2026[26]. This is due to the enormoous and still growing demand for therapies in this indication. According to research carried out by the Multiple Sclerosis Foundation, about 2.3 million people around the world live with MS.[27]

Table 8: Value of the multiple sclerosis drug market between 2015 and 2026 (source: Fortune Business Insights[28])



[26] https://www.medgadget.com/2020/02/multiple-sclerosis-drugs-market-size-growth-2020-global-analysis-by-share-value-trends-merger-business-insights-leading-players-statistics-competitive-landscape-and-regional-forecast-to-2026.htm

[27] https://www.medgadget.com/2020/02/multiple-sclerosis-drugs-market-size-growth-2020-global-analysis-by-share-value-trends-merger-business-insights-leading-players-statistics-competitive-landscape-and-regional-forecast-to-2026.html

[28] https://www.fortunebusinessinsights.com/industry-reports/multiple-sclerosis-drugs-market-100386

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

» Ocrelizumab (trade name: Ocrevus) – a Roche drug. Ocrevus is intended for the treatment of recurrent forms of multiple sclerosis and originally progressive multiple sclerosis, a highly impairing MS form. The drug was launched on the EU market on 8 January 2018;

» Glatiramer acetate (trade name: Copaxone) – a Teva drug, which is a combination of four amino acids (proteins) that influence the immune system. It is used to treat people with recurring forms of multiple sclerosis. Copaxone does not cure MS, but it can make the recurrence less frequent. The medicine was placed on the EU market on 7 April 2003;

» Fingolimod (trade name: Gilenya) – a drug of Novartis Europharm Ltd., which is used in the treatment of the recurrent highly-active multiple sclerosis in adults. The drug was launched on the EU market on 17 March 2011;

» Teriflunomide (trade name: Aubagio) is a drug of the Sanofi-Aventis group, used in multiple sclerosis in patients with exacerbated symptoms periods (relapses) followed by regeneration periods (remissions). The drug was placed on the EU market on 26 August 2013;

» Interferon beta-1b (e.g. Extavia – a biological drug of Novartis Europharm Ltd.), which is administered 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. Biogen's Avonex) is available in many forms, including intramuscular, subcutaneous and pegylated preparations for injection. It is used in patients with diagnosed recurrent form of multiple sclerosis;

» Dimethyl fumarate (trade name: Tecfidera) – a drug of Biogen Idec Ltd. used especially in adults with the MS type known as recurrent multiple sclerosis, in which the patient has exacerbated symptoms periods (relapses), followed by regeneration periods (remissions). The medicine was placed on the EU market on 30 January 2014;

» Natalizumab (trade name: Tysabri) – a humanised monoclonal antibody of Biogen, used in the absence of effectiveness of first-line therapy and in the aggressive form of multiple sclerosis. The drug was placed on the EU market on 27 June 2006;

» Alemtuzumab (trade name: Lemtrada) is a humanised monoclonal antibody produced by Sanofi. It is used in the active relapsing-remitting MS. The drug was placed on the EU market on 12 September 2013;

» Mitoxantron (e.g. Mitoxantron-Ebewe – a drug of EBEWE Pharma) used in the secondary progressive form of MS or in the relapsing-remitting form – as a second- or third-line therapy when first line medicines have proven ineffective.

MabionMS is an innovative therapy based on rituximab as the active substance, used in the treatment of multiple sclerosis. Similarly to ocrelizumab, rituximab binds specifically to the CD20 receptor on B lymphocytes. The mechanism of action is the same as in ocrelizumab. The safety data for this antibody are favourable. It has been used in the treatment of leukaemia, lymphoma and rheumatoid arthritis for several years, therefore there is an extensive database of a beneficial safety profile of this antibody in these indications.

The company currently has at its disposal a technology to produce this antibody and has highly-developed analytical tools. Moreover, it has already obtained the results of clinical trials conducted with patients suffering from rheumatoid arthritis and lymphoma. As a result of the research, the Company has thoroughly digested the clinical parameters of MabionCD20, including the mechanism of action and the safety profile. Taking this knowledge into account, as well as analysing the competitive multiple sclerosis therapies presented above, it is highly probable that MabionCD20 should have a high potential to treat this disease.

This will be an innovative therapy, as no such indication has been registered for rituximab yet. However, based on the available clinical data, the Company expects a favourable safety profile due to the much lower toxicity of MabionCD20 compared to the adverse effects of chemical drugs used to treat MS, while being highly effective. For biological drugs, such as Ocrevus, the patients and health systems in the European Union will benefit from the price. Ocrevus is an expensive drug. The price of 1 vial of concentrate to prepare a solution for infusion of 300 mg and 10 ml is on average USD 16,974, i.e. over PLN 73 thousand[29]. The recommended dose is 600 mg every 6 months, so to obtain the cost of annual therapy for one patient, you should multiply this amount by four. Knowing the prices of this medicine, as well as having the MabionCD20 manufacturing technology at its disposal, and thus being able to estimate the costs of a new therapy, the Company may assume that its therapy will be more attractive in terms of price compared to treatment with ocrelizumab.

Additionally, safety issues are a problem in the therapy of MS Ocrevus as these are worse selected parameters than for other biological drugs. One of the examples of such parameters are relatively frequent cases of PML (Progressive multifocal leukoencephalopathy)[30], observed in MS Ocrevus therapy. The Company has not found any reports indicating the occurrence of PML cases when administering rituximab in this indication, and a relatively small number of PLN cases in the main indications (RA[31] and NHL[32]). Moreover, a higher number of cases of breast cancer and other malignant neoplasms were observed in the MS Ocrevus study[33], which resulted in the FDA's recommendation to specifically follow up these safety parameters in post-marketing studies and long-term observation of patients undergoing therapy. In the case of rituximab, the safety studies conducted for almost two decades have not shown any serious concern as to the increased risk of cancer incidence as a result of therapy[34]. An attempt has also been made to use Ocrevus in RA, but for safety reasons these clinical studies have been discontinued (serious and opportunistic infections have been reported, some of which have caused the death of patients)[35].

According to GlobalData experts, the multiple sclerosis therapy market is moving towards earlier and more aggressive treatments. In the USA, research is being conducted on the introduction of therapies based on monoclonal antibodies already in people who have just been diagnosed with multiple sclerosis. The results indicate that starting such a therapy is beneficial, that monoclonal antibodies may become first-line drugs in most patients and this will be a major paradigm shift in the treatment algorithm[36].

2.3 Regulatory environment

Worldwide, standards for the registration of biological medicines, including biosimilar medicines, are complex and very demanding. In highly-regulated market (e.g. Europe, United States, Japan, Canada), regulators require to meet strict quality, safety and efficiency criteria. Companies wishing to register a drug on regulated markets must provide detailed product characteristics (physicochemical and biological analyses) 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 a drug in the indications analysed during clinical trials (US and Canada) or in all indications approved for the reference medicine (EU).

In the context of an overall development strategy, it is clear that most often several clinical trials are required, probably using products originating from different versions of the manufacturing process, to generate the data necessary for registration. The purpose of the guidelines is to address the quality requirements of the investigational medicinal product for a given clinical

[29] https://www.drugs.com/price-guide/ocrevus

[30] Clinical trials and post-marketing experience; www.ocrelizumabinfo.global

[31] Clifford DB, Ances B, Costello C, et al. Rituximab-associated progressive multifocal leukoencephalopathy in rheumatoid arthritis. Archives of neurology. 2011;68(9):1156-1164

[32] Tuccori M, Focosi D, Blandizzi C, et al. Inclusion of rituximab in treatment protocols for non-Hodgkin's lymphomas and risk for progressive multifocal leukoencephalopathy. The oncologist. 2010;15(11):1214-1219

[33] Canadian Agency for Drugs and Technologies in Health; 2018 May.

[34] Wadström H, Frisell T, Askling J; Anti-Rheumatic Therapy in Sweden (ARTIS) Study Group. Malignant Neoplasms in Patients With Rheumatoid Arthritis Treated With Tumor Necrosis Factor Inhibitors, Tocilizumab, Abatacept, or Rituximab in Clinical Practice: A Nationwide Cohort Study From Sweden. JAMA Intern Med. 2017 Nov 1;177(11):1605-1612

[35] Emery P, Rigby W, Tak PP, et al. Safety with ocrelizumab in rheumatoid arthritis: Results from the ocrelizumab phase III program. PLoS ONE 2014; 9: e87379

[36] GlobalData, Multiple Sclerosis: Dynamic Market Forecast to 2026, November 2018

trial. For all phases of clinical development, it is the responsibility of the sponsor (namely the entity responsible of undertaking, running and financing the clinical trial) to ensure patient safety in the clinical trial using a high-quality investigational medicinal product (IMP).

Pharmerging markets such as China, Brazil, India, Russia, Mexico, Turkey or South Korea, as well as other countries, have developed or are developing their own legislative frameworks setting out the conditions for registration of biosimilar medicines. These rules are often vague and the definition of biosimilars themselves is imprecise. In many pharmerging countries, unclear regulations and insufficient patent protection have already led to the registration of preparations similar to patented original medicines registered in these markets. An example of this is India, where since 2007 a medicine has been on the market which is a copy of rituximab but has been registered on the basis of a far less extensive clinical trial scheme than required in the European Union. Also in China, biosimilar drugs similar to the original oncological preparations and erythropoietin have been registered. It is likely that these medicines could not have been approved in the strict regulatory process required to authorise biosimilar medicines in the European Union. The EMA regulatory requirements ensure the same high standards of quality, safety and efficacy of biosimilars as for original biologicals, as well as rigorous comparative testing with the reference product[37]. It is worth noting, however, that in 2012, a drug named Kikuzubam was registered in Mexico. The medicine was quickly withdrawn from the market by the regulatory authority due to documented anaphylactic reactions and lack of clinical data[38]. This example confirms that regulatory agencies, even in less regulated markets, are increasingly conscientious, which in our view is beneficial to the Company.

Guidelines of the European Medicines Agency (EMA) of 2019

On 1 July 2019, the EMA Guideline on the reporting of physiologically-based pharmacokinetic (PBPK) modelling and simulation entered into force. Although PBPK modelling is currently mentioned in several other existing EMA guidelines, this is the first study that specifically provides detailed advice on what to include in a PBPK modelling report, including detailed information on the predictive performance of the drug model. If PBPK modelling is to support a regulatory decision, the PBPK platform must be qualified for its intended use. Therefore, the document in consideration also aims to clarify the supporting data required to qualify the PBPK platform accordingly.

On 1 August 2019, the EMA Guideline on the investigation of subgroups in confirmatory clinical trials came into force. The purpose of this document is to provide guidance to assessors at European regulatory agencies on the assessment of subgroups in confirmatory clinical trials that are presented in the marketing authorisation applications. These considerations affect the planning of a clinical trial and therefore the document should also be useful for clinical trial sponsors and assessors providing scientific advice. The guideline in consideration describes the assessment principles and strategies and does not impose any specific statistical methodology to estimate or test the effect of a treatment and its consistency within subgroups of the trial population.

Guidelines of the US Food and Administration Agency (FDA) of 2019

In January 2019, the FDA guideline titled "Immunogenicity Testing of Therapeutic Protein Products - Developing and Validating Assays for Anti-Drug Antibody Detection" was published. The guideline presents recommendations to facilitate the development and validation of tests to assess the immunogenicity of therapeutic protein products during clinical trials.

In March 2019, a draft version of the FDA guideline titled "A Risk-Based Approach to Monitoring of Clinical Investigations" was published. This document provides guidance on risk-based approaches to monitoring research on medicines and biological products for human use, medical devices and combinations thereof, and recommendations for planning the monitoring approach, developing the content of the monitoring plan, and addressing and communicating the results of monitoring.

In the same month, the FDA issued a guideline titled "Enrichment Strategies for Clinical Trials to Support Determination of Effectiveness of Human Drugs and Biological Products". The purpose of the guideline is to support industry in developing

[37] http://www.gabionline.net/Biosimilars/General/Biosimilars-of-rituximab

[38] Biosimilars in rheumatology: current perspectives and lessons learnt, T Dörner, J Kay - Nature Reviews Rheumatology, 2015

enrichment strategies that can be used in clinical trials to demonstrate the efficacy of medicines and biological products. Such enrichment allows the prospective application of any patient characteristic to select a population for investigation in which the effect of the drug (if actually present) is more likely to be detected than in an ordinary population.

In May 2019, a draft version of the guideline titled "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations" was published. This guideline describes the FDA recommendations for the design and evaluation of comparative analytical tests to demonstrate that the proposed monoclonal antibody is biosimilar to the reference product.

In May 2019, the FDA issued a guideline titled "Considerations in Demonstrating Interchangeability With a Reference Product" to help sponsors demonstrate that their therapeutic protein product can be used interchangeably with a reference product and to review important scientific considerations in demonstrating the interchangeability of the proposed therapeutic protein product.

In May 2019, also a draft guideline for document submission (Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics) was released. This guideline aims to encourage sponsors and applicants who use Real-World Data (RWD) to generate Real-World Evidence (RWE) as part of the registration applications submitted to the FDA, to provide information on RWE use in a simple, uniform format.

Over the past few decades, FDA policy initiatives have focused on promoting recruitment practices that lead to clinical trials better reflecting the population that is most likely to use the drug once it is released. In June 2019, an industry guidance was published to enhance the diversity of clinical trial populations ("Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs"). Its main idea is to broaden the eligibility criteria for participants (currently many people are excluded from participation without a clear clinical reason).

In June 2019, instructions developed by the FDA were also released: "Instructions for Use - Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products". They describe how patient information should be presented.

A document to help sponsors apply the population pharmacokinetic analysis ("Population Pharmacokinetics - Guidance for Industry") was also published this month. This guideline includes recommendations for sponsors on the labelling of medicines based on population pharmacokinetic analysis and on the general expectations regarding the format and content of population pharmacokinetic reports submitted to the Agency.

In July 2019, the FDA released a document ("Risk Evaluation and Mitigation Strategies: Modifications and Revisions") containing information on how the FDA defines the types of changes to the approved Risk Evaluation and Mitigation Strategies (REMS), how application holders should submit changes to the approved REMS and how the FDA will process applications for REMS changes submitted by the change owners.

August 2019 was an important month for industry due to a document on the use of placebo and blinding in randomized controlled cancer clinical trials for drugs and biological products ("Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products"). In schemes for malignant hematological and oncological diseases, the use of placebo may raise practical and ethical concerns. The FDA has given consideration to unblinding patients in some cases, which would allow informed decisions on additional treatment options.

In September 2019, a guideline titled "Evaluation of Internal Standard Responses During Chromatographic Bioanalysis: Questions and Answers" came into force. This guideline provides recommendations to sponsors, applicants and contract research organisations on the variability of the internal standard responses in chromatographic methods submitted during the registration of biological medicines.

In November 2019, the FDA prepared a document ("Adaptive Designs for Clinical Trials of Drugs and Biologics") that provides guidance on the proper use of adaptive designs for clinical trials to provide evidence for the efficacy and safety of a medicine or biological medicine. The guidelines describe important principles for designing, conducting and reporting the results of trials, and advise sponsors on the types of information to be sent to facilitate the FDA assessment of clinical trials with adaptive designs to improve the efficacy and safety of medicines.

In December 2019, the updated FDA's guideline on the approach to bridging trials in new drug applications (NDAs) or biologics license applications (BLAs), "Bridging for Drug-Device and Biologic-Device Combination Products Draft Guidance for Industry December 2019", came into force. The guidance explains how to combine data from different development programmes in support of a registration application.

The FDA positively evaluated the activities of the Main Pharmaceutical Inspectorate within the scope described in the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMP). This is part of the agreement between the European Union and the United States of America on mutual recognition of inspections of medicinal products and active substance manufacturers. The positive result allowed Poland to join this agreement.

Guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - ICH) applicable both to Europe and the United States (2019)

Between 10 May and 30 September 2019, an open public consultation was held on a new draft guideline by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, no. E8 R1) on general considerations for clinical trials. This guideline is the first revision of the ICH in consideration. The latest draft clearly focuses on critical quality factors in order to protect subjects and generate reliable data. E8 (R1) also states that the quality of clinical trials depends on good design and enforcement of good design of the project. For the first time, risk is introduced as a quality factor; i.e. identification of factors critical to quality (CTQ), probability and impact of risk, together with the implementation of a control process to manage risk.

In May 2019, ICH guideline Q3D(R1) titled "Elemental Impurities" was published. This guideline recommends the level of elemental impurities acceptable in a medicinal product to be controlled as part of the established permitted daily exposure (PDE) for each component of toxicological concern.

In the same month, ICH guideline document E8(R1), "General Considerations for Clinical Studies) was updated. It focuses on quality design in clinical trials, taking into account the diversity of clinical trial designs and data sources used to support regulatory and other health policy decisions.

In July 2019, the ICH E9 (R1) Addendum on statistical analyses in clinical trials concerning estimands and sensitivity analyses also entered into force.

In September 2019, the ICH closed the consultation period for draft ICH guideline M10 on validation of bioanalytical methods. These methods are used to assess the amount of drugs in biological matrices to assess the safety and efficacy of drugs. The guideline aims to ensure that analytical methods are appropriately characterised, validated and documented to provide reliable data for regulatory decisions.

2.4 Listing Information

The Company's core business in the future will be the development, manufacture and sales of the medicines which are currently at various stages of development. In 2019, the Company did not generate sales revenues, focusing on the implementation of own projects and work related to the registration procedure for MabionCD20.

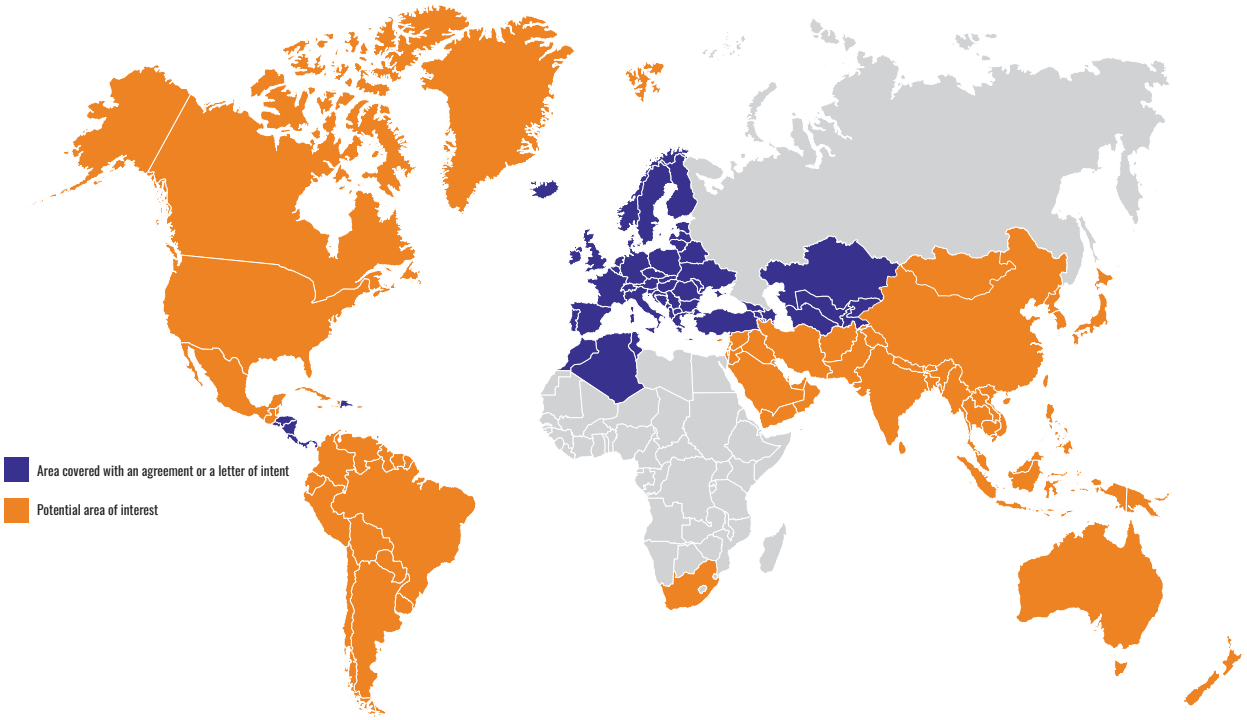
In 2019, Mabion S.A. continued its cooperation with Plexus Ventures LLC, which supports the Company in obtaining a partner for the sale and distribution of MabionCD20 on the global market. Numerous meetings and discussions with potential partners

in the non-European market were organised. The negotiation process in this area is complicated, since the offers concern both independent and several connected regions. it is also spread over time, because it is necessary to take into account issues related to the implementation of the appropriate provisions of partnering agreements on both sides, that is elements naturally occurring in business negotiations.

The American, Chinese and Japanese markets should be treated separately due to their specificity. Regulators in less regulated countries often consider the EMA and FDA guidelines as leading guidelines, which means that it is unlikely that MabionCD20 will be registered in any of these countries before it is registered with the EMA or the FDA.

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

Table 9. Markets for which the Company has entered into distribution agreements, signed letters of intent or which are under discussion with potential distributors.



2.5 Procurement sources

The Company carries out development work to obtain biotechnological medicines. The degrees of development of various projects differ. In 2019, work was conducted on all possible molecular levels, from developing molecular biology techniques at the DNA level through obtaining a 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 advancement of technologies developed in Mabion and the much differentiated level of project topics, the Company uses a very wide range of products and services available on the market. The research and development work is characterised 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 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 characterised reagents or outsourcing analyses to appropriately certified bodies.

In 2019, the Sartorius group was the only supplier with Company's purchases reaching over 10% of its annual operating costs (decreased by the costs of employee remunerations), supplying consumables, production equipment and analytical services, with a share in purchases of 12.98%.

None of the entities of the Sartorius Group is related to Mabion S.A.

The Company has been cooperating closely with the Sartorius group for many years in the field of supplies of process equipment and consumables. These goods are directly related to the "single use" technology employed in the Company and withdrawal of the Sartorius group from cooperation would require Mabion S.A. to find an alternative supplier, a situation that could threaten the continuity and profitability of the production process.

In the Company's opinion, Sartorius is its key supplier, on which the Company is significantly dependent. In order to prevent possible risks in this area, the Company takes into account alternative solutions by monitoring the market of producers and suppliers. Nevertheless, there are certain technological limitations in the current plant, so the scope of possible changes is limited.

2.6 Main domestic and foreign investments

In 2019, the Company did not make any significant investments in securities, financial instruments, intangible assets or property, plant and equipment.

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

2.7.1 Significant agreements relating to operating activities

In 2019, the Company did not enter into any significant agreements concerning its operating activities.

2.7.2 Other agreements relating to operating activities

On 31 January 2019, the Company entered into an agreement with IMA S.A. with its registered office in Bologna (Italy) ('IMA') under which IMA undertook to manufacture and sell to the Company the packaging line necessary to carry out the process of packaging the vials with the finished product in an outer packaging, including delivery, installation, commissioning, qualification and training. The value of the agreement is EUR 1.83 million. . Due to a number of incompatibilities on the part of the manufacturer, the specificity of the order and the need to involve many parties in the implementation of the subject of the agreement, it was not completed on time (November 2019).. At the end of January 2020, the acceptance of the line was started at the manufacturer's headquarters in Italy, however the manufacturer did not meet all the criteria and no final acceptance was made. Currently, due to the SARS-COVID 19 pandemic , it is not possible to carry out tests and acceptance again. In the current situation, it is also difficult to determine when this will be possible. However, the Company does not identify any risk relating to the implementation of this agreement.

In connection with the expiration of the lease agreement concerning office, service and warehouse space at ul. Fabryczna 17 in Łódź on 31 December 2019, the Company entered into a new lease agreement on 17 December 2019 for a period of 4 years from 1 January 2020. The site houses a research and development laboratory for biotechnological medicinal products.

2.7.3 Agreements relating to loans and borrowings received in 2019

The Company did not entered into any loan agreements with related parties in 2019. As at 31 December 2019, there are no loans from related parties not repaid by the Company.

As at the balance-sheet date, the Company has a bank loan resulting from the Agreement concluded on 17 July 2018 with Santander Bank Polska S.A. The amount of the Loan granted is PLN 30 million, whereas the disbursement of PLN 15 million

was possible after meeting the formal and legal conditions and the establishment of collaterals. An amount beyond the PLN 15 million may be disbursed after the Company has received a positive decision of the European Medicines Agency concerning the registration of MabionCD20. The Loan bears interest at a variable rate and is based on WIBOR 1M plus the Bank's margin determined on arm's length terms. The collateral for the Loan is a first-rank contractual mortgage up to the maximum amount of PLN 45 million established on the Company's ownership right of the real estate in Konstantynów Łódzki and an assignment of receivables to the Bank under an insurance contract for the buildings/structures on that real estate, a declaration 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 an amount constituting 150% of the amount of Loan, and a surety and other forms of collateral granted by entities related to the Company (main shareholders of the Company). The agreement provides for numerous obligations of the Company towards the Bank and envisages situations constituting 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.

The Company used the first tranche of the loan of PLN 15 million in 2019 Q4. The loan matures on 17 July 2020 and the agreement expires on 17 July 2020.

On 21 October 2019, the Company agreed with the European Investment Bank ('EIB') on financing conditions for granting the Company an unsecured loan disbursed in three tranches, to be mobilised upon fulfilment of certain conditions, up to a total amount of EUR 30 million. The terms of the Financing Agreement stipulate that particular tranches of financing will be repaid within 5 years from the date of disbursement of respective tranches. The loan availability period is 36 months from the date of conclusion of the Financing Agreement. It bears interest at a fixed interest rate not exceeding 2.7% per annum. The Financing Agreement contains restrictions, inter alia, with respect to the disposal of material assets and their encumbrance, granting loans and guarantees, as well as with respect to the payment of dividends and incurring financial liabilities exceeding the agreed amounts. A breach of the Company's obligations specified in the Financing Agreement will entitle the EIB to demand immediate repayment of the loan.

As at 31 December 2019, the Company did not use the facility granted by the EIB.

2.7.4 Agreements relating to loans or borrowings terminated or dissolved in 2019

In the financial year 2019, no loan or borrowing agreements were terminated or dissolved.

2.7.5 Agreements relating to borrowings granted

In the financial year 2019, the Company did not grant any borrowings.

2.7.6 Sureties and guarantees

In the reporting period ended 31 December 2019, the free of charge surety granted by Glatton Sp. z o.o. to the Company in 2018, in the amount up to PLN 45 million, was in force. The surety relates to the revolving loan agreement of 17 July 2018 concluded with Santander Bank Polska S.A. (formerly Bank Zachodni WBK S.A.) for a period of two years to finance the Company's operations.

In 2020, the Company signed an agreement on arm's length with the above mentioned related entity, governing the rules of payment for the surety referred to above.

2.7.7 Transactions with related parties

In 2019, the Company did not enter into transactions with related parties on terms other than arm's length.

2.8 Information on other significant events

2.8.1 Significant events and factors during the financial year

March

On 20 March 2019, an inspection was carried out in the Company regarding the implementation of the condition of permit no. 203 of 12 April 2012 to operate in the Łódź Special Economic Zone (LSEZ) concerning the completion by 31 December 2018 of the construction of a new manufacturing plant for technologically innovative biotechnological medicines used in the targeted treatment of cancer, immune system disorders, and metabolic diseases, in the LSEZ - Łódź Subzone, Complex 1. On the basis of the control activities, it was concluded that the aforementioned condition has been implemented. The Company incurred investment expenditures in the total amount of about PLN 74.6 million, out of which PLN 45 million are eligible investment costs. This information was published in Current Report no. 5/2019 of 20 March 2019.

April

On 1 April 2019, the Company received a letter from the Turkish Ministry of Health concerning the issue of compliance of the Company's Scientific and Industrial Complex for Medical Biotechnology in Konstantynów Łódzki (Complex) with the Good Manufacturing Practice (GMP) requirements recognised in the territory of Turkey. The letter was issued as a result of an inspection carried out at the Complex in February 2019 by the Turkish Medicines and Medical Devices Agency. According to the letter, no critical non-conformities were found during the inspection. The issues to be completed were few and, in the Company's opinion, easy to correct and therefore the Company positively assesses the inspection and the nature of comments received. The Company responded to this letter by submitting a schedule of Correcting and Preventive Actions to the Turkish Ministry of Health, to which the Turkish party did not raise objections. At present, the Company is in contact with the Turkish regulator for further proceedings to file registration documentation for MabionCD20 in Turkey. A positive verification of the GMP system with respect to Turkish requirements is a necessary event for the submission of a dossier in Turkey and the event is the first milestone in this regard. Turkey has its own independent regulatory system and therefore European certification does not ensure GMP status in Turkey. This information was published in Current Report no. 6/2019 of 1 April 2019.

On 3 April 2019, the Management Board of the Company adopted a resolution approving changes in the current strategy of development of medicinal products. In accordance with the resolution, the catalogue of projects which the Company, now or in the future, on its own or with partners, is interested in implementing was changed. The Company also qualified scientific and research projects to three groups of projects, i.e. active projects, new projects planned for 2019, and partner projects. Information on the updated development strategy for medicinal products can be found in point 4.2 of this report. This information was published in Current Report no. 8/2019 of 3 April 2019.

On 24 April 2019, the Company submitted answers to questions received from the European Medicines Agency (EMA) as part of Day 120 of the registration procedure for MabionCD20 at the EMA (Day 121). This information was published in Current Report no. 10/2019 of 24 April 2019.

On 25 April 2019, Mr. Artur Chabowski tendered his resignation from the position of President of the Management Board of the Company. The resignation came into force on 30 June 2019. This information was published in Current Report no. 11/2019 of 25 April 2019.

May

On 6 May 2019, the Company received a confirmation from a partner that the duplicate application for the drug under the working name of MabionCD20 was correctly submitted to the EMA. Submitting the duplicate application, if the registration procedure is successful, was to enable the Company to obtain an additional trade name for the drug, for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). In the Company's opinion, this action was to accelerate the commercialization of the drug under the working name of MabionCD20 in markets where RA is still

protected by a patent for MabThera. On 27 May 2019, the Company received information about the positive conclusion of the validation of the above application by the EMA and thus its acceptance into the evaluation procedure. This information was published in Current Reports no. 13/2019 of 6 May 2019 and no. 15/2019 of 27 May 2019.

June

On 12 June 2019, an inspection took place in the Company concerning the Company's implementation of the condition of permit no. 203 of 12 April 2012 to operate within the Łódź Special Economic Zone (LSEZ) in terms of maintaining at least 30 employees in the LSEZ between 1 January 2017 and 31 March 2019. This was the last condition necessary for the Company to obtain the right to take advantage of the tax exemption when conducting business within the LSEZ. On the basis of the control activities, it was concluded that the aforementioned condition has been fulfilled. The Company informed the EIB about obtaining the above mentioned permit in Current Report no. 10/2012 of 16 April 2012, and about meeting the previous conditions of this permit – in Current Reports No. 5/2017 of 11 January 2017 and no. 5/2019 of 20 March 2019. The Company informed about the fulfilment of the last condition of the permit in Current Report No. 16/2019 of 12 June 2019.

July

On 1 July 2019, the Company received a second round of questions from the European Medicines Agency as part of the registration procedure for the drug under the working name of MabionCD20 (Day 180). The Company informed about the event in Current Report no. 20/2019 of 1 July 2019.

On 23 July 2019, the Company was informed that as a result of an inspection carried out by the Main Pharmaceutical Inspectorate (MPI), it obtained a GMP (Good Manufacturing Practice) certificate for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki in the field of active substance manufacturing (Rituximab). The MPI inspection was commissioned by the EMA as part of the evaluation of the application for marketing authorisation of MabionCD20, submitted by the Company. The GMP certificate confirms that the Company conducts production processes in accordance with GMP principles in the scope of manufacturing of the active substance (Rituximab) used to obtain the finished product. This is the first certificate in the above-mentioned scope that the Company has obtained so far. The certificate is valid for 3 years from the last day of inspection (i.e. 17 May 2019). The Company informed about the event in Current Report no. 21/2019 of 23 July 2019.

On 25 July 2019, the Company received a letter from the EMA informing that on the basis of an inspection carried out by MPI on behalf of the EMA, classified as a pre-authorisation inspection concerning the drug under the working name of MabionCD20, the Authority considers that the manufacturing processes in the Company are in accordance with the principles and guidelines of Good Manufacturing Practice (GMP) specified in Directive 2003/94/EC. The findings of the inspection allowed the inspectors to recommend the EMA to classify the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki as a manufacturing site for the drug under the working name of MabionCD20. This was one of the milestones in the registration process of MabionCD20. The Company informed about the event in Current Report no. 22/2019 of 25 July 2019.

August

On 14 August 2019, the company received information from Mylan's legal department that, following information on the intention to merge Mylan NV (Mylan) with Upjohn, a spin-off entity of the Pfizer group, they do not anticipate at that time that the planned merger would affect cooperation between Mabion and Mylan in registering MabionCD20 in the European market and the Development and Commercialization Agreement between Mabion and Mylan. The Company informed about signing the Development and Commercialization Agreement in Current Report no. 31/2016 of 8 November 2016. This state of affairs is confirmed by the fact that the cooperation between the Company and Mylan proceeds in accordance with the adopted assumptions, and meetings of working groups are held regularly and adequately to the needs of work related to the process of registration of MabionCD20 at the EMA. However, it cannot be excluded that Mylan's position will change in the future. Mabion has no influence on the extent of third party cooperation, and it is possible that the newly created entity's drug development

strategy will be competitive to Mabion. In the Company's opinion, possible changes in the scope of cooperation with Mylan should not affect sales of MabionCD20 in the future due to the form of distribution of this medicine (cyclically changing lists of products reimbursed by health systems) and market capacity. The Company is in ongoing contact with Mylan representatives. The Company informed about the event in its Current Report no. 24/2019 of 14 August 2019.

On 19 August 2019, the Company was informed that as a result of an inspection carried out by MFI, it obtained a GMP certificate for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki for the following manufacturing operations: production of sterile forms of biotechnological products, quality control tests, batch release, and packaging of medicinal products. This is the second GMP certificate obtained by the Company as a result of an MFI inspection commissioned by the EMA as part of the assessment of the application for marketing authorisation of MabionCD20. The GMP certificate in consideration confirms that the Company conducts its manufacturing processes in accordance with the principles of GMP in the above-mentioned scope. The certificate is valid for 3 years from the last day of the inspection (i.e. 17 May 2019). The obtained GMP certificates are necessary for manufacturing, registration and commercialization of MabionCD20. The Company informed about the event in Current Report no. 25/2019 of 19 August 2019.

October

On 21 October 2019, the Management Board of Mabion S.A. agreed with the European Investment Bank (EIB) on financing conditions for an unsecured loan for the Company in three tranches, to be disbursed under certain conditions, up to a total amount of EUR 30 million, upon conclusion of relevant documentation, including a Financing Agreement and an agreement on issuing subscription warrants to the EIB (Warrant Agreement). On the same day, the Management Board of Mabion S.A. adopted a resolution on the decision to conclude financing documentation, including the Financing Agreement and the Warrant Agreement, under conditions agreed with the EIB. As regards the adoption of the resolution in consideration on 21 October 2019, the Supervisory Board of the Company issued a positive recommendation to the Management Board. On the basis of financing conditions agreed with the EIB, the Financing Agreement was signed on 24 October 2019, and on 31 October 2019, the Warrant Agreement was signed.

The funds raised under the loan will be used to finance investment and R&D projects, including the development of biosimilar and innovative biological drugs in Poland, and the expansion of the Company's R&D infrastructure and production capacity. The terms of the Financing Agreement stipulate that individual tranches of financing will be repayable within 5 years from the date of disbursement of respective tranches. The loan availability period is 36 months from the date of the Financing Agreement. The loan bears interest at a fixed interest rate, not exceeding 2.7% per annum. The Agreement imposes restrictions on the Company, among other things with respect to the disposal of significant assets and their encumbrance, granting loans and guarantees, as well as with respect to the payment of dividends and incurring financial liabilities above the agreed amounts. Breaching the Company's obligations specified in the Financing Agreement will entitle the EIB to demand immediate repayment of the loan. The condition for making the financing available (disbursement) by the EIB is, among others, the issue by the Company of C series subscription warrants, which will be subscribed for by the EIB and will entitle to take up T series shares of the Company constituting 2.85% of its share capital as at the date of issue. For this purpose, the Extraordinary General Meeting convened on 29 November 2019 adopted a resolution on the conditional increase of the Company's share capital through the issue of ordinary bearer T series shares with the simultaneous full exclusion of the pre-emptive right of the existing shareholders of the Company, on the issue of C series subscription warrants with the simultaneous full exclusion of the pre-emptive right of the existing shareholders of the Company, and on amendments to the Company's Articles of Association. The issue of subscription warrants in favour of the EIB is an element of remuneration for the EIB for making the financing available and enables a significant reduction of current costs of debt service in relation to standard credit products offered by financial institutions. In accordance with the Warrant Agreement, the main conditions of issuing subscription warrants and taking up shares are as follows:

1. the warrants will be taken up by the EIB free of charge and will entitle to take up T series shares of the Company at the issue price of PLN 0.1 per share;

2. the subscription warrants will be freely transferable to the EIB's affiliates, and to other entities only on the basis of a sales contract;

3. in cases specified in the agreement resulting in the reduction of the participation of T series shares in the Company's share capital below 2.85%, the Company shall issue additional warrants to the EIB in such a number that the shares taken up under the warrants represent such a percentage of the Company's share capital.

The Warrant Agreement governs the cases in which the rights carried by subscription warrants may be exercised, as well as the rights and obligations of the parties with respect to the sales and purchase of subscription warrants and T series shares (including the limitation on the transferability of T series shares within 6 months from the date of their acquisition, subject to exceptions specified in the Warrant Agreement).

The Company informed on agreeing on the terms of financing in Current Report no. 26/2019 of 21 October 2019, and on the adoption of the resolution by the Extraordinary General Meeting – in Current Report no. 32/2019 of 29 November 2019. The payment of the tranches is subject to the implementation of the conditions provided for in the agreement, which include achieving the milestones for the registration and commercialization of MabionCD20. The Company, after changing its strategy for the registration process, has taken actions aimed at changing the conditions provided for in the binding agreement. Until the date of publication of this report, the funds under the Financing Agreement have not been released, nor have the Company issued the warrants specified in the Warrant Agreement.

On 23 October 2019, the Company received information from an agent representing the Company before the US Food and Drug Administration (FDA) that the Company had been granted the opportunity to hold a Type 3 BPD (Biosimilar Biological Product Development) meeting with the FDA and that the meeting was scheduled for 22 January 2020. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of submitting an application for registration of MabionCD20 in the United States of America. The appointment of a Type 3 meeting was the next stage of implementation of the activities aimed at obtaining registration of MabionCD20 in the USA. It was the result of the FDA's evaluation of the dossier submitted by the Company, including full reports of clinical trials on MabionCD20 conducted using the European reference drug MabThera in patients suffering from RA and NHL, the results of the analytical similarity study of MabionCD20 (batches of the drug tested clinically) and the European reference (MabThera) to American (Rituxan) reference, as well as the clinical bridging trial protocol. The Company informed about the event in its Current Report No. 27/2019 dated 23 October 2019.

November

On 10 November 2019, the Company received a confirmation from a company contracted to deposit the answers to the second round of questions under the registration procedure for MabionCD20, that the answers had been successfully entered into the EMA electronic system (Day 181). The submission of the answers allowed the Agency to continue evaluating the application. The Company informed about the event in its Current Report no. 29/2019 of 10 November 2019.

On 11 November 2019, the Company received, from a company contracted to deposit the answers, confirmation of the successful receipt of the answers in the EMA electronic system as part of the registration procedure for the duplicate application for MabionCD20. The list of indications for this product will not include rheumatoid arthritis (RA). Since Day 181 of the procedure, the two applications were considered in parallel. The submission of the answers allowed the Agency to continue its evaluation of the duplicate application. The Company informed about the event in its Current Report no. 30/2019 of 11 November 2019. On 29 November 2019, the Extraordinary General Meeting of the Company, acting pursuant to Article 397 of the Code of Commercial Companies, passed a resolution on further existence of Mabion S.A. in connection with the level of the Company's equity as at 30 September 2019, which showed a loss exceeding the sum of supplementary capital and reserves and one third of the share capital. This information was published in Current Report no. 32/2019 of 29 November 2019.

December

On 9 December 2019, the Company was informed that the National Centre for Research and Development (NCBR) granted it a permit to extend by 9 months, i.e. until 30 September 2020, the deadline for implementation of the project titled "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". The project financing

agreement was concluded on 19 September 2017 (Current Report no. 44/2017). The value of the project is PLN 54.2 million, while the amount of the co-financing (contribution from the EU funds) is PLN 27 million. The previous project implementation deadline was 31 December 2019. The Company informed about the event in Current Report no. 36/2019 of 9 December 2019.

On 9–12 December 2019, a meeting of the Committee for Medicinal Products for Human Use (CHMP) was held at which the Company's applications for the marketing authorisation of the drug under the working name of MabionCD20 were handled. On 29 November 2019, the Company received preliminary information from rapporteurs regarding further processing of the Company's application. This was internal, non-binding and preliminary information (prior to CHMP making a final decision on how to proceed with the applications at its 9–12 December 2019 meeting, i.e. in accordance with the applicable registration procedures). On the basis of the information received at that time, the Company was not able to clearly indicate the course of consideration of the Company's applications at the CHMP meeting and the final outcome of that meeting. In the Company's opinion, however, in the preliminary information received from the rapporteurs, issues were present that were not signalled in the EMA's previous questions. The information received from the rapporteurs formed only internal draft documents prior to the CHMP meeting, so these documents may have differed significantly from those finally adopted at the Committee meeting. The above information was published by the Company in Current Report no. 37/2019 of 12 December 2019.

On 13 December 2019, the Company received a summary of the CHMP meeting referred to above. The document was immediately analysed to enable the Company to assess the issues contained in it and to publish the results of this assessment in the shortest possible time. The CHMP meeting summary included a list of issues addressed by the EMA, to which the Company was required to respond in order to continue the registration procedure. The regulator's comments received concerned primarily the commercial manufacturing process of MabionCD20, as well as the similarity of the product originating from this process to MabionCD20 tested in a clinical trial and the reference drug. The final list of issues raised by the EMA differed from the preliminary information received from the rapporteurs referred to above – the range of issues received was narrower than the previously obtained information. The preliminary assessment of the situation indicated that the tasks already planned and implemented are consistent with the scope of work needed to address the regulator's questions, and therefore the internal work schedules remained unchanged. The Company informed about the receipt of the summary of the CHMP meeting in Current Report no. 38/2019 of 16 December 2019.

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

On 13 January 2020, the Management Board informed that as a result of telephone consultations with the EMA, it plans to submit answers, in January 2020, to the list of questions received on 13 December 2019. This was intended to enable the Company to proceed with its registration application at a meeting of the Committee for Medicinal Products for Human Use (CHMP), on 24–27 February 2020. In addition, the Company emphasised that the regulator had a number of tools to ensure its discretion and the possibility of adjusting the solution to the needs of a registration procedure. The Company has also informed that it had no influence on the assessment of the EMA, and there were a number of possible events – a positive or negative decision, obtaining a list of additional questions (once or more), inviting to a round of oral answers (once or more), withdrawal of the application by the Company and its resubmission after additions, or other events not anticipated at this stage by the Company. The Company informed about the above event in Current Report no. 2/2020 of 13 January 2020

On 22 January 2020, a Type 3 BPD (Biosimilar Biological Product Development) meeting was held with the US Food and Drug Administration (FDA) on the registration and marketing authorisation of MabionCD20 in the US. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the United States of America. During the meeting, a productive discussion was held on the data needed to apply for registration in the USA for all indications of the reference drug. The Company was invited to contact the FDA on a regular basis in order to smoothly carry out the activities aimed at filing the application for registration of the drug in the USA. The Type 3 BPD meeting is a stage of implementation of activities aimed at obtaining registration of MabionCD20 in the USA. The Company emphasises that holding a Type 3 meeting does not guarantee a positive effect of these activities, the process of registration and approval of the drug for marketing in the US is multi-stage, and it cannot be ruled out that there will be additional requirements related to product approval by the FDA in the future. The Company informed about the above event in Current Report no. 4/2020 of 22 January 2020.

On 28 January 2020, the Company received confirmation from a company contracted to deposit answers, that the Company's answers to the list of questions received from the EMA in December 2019 had been successfully submitted to the electronic system of the EMA. The answers concern both authorisation applications – the basic application and the application in which the list of indications for the product does not include rheumatoid arthritis (duplicate application). The submission of the answers allowed the EMA to continue its evaluation of the applications. The Company informed about the above event in its Current Report no. 7/2020 of 28 January 2020.

On 7 February 2020, the Company received a decision of the Minister of Development on the amendment of permit no. 301 to conduct business activity in the Łódź Special Economic Zone ('Zone'), of which the Company informed in Current Report no. 2/2017 of 3 January 2017. By virtue of the above mentioned decision, at the request of the Company the deadline for incurring investment expenditure in the Zone within the meaning of § 6.1 of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit to conduct business in special economic zones, in the amount of at least 20 million PLN, was extended from 31 December 2019 to 30 June 2021. The application for the above change resulted from a change in the schedule of the commencement of the Company's investment. As of 31 December 2019, the expenditure incurred under the investment covered by permit no. 301 amounted to PLN 2.8 million. At the same time, the investment completion date planned for 31 December 2021 did not change. The Company informed about the event in Current Report no. 9/2020 of 7 February 2020.

On 12 February 2020, the Company was informed of a decision of the Pabianice District Governor to change the building permit for the construction of the building under the investment called "Scientific and Industrial Centre for Advanced Medical Biotechnology for Mabion S.A." together with the necessary infrastructure in Konstantynów Łódzki, of which the Company informed in Current Report no. 60/2018 of 14 November 2018. The change consists in increasing the cubic capacity of the building to the target size necessary for the Company to implement its investment plans, including increasing the Company's production and R&D capacity. The Company informed about the event in Current Report no. 10/2020 of 12 February 2020.

On 13 February 2020, the Company received from the EMA a list of issues to be presented at the CHMP meeting, which was scheduled for 24–27 February 2020, of which the Company informed in Current Report no. 11/2020 of 13 February 2020.

On 14 February 2020, the Company received from the FDA a summary of the Type 3 Biosimilar Biological Product Development (BPD) meeting with the FDA held on 22 January 2020 and attended by representatives of the Company and the FDA. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the United States of America. The Company has proceeded to analyse the document received and the applications and guidelines contained therein, as well as to assess their impact on the actions planned by the Company to date to register and admit the drug to trading in the USA. The Company has reserved that the process of registration and approval of the drug for marketing in the United States was multi-stage and it cannot be ruled out that additional requirements related to product approval by the FDA might appear in the future. The Company informed about the event in Current Report no. 12/2020 of 14 February 2020.

On 26 February 2020, the Company's Management Board participated in a CHMP meeting together with a team of experts, presenting the issues indicated by the EMA in the invitation received on 13 February 2012 (oral explanation). The Company informed about the event in Current Report no. 13/2020 of 26 February 2020.

On 16 March 2020, the Company's Management Board decided to modify the regulatory strategy for MabionCD20 pursued in the procedures carried out with the EMA. The basic change aims at obtaining marketing authorisation for the drug at the EMA directly for a large commercial scale as opposed to the previously planned 2-step strategy, i.e. obtaining marketing authorisation for a small scale production process – step 1, and then on the basis of a variation, a marketing authorisation for large commercial manufacturing – step 2. The Company's Management Board made this decision on the basis of the opinion of external consultants and recommendations of the Company's Supervisory Board received on 16 March 2020. The change of the strategy involves the withdrawal of registration applications submitted on 1 June 2018 and 6 May 2019. The new application, in which the target production scale will be evaluated by the Agency, will be submitted after obtaining validation and biosimilarity data for the product coming from the full-scale production. For procedural and formal reasons, the Company could not proceed with its

previously submitted and pending applications supplemented by the additional large-scale data. At the time of deciding on the change in the strategy, work on the commencement of the 3rd large scale production validation batch was in progress. In the opinion of the Company's Management Board, changing the strategy was the most optimal path in terms of both cost and time as regards registering Mabion CD20 and the possibility of its commercialization in the European Union. The Company plans to complete the validation of the large-scale manufacturing process for the product in June 2020. The scope and format of the new applications will be consulted first with representatives of the EMA as part of a scientific advice procedure (consultations planned for April/May 2020) in order to adapt them to the Agency's expectations, which will streamline the registration procedure for a large scale, targeted application. The decision to withdraw applications for registration of MabionCD20 in the EMA did not affect the adopted schedule of work on the large-scale manufacturing and bridging trial validation as well as work on registering MabionCD20 in the US market. However, the current work schedule may be changed as a result of guidelines obtained from the regulator. The Company informed about the event in its Current Report no. 15/2020 of 16 March 2020.

On 16 March 2020, the Supervisory Board held a meeting with representatives of the Management Board of the Company, at which a discussion took place on the financing of the Company's activities in light of the new regulatory strategy for MabionCD20 as part of the procedures carried out with the EMA. The Company's Management Board received supporting documents from the Company's main (founding) shareholders ("Shareholders"), according to which the Shareholders declared to inject capital in the Company in an amount not lower than PLN 15 million in 2020. The capital injection, in accordance with the Shareholders' declaration of 16 March 2020, will take place in 2020 in tranches, in response to the Company's financial needs. The recapitalisation of the Company, in accordance with the declarations received, may take place by taking up new issue shares or using debt instruments. The Management Board of the Company adopted supporting documents from the Shareholders and decided to start activities aimed at obtaining debt financing, which will enable effective implementation of the new strategy of registration of MabionCD20 with the EMA. In the opinion of the Company's Management Board, it should be possible to obtain external debt financing thanks to the strong support it received from the Company's major shareholders. The capital injection and debt financing should ensure that the drug will be admitted to trading both in the EU and in the USA. In addition, the Company does not preclude seeking and using other sources of funding such as grants, subsidies from the EU funds, targeted funds for new projects or other options depending on the Company's needs and capabilities. The Company informed of the event in Current Report no. 16/2020 dated 16 March 2020.

On 16 March 2020, in connection with the epidemic emergency introduced in Poland and the COVID-19 pandemic announced by the WHO (World Health Organization) worldwide, the Management Board provided information on the possible impact of this situation on the Company's operations. The Management Board of Mabion S.A. ascertained that the Company's operations might be temporarily affected by reduced employee availability and, as a consequence, delays in research and development processes, due to the need to introduce home office for certain positions. The Management Board noted that it had a certain degree of control over the pace and continuity of manufacturing processes, but it could not be ruled out that the introduction of remote work in certain positions and possible disturbances in the supply chain integrity of certain components, materials, and machinery and equipment will temporarily slow down R&D and manufacturing processes, including the production of the last of the three planned Mabion CD20 large-scale validation batches. At the same time, the Company's Management Board stressed that the Company's processes were focused on maintaining progress and completing work on Mabion CD20 validation, enabling to proceed to subsequent stages of research on the medicinal product manufactured on a large scale (i.e. stability and analytical similarity studies). As at the date of publication of the related current report as well as at the date of publication of these financial statements, this work is progressing smoothly, according to the planned schedules, and the Management Board is not aware of any delays in the delivery of components, materials or machinery or equipment. However, it could not be excluded that such delays will occur in the future. The Company has also recognised the risks associated with the liquidity disruption in the markets resulting from the spread of COVID-19 and the consequent possible restriction of the Company's access to finance. Furthermore, it noted potential shifts in administrative processes, both in the area of decisions of the authorities governing the release of medicinal products to the market and in the area of decisions of public authorities granting and settling subsidies and grants or VAT refunds. At the time of submitting the current report as well as at the date of publication of these financial statements, the Management Board had not received any information from the above-mentioned authorities concerning the shift in the processes in progress. The continuing state of pandemic, including, among others, the reduction of passenger traffic may also result in a temporary need to reduce the Company's marketing activity in the area of business development, as well as the suspension of key business decisions as part of the conducted talks. Due to the dynamics of events, the Issuer's

Management Board monitors the situation on an ongoing basis. The Company has also declared that it would comply with all applicable administrative decisions. The Company informed about the event in Current Report no. 17/2020 of 16 March 2020.

On 30 March 2020, the EMA website published information confirming the withdrawal of the Company's registration applications submitted in June 2018 and May 2019. The confirmation of the withdrawal of the registration application by the Company has ended the previous registration procedure initially based on a two-year strategy (obtaining approval for a small scale and then submitting a variation for a large scale manufacturing process). Although the Company responded to the vast majority of requests for additional information, in light of the Company's objective of registering a product based on a high quality, commercially attractive large-scale production process, the Company, given its interactions with the Agency to date, decided that the data will be revised in future application, and therefore the application for the small-scale manufacturing process was withdrawn. On 30 March 2020, the Agency published a "Questions and Answers" document ("Q&A"), containing a short summary of the process, but details of the completed registration procedure (European public assessment report, EPAR), in line with the EMA regulations, will be published by the regulator in the coming months. The EPAR will be based on the latest CHMP-approved version of the assessment report (Day 195), which identified more unresolved issues than those pending at the time of withdrawal of the application, and therefore the report will not reflect the most current status of the procedure. While the Company considered all other questions to be current based on the data available at the time of drawing up the last approved version of the assessment report (Day 195), the Company has since then made significant progress towards the submission of a new marketing authorisation application based on a high quality production process for a commercial scale. The Company is currently preparing a new marketing authorisation application to obtain marketing authorisation for MabionCD20 from the EMA in due course. The scope and format of the new application will be reviewed with the EMA as part of the scientific advice procedure to verify that it meets all the Agency's expectations. The Company informed about the event in its Current Report no. 19/2020 of 30 March 2020.

2.8.3 Other events

On 28 March 2019, the Company was informed by the Polish Agency for Enterprise Development (PARP) about receiving the Company's report on the dissemination of the results of industrial research in the project titled "An innovative double cutting technology for obtaining modern analogues of the human insulin hormone". The report in consideration has been accepted, thus the condition for granting a bonus for wide dissemination of results, in accordance with the provisions of the agreement on co-financing of the project in question (agreement of 2 February 2012), has been fulfilled. The project was implemented by the Company in 2011–2016. In 2015, the Company applied to PARP for ending the project early. The technology developed under the project was used to obtain an exemplary prototype of an analogue insulin, however, it was not possible to develop an appropriate formulation, i.e. a solution in which the drug would be stable for a long time, long enough for a pharmaceutical product. In 2016, the Company received a letter from PARP informing about the acceptance of the report on the implementation of industrial research and development work together with economic analysis and market research on the project implementation. At the same time, it was stated that it was not advisable to implement the results obtained under the co-financing agreement. Therefore, the Company was exempted from the requirement to implement the results of industrial research or development work in the form, scope and within the deadline specified in the application for co-financing. In the project sustainability period (3 years from the date of project completion – I.e. until 7 March 2019), the Company was obligated to disseminate the results of industrial research carried out as part of the project. The assumed work (dissemination of results through open source software) was performed by the Company and reported to PARP. The letter received on 28 March 2019 confirms the correctness of the work and the final settlement of the project in terms of its merit.

2.8.4 Atypical factors and events

In the opinion of the Company, in the financial year 2019 there were no factors or events of an untypical nature, other than those described in other points of this report.

3 ANALYSIS OF THE COMPANY'S FINANCIAL AND ASSETS POSITION

3.1 Selected financial data

Table 11: Selected financial data of Mabion S.A.

	in PLN thousand		in EUR thousand	
Selected financial data	**2019**	**2018**	**2019**	**2018**
Net income from sales	0	0	0	0
Operating profit (loss)	-63,272	-64,625	-14,708	-15,146
Profit (loss) before tax	-63,738	-68,870	-14,817	-16,140
Net profit (loss)	-63,738	-68,870	-14,817	-16,140
Net cash flows from operating activities	-33,755	-38,938	-7,847	-9,126
Net cash flows from investing activities	-9,159	-6,767	-2,129	-1,586
Net cash flows from financing activities	12,466	103,086	2,898	24,159
Total net cash flows	-33,755	-38,938	-7,847	13,448
	31.12.2019	**31.12.2018**	**31.12.2019**	**31.12.2018**
Total assets	113,545	144,717	26,663	33,655
Cash and cash equivalents**	27,970	58,418	6,568	13,586
Liabilities and provisions for liabilities	135,125	102,578	31,731	23,855
Long-term liabilities	48,743	36,069	11,446	8,388
Current liabilities	86,382	66,509	20,285	15,467
Equity	-21,580	42,139	-5,068	9,800
Share capital	1,373	1,372	322	319
Number of shares (in pcs)	13,730,272	13,720,772	13,730,272	13,720,772
Weighted average number of shares (in pcs)	13,721,917	13,089,285	13,721,917	13,089,285
Net profit (loss) per ordinary share	-4.64	-5.26	-1.08	-1.23
Book value per share	8.27*	11.06*	1.94	2.57
Dividend declared or paid per share	0	0	0	0

* *Total assets/Weighted average number of shares*

** *Disclosed in Total assets*

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 2019 - PLN 4.2585, 31 December 2018 - PLN 4.3000). 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 (2019 - 4.3018, 2017 - 4.2669).

3.2 Accounting principles applied to preparing financial statements

The separate financial statements of Mabion have been drawn up in accordance with the International Financial Reporting Standards (IFRS) approved by the European Union as at the reporting date.

The separate annual financial statements of Mabion S.A. include:

statement of financial position as at 31 December 2019 and the following statements for the financial year from 1 January to 31 December 2019:

» statement of comprehensive income;

» statement of changes in equity;

» cash flow statement;

and

» additional information including a description of the adopted accounting principles and other explanatory information, including the Statement of the President of the Management Board of 8 April 2020 on the impossibility of obtaining an electronic signature.

The financial statements cover the annual reporting period from 1 January to 31 December 2019 and the comparative period from 1 January to 31 December 2018.

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 drawn up in accordance with the going concern principle, which provides that the Company will continue to operate in the foreseeable future. Therefore, no adjustments have been made to the financial statements which might be necessary if there was a risk that the Company would not continue as a going concern. Since its establishment, the Company has focused on research and development activities in order to develop and commercially launch its products. As a result, the Company has incurred operating losses and generated negative cash flows from operating activities. As at 31 December 2019, the Company generated a cumulative loss which resulted in negative equity. On 29 November 2019, the Extraordinary General Meeting of the Company adopted Resolution No. 4/XI/2019 concerning confirmation of further existence of the Company in connection with the occurrence of the circumstances provided for in Article 397 of the Code of Commercial Companies. It is expected that such a situation may reoccur in the foreseeable future. The change in the terms of the currently binding debt financing agreements and further leveraging of financing available on the market, including exclusive agreements with future distribution partners or support declared on 16 March 2020 and new support from shareholders (both strategic and stock market participants) should provide the Company with funds necessary to complete the registration process and commercialization of MabionCD20. The Company has also taken steps to acquire a distribution partner for the US market and other markets not covered by existing agreements.

In the context of the COVID-19 coronavirus pandemic announced by the WHO (World Health Organisation), additional risks have been identified, e.g. related to the liquidity imbalance in the markets, the effects of which could not be fully anticipated at the date of publication of the report.

In the financial statements for the year 2019, the same accounting principles (policies) as in the financial statements for the year 2018 were applied. There were no changes in the rules for measuring assets and liabilities and financial result in 2019.

The scope of the annual report of the Company is consistent with the Minister of Finance Regulation of 29 March 2018 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 2019.

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

In 2019, the Company did not conduct any product sales. Since its establishment, the Company has focused on research and development activities in order to develop and commercially launch its products. As a result, the Company has incurred operating losses and generates negative cash flows from operating activities. This situation is expected to continue in the foreseeable future, until the successful registration and commercialisation of products currently at the stage of research and development.

The costs of operating activities in the period of 12 months of 2019 amounted to PLN 65,427 thousand. Their volume was mostly influenced by the costs of development work, which in 2019 amounted to PLN 40,710 thousand, and the costs of general administration, which amounted to PLN 24,207 thousand. The loss on operating activities for 2019 stood at PLN 63,272 thousand and was PLN 1,353 thousand lower than in 2018. The Company's net loss during the 12 months of 2019 amounted to PLN 63,738 thousand.

The Company's balance-sheet total at the end of December 2019 amounted to PLN 113,545 thousand and decreased by PLN 31,172 thousand in relation to the end of December 2018. At the end of 2019, a significant share in the total assets, i.e. PLN 73,246 thousand, were fixed assets, including property, plant and equipment (mainly fixed assets related to the implementation of investments in Konstantynów Łódzki). Cash at the end of December 2019 amounted to PLN 27,970 thousand and came from funds obtained under earlier share issues in 2018, and also a loan, grants, and VAT refund.

In turn, on the equity and liabilities side of the Company at the end of 2019, there is a clear decrease in the value of equity, by PLN 63,719 thousand in relation to the end of December 2018, resulting from the net loss on operations in the reporting period. The negative level of equity results from the specific nature of the Company's biotech activity, i.e. constant incurring of high research costs with no sales revenue until the project is commercialised. As far as short-term liabilities are concerned, there is a clear increase in loan liabilities, which results from the disbursement of the first tranche of the Santander bank loan. The Company recognises all costs as cost of the period in the financial result and does not disclose any component of intangible assets arising from research work in accordance with IAS 38.

In the opinion of the Company's Management Board, support from shareholders (both strategic shareholders and stock market participants), external financing in the form of loans and borrowings, grants, and the long-term cooperation agreement with Mylan and other possible partners can provide the Company with funds necessary to complete the development of MabionCD20 and commercialise it, and justify the continuation of the Company's operations in accordance with the adopted development strategy.

3.4 Financial and non-financial performance indicators

In 2018 and 2019, the Company did not conduct any sales of products coming from its core operations.

At the same time, the Company incurred operating expenses in connection with the costs of conducted development work, investments in machines and equipment used for conducting development work and for the production of medicines in the future, as well as general administration costs related to, among others, obtaining funds for current operations. Therefore, both

in 2018 and 2019, the Company recognised 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 Management Board of the Company does not identify non-financial performance indicators significant for the assessment of the development, results and situation of the Issuer.

3.5 Product and geographical structure of revenues

In 2019, Mabion S.A. did not recognised any sales income related to products from core operations.

3.6 Issues of securities

On 18 November 2019, the Company issued 9,500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2018. The Incentive Scheme for persons of key importance to the Company was adopted by Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the introduction of the Incentive Scheme, and the issue of B series warrants took place in the execution of Resolution No. 25/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the issue, for the purpose of implementing the Incentive Scheme, of A and B series subscription warrants with the exclusion of the pre-emptive right of the existing shareholders to subscribe for R series shares and S series shares and a conditional increase of the share capital through the issue of R series shares and S series shares with the exclusion of the pre-emptive right of the existing shareholders, and the related amendment to the Company's Articles of Association. The subscription warrants were taken up on 18 November 2019, free of charge, by eligible persons, i.e. persons appointed by the Company's Supervisory Board. Each B series subscription warrant entitled to take up 1 S series ordinary bearer share of the Company at the issue price equal to the nominal value of shares of PLN 0.10 each. All eligible persons submitted declarations on taking up their S series shares of the Company on 18 November 2019. The S series shares were issued as part of a conditional share capital increase, therefore no allocation of shares took place. Due to the fact that the S series shares were issued as dematerialized shares and were subject to the application for admission to trading on the regulated market, the shares were issued by recording them on the securities accounts of the eligible persons. The S series shares were issued on 29 January 2020 (event after the balance-sheet date). A total of 9,500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were issued.

On 24 October 2019, the Company entered into a Financing Agreement with the EIB. The condition for making the financing available (disbursement) by the EIB is, among other things, the issue by the Company of C series subscription warrants, which will be taken up by the EIB and will entitle to take up T series shares of the Company constituting 2.85% of its share capital. For this purpose, the Extraordinary General Meeting convened on 29 November 2019 adopted a resolution on conditional increase of the share capital, exclusion of pre-emptive rights and issue of subscription warrants to the EIB.

The issue of subscription warrants to the EIB is part of the remuneration of the EIB for providing the financing.

In accordance with the Warrant Agreement entered into between the Company and the EIB on 31 October 2019, the main terms and conditions for issuing subscription warrants and taking up shares are as follows:

1. the warrants will be taken up by the EIB free of charge and will entitle to take up T series shares of the Company at the issue price of PLN 0.10 per share;

2. the subscription warrants will be transferable without restrictions to entities related to the EIB, and to other entities exclusively on the basis of a sales contract.

3. in cases specified in the agreement resulting in the reduction of the participation of T series shares in the Company's share capital below 2.85%, the Company shall issue additional warrants to the EIB in such a number that the shares subscribed for on the basis of the warrants represent such a percentage of the Company's share capital

Until the date of drawing up this report, the Company has not issued C series subscription warrants, entitling to take up T series shares, to the EIB.

3.7 Financial instruments used

In 2019, 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 2019, 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.

On 29 November 2019, the Extraordinary General Meeting of the Company, acting pursuant to Article 397 of the Code of Commercial Companies (CCC), adopted a resolution on further continuation of the activities of Mabion S.A., in connection with the level of the Company's equity as at 30 September 2019, which showed a loss exceeding the sum of supplementary capital and reserves and one third of the share capital. The occurrence of negative equity, which is a premise specified in Article 397 of the CCC, results from the nature of the Company's operations. In the period 2019, there were no one-time events and the Company's activity was comparable to previous periods. The above-mentioned level of equity results from the specific nature of the Company's biotechnological activities (continuous high research costs with no sales revenues until the project is commercialized) is typical for research and development companies.

The Company's key distribution partner is Mylan, the agreement with whom was signed in November 2016. As a strategic partner, Mylan agreed that in return for the funds and strategic development support for the Company, Mylan will receive distribution rights in Europe for the contracted countries once MabionCD20 is approved. During the reporting period and previous periods, the Company pursued a strategy, with the support of Mylan, to register its product with the European Medicines Agency using small batch production. In February 2020, the Company, on the basis of the interactions with the EMA up to that time and the recommendations provided by external experts and the Supervisory Board, decided to change its registration strategy and abandon the small batch registration process. It was decided to proceed directly to the registration of production of large batches, which may also be justified in terms of cost-effectiveness of the commercialization of MabionCD20. The result of this change is an expected delay in the possibility of registering the drug, which may also result in the expected next payment from the distribution partner, conditional on this event, not being made in the short term. The existing agreement with the distribution partner also provides for the possibility of termination after 2020 in case the drug is not registered by that time. In case of lack of registration of MabionCD20 by December 31, 2020, Mylan may terminate the contract, consequently, may require the Company to reimburse most of the advances obtained in Note 19 to the financial statements. In such a case, the Company will have to acquire a new partner or distribution partners.. The change in the registration strategy will also require the Company to finance ongoing commitments and additional costs for the implementation of the updated strategy over an extended period of time. The Company will use the knowledge gained in the registration process to date. However, this process is longer than originally expected and goes beyond the current period provided for in the applicable agreement with Mylan. Following the change in the registration strategy, the Company remains in direct contact with the distribution partner and is taking steps to continue the existing agreement and to amend its relevant terms accordingly.

The Company has financing of PLN 30 million under the loan from Santander Bank Polska S.A. As at the date of this report, the Company used part of the available loan from Santander Bank Polska S.A., amounting to PLN 15 million. The remaining amount of financing, in the amount of PLN 15 million, may be used depending on meeting the conditions contained in the agreement, and in particular the consent of the EMA regulator for the registration of MabionCD20. According to the agreement in force, the loan is due and the loan agreement will expire in July 2020. The Company has taken steps to set and change the conditions, including the extension of financing for subsequent reporting periods.

On 24 October 2019, the Company entered an agreement with the European Investment Bank ("EIB") for a loan in a total amount of EUR 30 million to finance the implementation of investment and R&D projects, including the development of the Company's R&D infrastructure and production capacity, for a maximum of 5 years from the date of disbursement of individual tranches. Detailed terms and conditions for the disbursement of individual tranches are specified in the agreement under which the release of tranche A is subject to the submission to the EIB, by 30 September 2020, of a copy of the scientific opinion issued by the European Medicines Agency (Committee for Medicinal Products for Human Use) containing the recommendation on the marketing authorisation of MabionCD20. The Company has taken steps to adapt the existing agreement to the Company's current strategy for registration of its key drug, MabionCD20, including the conditions for drawing individual tranches as well as the drawing schedule. As at the date of this report, the loan has not been disbursed.

Having in regard the foregoing, extending the registration period for Mabion CD20 may affect the continuation of the contract with Mylan and will require additional funding. In its strategy, the Company assumes the continuation of cooperation with Mylan and obtaining or maintaining the required financing. Extending the registration process creates the risk that cooperation with Mylan will not be continued, the Company will not attract other partners and will not obtain the required financing. These factors indicate the existence of significant uncertainty that may raise doubts as to the Company's ability to continue as a going concern in the foreseeable future.

In connection with the global COVID-19 coronavirus pandemic announced by the WHO (World Health Organization), additional financial risks have been identified in connection with the liquidity disruption in the markets resulting from the spread of COVID-19 virus and the consequent possible restriction of the Company's access to funding. In addition, potential shifts in administrative processes cannot be ruled out, including both in the area of decisions of the authorities regulating the authorisation of medicinal products and in the area of decisions of public authorities granting and accounting for grants and subsidies or VAT refunds. At the time of submission of this report, no information on the redeployment of ongoing processes was received from these authorities.

The persisting state of pandemic, including, among other things, passenger traffic limitations, may also contribute to the temporary need to reduce the Company's marketing activity, as well as the suspension of key business decisions as part of the conducted talks.

Financial resource management in 2019

The costs of research and development, in particular clinical trials and costs related to the manufacturing process of MabionCD20 had the greatest impact on the Company's operations in 2019.

As at 31 December 2019, the Company's equity had a negative value constituting approx. 19% of total assets. Whereas, as at the end of December 2019, the general debt ratio on account of long- and short-term liabilities (supplies of goods and services) and loans stands at approx. 119%

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

» current and planned level of cash generated from grants, subsidies, VAT refund and finance activities;

» current structure of financing of non-current and current assets;

» anticipated real investment level;

» planned scale of core operations (research and development).

» Modification of the registration strategy for MabionCD20 at the EMA.

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 cash flows.

According to the Company's assumptions, funds for the continuation of operations, including:

» completion of research and development work on and registration of MabionCD20 on key markets: European and American;

» launching the commercial scale of production in the Scientific and 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;

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

may be derived from:

» aid from EU funds;

» loans provided by banks;

» funds obtained under leases;

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

» declared financial support from key shareholders;

▪ future share issues.

» joint ventures with industry and business partners

» expected distribution fees for MabionCD20 (milestone payments);

3.10 Assessment of the feasibility of investment plans

The Company's investment plans include commercial scale production at the Scientific an 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 and innovative medicines.

The Company intends to raise funds for investment tasks from the sources indicated in point 3.9.

The Management Board is committed to ensuring that the maturity structure of individual payments related to the implementation of investment tasks is adjusted primarily to the period of receipt of due funds.

The Company's liquidity may be adversely affected by:

» untimely disbursement of funds by state institutions dealing with the distribution of means under projects co-financed from EU funds;

» COVID-19 coronavirus pandemic and the resulting limitation of access to financing for the Company (possible restrictions for capital issuance);

» delays in payments of subsequent tranches of the distribution fee and tranches of the loan from EBI and Santander Bank Polska S.A. , due to failure to reach the assumed milestones within a specified period;

» delays in the reimbursement of Value Added Tax (VAT).

These negative phenomena should not significantly affect the scope of Company's activities. In such a case, the Management Board plans to launch alternative sources of financing for current operations. In particular, the Company may consider seeking assistance from shareholders who have supported the financing of the Company in the past through short-term loans until the Company obtains other external financing.

On 16 March 2020, the Management Board received supporting documents from the Company's main (founding) shareholders ("Shareholders"), according to which the Shareholders declared to recapitalise the Company with an amount not lower than PLN 15 million in 2020. The capital injection, as declared by the Shareholders, will take place in 2020 in tranches in accordance with the Company's financial needs. The Company's recapitalisation, in accordance with the declarations received, may be carried out by taking up new issue shares or using debt instruments.

In the Company's opinion, the declaration of the main shareholders concerning the recapitalisation is a confirmation of and significantly support the possibility of implementing the adopted strategy of registration of the key project. At the same time, it should provide a basis for further increase of financing under both existing loan agreements and potential new external sources. However, the risk related to limited access to financing caused by the global liquidity situation or the financial standing of the Company and the assessment of the possibility of registering the key drug, MabionCD20, cannot be excluded. It is important to point out here the risk related to the impossibility of changing the terms and conditions of the existing loan agreements, including for the possibility of disbursement of particular financing tranches, or changes in the terms and conditions of the agreement with Mylan. In particular, the current situation caused by the pandemic and its impact on capital markets should be borne in mind, as it may result in significant limitations in terms of sources of financing, including equity financing.

3.11 Dividend policy

In the financial year 2019, the Company did not pay any dividend. The Company's Management Board adjusts its dividend policy to the Company's changing business situation, taking into account the scope of necessary investment expenditure. Currently, the Company is in the growth stage and it does not intend to pay any dividend.

In the Company's opinion, the declaration of the main shareholders concerning the recapitalisation is a confirmation and significant support for the key project registration strategy adopted by the Company. At the same time, it should provide a basis for further increase of financing under both existing loan agreements and potential new external sources. However, the risk related to limited access to financing caused by the global liquidity situation or the financial standing of the Company and the assessment of the possibility of registering the key drug, MabionCD20, cannot be excluded. It is important to point out here the risk related to the impossibility of changing the terms and conditions of the existing loan agreements, including for the possibility of disbursement of particular financing tranches, or changes in the terms and conditions of the agreement with Mylan. In particular, the current situation caused by the pandemic and its impact on capital markets should be borne in mind, as it may result in significant limitations in terms of sources of financing, including equity financing.

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. 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 capacity and reducing fixed manufacturing costs;

» industrial orbital shaking technology, which enables a cost-effective development of biofermentation processes.

The technology of manufacturing therapeutic monoclonal antibodies is a relatively new area of medical biotechnology explored by the largest global pharmaceutical concerns, an area which has been dynamically developing over the last 20 years. The process of manufacturing therapeutic preparations – one of the most eminent achievements of modern biotechnology, enables the manufacture of targeted medicines which selectively interfere with cancer cells, ensuring 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 in the area of modern biotechnology, not only on a domestic scale, but also in the area of Central and Eastern Europe. The global supply of biosimilars is provided exclusively by large international pharmaceutical corporations. Within several years Mabion S.A. acquired competencies to manufacture any biotechnological medicine, from the stage of designing, through the selection of the technological path, to manufacturing the finished medicine. Only a few companies in Europe have a relevant capability to carry out 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 resulted from the dates of expiry of the patent protection of respective reference medicines and the high 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, in cooperation with Mylan and aided by external consultants, through the registration process of 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 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 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 original biotech medicines already present on the market (reference medicines).

Starting from 2017, the Company's Management Board analyses the development plan for medicinal products every year and modifies it taking into account, among other things, the expiry dates of patents for reference medicines, the current and forecasted size of the market for reference medicines, the Company's manufacturing technology, the competence and experience of the team, and competition in the field of biosimilar medicines.

On 3 April 2019, after reviewing and updating the development strategy for medicinal products, the Management Board of the Company adopted a resolution approving the changes in the current development strategy of the Company. In accordance with the resolution, the catalogue of projects which the Company, currently or in the future, on its own or with partners, is interested in implementing, was changed. The Company also classified scientific and research projects in three groups of projects, i.e. active projects, new projects which were planned for 2019, and partner projects.

Active projects

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

Projects launched in 2019

The projects for which the Company started research and development work in 2019 are three biosimilar drugs in the area of autoimmunity, metabolic diseases and oncology.

With regard to the above-mentioned antibodies, the following work was carried out in 2019:

» Reference drug Prolia and Xgeva (based on denosumab) - the amino acid sequence of the reference drug was verified and confirmed and work on the construction of the vector encoding the biosimilar antibody was started. A reference material bank was launched.

» Reference drug Xolair - the amino acid sequence of the reference drug was verified and a reference material bank was launched.

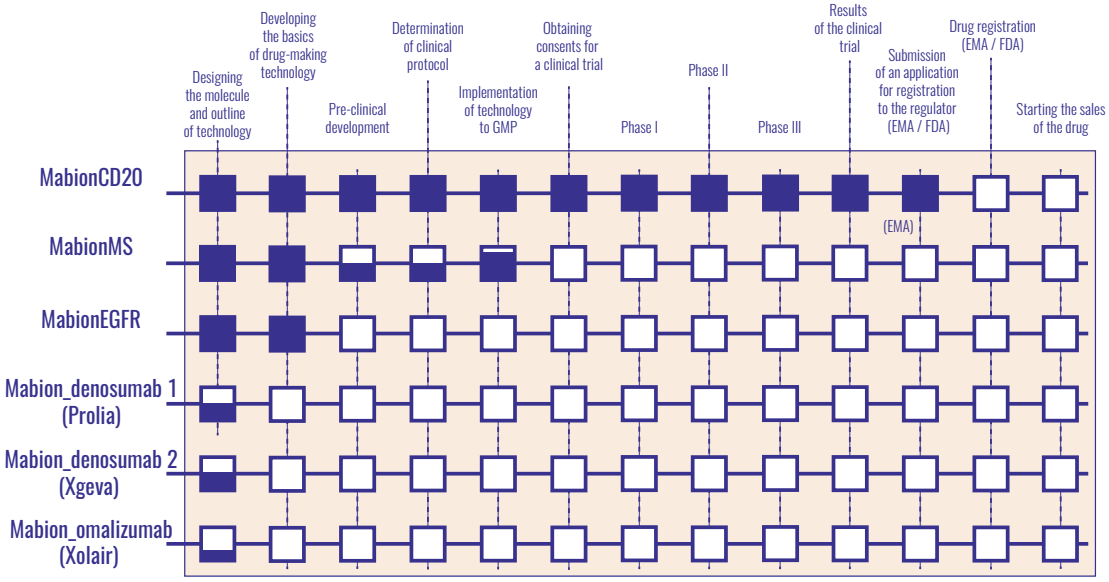
Partnership projects

These are the projects for which the Company considers starting implementation in the mid or long term, preferably in cooperation with a partner. The projects will concern, inter alia, autoimmune and oncological diseases.

In March 2020, the Management Board started work related to the annual update of the development strategy plan for medicinal products, continued as at the date of publication of this report.

The status of projects implemented by Mabion S.A. is as follows.

Table 13: Stages of development of projects in progress.



MabionCD20

The priority and most advanced project of the Company is the central registration procedure of the drug under the working name of MabionCD20. In June 2018, the Company applied to the European Medicines Agency for marketing authorisation (MAA) for the drug on the EMA regulated market. In May 2019, the Company filed a duplicate application) with the EMA, the purpose of which was to obtain an additional trade name for which the list of indications for the product would be limited and would not cover rheumatoid arthritis (this might have accelerated the drug's commercialization in markets where RA is still covered by patent protection for MabThera). Both applications were accepted by the EMA for the assessment procedure.

Under the registration procedure for the original application, the Company submitted answers to the EMA's questions received as part of Day 120 (April 2019) and Day 180 (November 2019) of the registration procedure for MabionCD20 on 24 April 2019. Under the registration procedure of the duplicate application, the Company submitted answers in November 2019. Since Day 181 of the procedure, both applications were processed in parallel. In December 2019, the Company received a summary of the meeting of the Committee for Medicinal Products for Human Use (CHMP), at which the Company's registration applications were handled. The summary included a list of issues raised by the EMA to which the Company was required to respond in order to continue the registration process. The Company submitted answers to the EMA's list of questions in January 2020, and in February 2020, it received a list of questions from the EMA to be presented at a CHMP meeting which was scheduled for 24-27 February 2020. On 26 February 2020, the Company's Management Board, together with a team of experts, participated in the CHMP meeting, presenting the issues indicated by the EMA in the invitation (oral explanation).

On 16 March 2020, the Management Board decided to modify the regulatory strategy of MabionCD20 in the EMA. The basic change is to seek marketing authorisation for the medicine in the EMA directly for a large commercial scale as opposed to the previously planned 2-step strategy, i.e. obtaining marketing authorisation for a small scale production - step 1, and then on the basis of a application for change - for a large commercial scale - step 2.

The strategy change was related to the withdrawal of registration applications referred to above, which took place on 16 March 2020. On 30 March 2020, the EMA confirmed the withdrawal of the Company's registration applications. A new application, which will be assessed by the Agency in terms of the target scale, will be submitted after the validation and biosimilarity data for the product from the large scale production are available. The existing large-scale analytical data indicate a reproducible quality and high degree of analytical similarity, which, in the Company's opinion, significantly translates into the probability of abandoning additional, larger clinical trials.

As of the date of publication of this report, work is in progress on the large-scale validation. In the opinion of the Company's Management Board, the change in the regulatory strategy is currently the most optimal path in terms of both cost and time of registering MabionCD20 and the possibility of commercializing it in the European Union. The Company is planning to complete the validation of the large-scale manufacturing process for MabionCD20 in June 2020. The work is currently at an advanced stage. The scope and format of the new applications will first be consulted with representatives of the EMA as part of the scientific advice procedure (consultation planned for April/May this year) in order to adapt them to the Agency's expectations, which will streamline the registration procedure for the application concerning large, targeted production scale.

In relation to the activities aimed at admitting the drug under the working name of MabionCD20 to the US market, in June 2018, the Company received a summary from the US Food and Drug Administration (FDA), following a Type 2 BPD (Biosimilar Biological Product Development) meeting. The purpose of the meeting was to provide an initial general presentation of the Company's development data for MabionCD20 with regard to the reference drug, MabThera, as well as to identify key issues relating to the ability to work with the Agency on the basis of these data to obtain registration of MabionCD20 in the United States. In accordance with the content of the summary, the Agency has allowed the data held by the Company to be used as support for the application process. At the same time, it proposed an overall strategy for linking the product registered in the European Union (MabThera) with the product authorised in the USA (Rituxan). On the basis of the data available at that time, the Agency did not indicate the need for a completely separate process of developing MabionCD20 for the US market. The Agency considered that there was a need for a bridging trial with regard to research performed in Europe based on the reference drug MabThera. The bridging trial should be three-armed and include the US Rituxan, European MabThera and MabionCD20.

A three-arm analytical research will also need to be performed. The US registration and marketing authorisation process for MabionCD20 is a multi-stage process and it cannot be excluded that additional FDA approval requirements may arise in the future.

On the basis of the Agency's recommendation to date, the Company has prepared a research protocol and, together with the Briefing Package, submitted it to the FDA in September 2019. As a result of the FDA's evaluation of the documentation package submitted by the Company, including reports on full clinical trials for MabionCD20 conducted using the European reference drug, MabThera, in patients suffering from RA and NHL, the results of the analytical similarity study of MabionCD20 (clinically tested drug series) and the European (MabThera) to American (Rituxan) reference drug, and the clinical trial protocol (bridging). In October 2019, the FDA granted the Company an opportunity to hold a Type 3 BPD meeting and set the date of the meeting for 22 January 2020.

The Type 3 BPD meeting was held on the indicated date and its aim was to obtain confirmation of the regulatory strategy. During the meeting, there was a productive discussion on the data needed to apply for registration in the US for all indications of the reference medicine. In February 2020, the Company received from the FDA a summary of the meeting with the FDA and started the analysis of the document and the conclusions and guidelines contained therein, as well as the assessment of their impact on the actions planned by the Company so far to register and admit the drug to trading in the USA. The FDA has confirmed the possibility of submitting an application for MabionCD20 and the validity of the approach presented by the Company.

Mabion is planning to ask the Agency further questions to clarify the examined clinical parameters as well as to conduct detailed comparative analyses of MabionCD20 with the reference drug Rituxan.

In order to start a bridging trial, the Company, based on the trial protocol, must obtain the consent of the competent authorities and the consent of the bioethics committees. At the same time, the Company has to provide financing for the trial, which is a prerequisite for its commencement and thus determines the date of the trial. Funds for the implementation of the above may come from a potential distribution partner, European Union funds, or other sources. As for partners from the US, Mylan is a potential partner for the Company, which has priority to conclude an agreement with the Company regarding the right to sell MabionCD20 on the US market. Mabion will be able to contact other potential partners, however the Company could commence cooperation with a specific partner other than Mylan only in the event that Mylan resigns its priority.

To sum up, in the research and development work on MabionCD20, the following activities were successfully carried out in 2019 and until the date of publication of this report:

» full validation/qualification of biological analytical methods has been completed (according to the latest EMA/FDA guidelines);

» biosimilarity study (MabionCD20 vs. MabThera) and bioequivalence study (MabionCD20 2x250L clinical batches vs. MabionCD20 2x250L commercial batches) have been completed;

» the preliminary analytical similarity study has been completed and a plan for a complete analytical similarity study (MabionCD20 vs. Rituxan) has been developed;

» a continuous process of stability testing for MabionCD20 and the reference drug MabThera was conducted;

» degradation studies of MabionCD20 and MabThera have been completed;

» answers have been developed as part of the registration process at the European Medicines Agency (Day 120, 180 and 181+[39]) for the original application and the duplicate application for registration of MabionCD20;

» the scope of work on the determining the process space for the manufacturing process has been extended;

[39] "Day 181+" stands for the answers provided after Day 180.

- additional analytical methods have been developed to enable a wider in-house characterisation of the MabionCD20 particle;
- an additional 2x250L batch was produced to answer EMA questions received on Day 120 of the MabionCD20 registration procedure;
- quality parameters of the antibody produced within technical, validation and additional 2x250L batch have been verified;
- quality parameters of the antibody produced within technical, validation and additional batch have been verified on a 2x250L scale;
- two technical batches of MabionCD20 on a scale of 2x2500L have been conducted;
- technological, system and validation documentation has been prepared for process validation on the 2x2500L bioreactor scale; in 2019, two validation batches on a scale of 2x2500L were launched, while in January 2020, the third validation batch was launched;
- physicochemical, biological and microbiological analyses of technical and validation batches were conducted according to the developed MabionCD20 manufacturing process control strategy;
- work related to the preparation of the clinical trial protocol and the Briefing Package based on the findings of the FDA has been completed;
- on 22 January 2020, the Company took part in a meeting with the FDA to confirm the compliance of the Company's registration strategy with the expectations of the regulator;
- analytical methods have been optimised, which, after their prior validation, will allow for characterisation of pharmacokinetics, pharmacodynamics and immunogenicity in subsequent clinical trials related to MabionCD20.

MabionMS

With regard to the MabionMS innovative therapy project, the Company has so far reported the submission of two patent applications in this therapeutic area.

In 2017, Mabion filed a European patent application with the Patent Office of the Republic of Poland (with the possibility of extension under the PCT procedure), on the basis of which the Company applies for legal protection for its invention entitled "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand". The subject of the patent application is an innovative therapy for the treatment of multiple sclerosis patients using MabionCD20 antibody combined with other substances (MabionMS combination therapy project). In 2018, the Company filed an application with the European Patent Office in the Hague to extend patent protection for the above mentioned invention under the PCT procedure. In order to avoid a dangerous situation in which the Patent Office accuses an attempt to double patent the same scope of protection (the so-called double patenting), in March 2019 the Company withdrew its original European application in order to benefit from the protection granted on the basis of the international application (also covering the European area). This is a procedural step to optimise the process in consideration.

In 2018, the Company filed another patent application with the Patent Office of the Republic of Poland (with the possibility of extension under the PCT procedure) in 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 in the area of use of MabionCD20 for the treatment of multiple sclerosis, constituting an innovative indication for the molecule. This application concerns the use of MabionCD20 as a monotherapy. Currently, the Company is looking for partners for further work related to the development of the above-mentioned therapy.

For this project, in 2019, the Company prepared both a clinical trial synopsis and a Briefing package. The content and regulatory assumptions of the project were consulted with external experts in the area of clinical trials in multiple sclerosis therapy. After the consultation and approval of the final version of these documents, the Company submitted them to the EMA on 9 August 2019. On 12 September 2019, the Briefing Package was handed over to an external company (the Company's US representative for the project) for the purpose of submission to the FDA. Both events start the process of scientific consultations with regulators in order to confirm the compliance of the project assumptions with the requirements of both agencies. The consultation with regulators is a multi-stage process, which may consist of research and development reports and a round of scientific advice enquiries. A consensus in the course of the consultation may be difficult to predict in relation to the timing of the consensus.

MabionEGFR

For the MabionEGFR project, the Company is in the process of developing technological bases and analytical tools. Part of the expenditure related to the development of the drug is co-financed from EU funds.

With regard to the above project, in 2019 the Company continued its activities related to:

» determining the scope of the quality target product profile (QTPP) for qualitative attributes of protein;

» developing a reference material bank;

» optimising subsequent versions and verification of the genetic construct;

» developing biological and physico-chemical analytical methods to characterise the protein obtained;

» optimising the conditions for introducing the vector into host cells;

» preselecting chromatographic deposits and preoptimising antibody purification conditions.

Other activities as part of the implementation of the Company' s development strategy

In the reporting period, the Company continued cooperation with Plexus Ventures LLC - an experienced advisor supporting the Company in the field of business development. Plexus is engaged in activities aimed at acquiring partners who can effectively sell medicines included in the above mentioned Mabion's pipeline. The process is complex and lengthy - it consists in contacting companies, signing confidentiality agreements and presenting data at different levels of detail, depending on the level of advancement of the process. At the same time, the companies update their offers.

The current production capacity for the drug under the working name of MabionCD20 allows the Company to partially cover the estimated demand from customers in European Union countries (the supply of the drug will cover the first sales). The implementation of long-term plans requires the Company to achieve adequate production capacity, which requires investment. A necessary stage in the development of the Company is to equip the existing production line in order to respond to potential demand.

Additional equipment for the existing plant

The investment which is the subject of permit no. 301 for conducting business activity in the Łódź Special Economic Zone consists in increasing the production capacity of the current plant and includes:

» retrofitting the existing 2x2500 L production line, and

» purchasing and installing production equipment for a second 2x2500 L production line to be located in the existing building.

As part of permit No 301, the Company undertook to incur investment expenditure in the area of the Zone in the amount of at least PLN 20 million (within the meaning of § 6 of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit for conducting business activity in special economic zones). The deadline for incurring these expenditures was originally set to 31 December 2019. In June 2019, the Company submitted a request to extend the deadline. The request for the above change resulted from the change in the schedule of the Company's commencement of the investment. On 7 February 2020 (an event after the balance-sheet date), the Minister of Development agreed to amend permit no. 301 by extending the deadline for incurring investment expenditures until 30 June 2021. The investment is planned to be completed by 31 December 2021. Under permit no. 301, as at 31 December 2019, the Company made investment expenditures of PLN 2.8 million.

Extension of the existing establishment

In 2017, the Company started preparation activities connected with the 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 2018, the Company selected an international consortium of architectural and technological companies, to which it entrusted the development of a technological and construction design. In November 2018, the Company received the decision of the Pabianice Governor approving the construction design and granting a building permit for the aforementioned investment called "Science and Technology Centre for Advanced Medical Biotechnology of Mabion S.A." together with the necessary infrastructure in Konstantynów Łódzki.

In 2019, work was underway to prepare detailed designs for all construction and installation sectors. By December 2019, about 75% of all contracting projects were prepared, and the end of works is planned for May 2020. Detailed specifications of user requirements were prepared for critical installations and main process lines. In November 2019, an application for a replacement building permit was also submitted, allowing to increase the cubic volume of the building to the target size necessary for the Company to implement the intended investment plans, including the increase of the Company's production and R&D capacity. On 12 February 2020, the Company received a decision of the District Governor of Pabianice changing the above mentioned building permit. The building permit allows for the commencement of works on the extension of the existing plant, however, the moment of their commencement depends on the Company's financial situation (obtaining funds, liquidity, etc.) as well as formal possibilities of entering non-European markets (signed distribution agreements, formal approvals of regulators, etc.).

Table 14. Planned expansion of the existing Mabion's plant - visualization.

4.3 Factors important for the development

Standards relating to studies

Part of the Company's research and development work is carried out, in accordance with regulatory requirements, in the environment of quality systems.

The medicines are manufactured according to the principles of Good Manufacturing Practice. This was confirmed by obtaining the GMP certificate from the Main 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.;

» in July 2019, for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki at ul. Gen. M. Langiewicza 60 (in the scope of production of active substance);

» in August 2019, for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstantynów Łódzki at ul. Gen. M. Langiewicza 60 (in the area of medicinal product manufacturing).

The analyses related to samples originating from the clinical trial is carried out in accordance with Good Laboratory Practice. This was confirmed by obtaining a 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 (pharmacokinetics, pharmacodynamics, immunogenetics) 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 successfully underwent another GPL inspection and the validity of its certificate was extended.

The plans for the clinical development were consulted 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 was aimed at reducing the registration risk.

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 has gathered a stable and experienced research personnel team. The team whose knowledge is of key importance to the results of research and development operations includes:

» 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 (Deputy President of the Company's Supervisory Board, previously Chairman of the Supervisory Board and President of the Management Board, 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 Łódź and the Faculty of Biotechnology and Food Sciences at the Łódź University of Technology. In addition, it cooperates with universities in the implementation of student internships and mentoring programmes (e.g. "Młodzi w Łodzi"). 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 Łódź University of Technology and the Medical University of Łódź, 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 15. Thematic areas of selected training courses

1.	QA training
2.	IPMA NCB 3.0 Project Management
3.	Quality Design principles
4.	Verification of Transportation of Medicinal Products
5.	ICH GCP E6 R2
6.	Audits and controls in clinical trials
7.	Inoculum production
8.	Training in column packaging
9.	Management of outsourced activities in manufacturing and services
10.	Batch management-a practical approach
11.	Current GMP requirements for input materials
12.	Extended EUdra Vigilance Medicinal Product Dictionary
13.	The new Edura Vigilance System and the electronic reporting of ICSRs in the ISO
14.	MEB/CIA Excellence in Pharmacovigilance : Clinical Trials and Post – Marketing
15.	Practical data analysis in the pharmaceutical industry
16.	US/FDA Drug Submission Procedures for Biosimilars
17.	GCP E6 R2; Changes as a result of ICH GCP
18.	Microbiological substrates in pharmacy
19.	Validation and maintenance of computerised systems
20.	Communication as a management tool
21.	New regulations on waste management
22.	TH Gene Quantification Event qPCR dPCR & NGS 2019
23.	Control of microbiological and mechanical contamination in the manufacturing process of sterile medicinal products and active substances according to ANNEX 1
24.	Practical validation of microbiological methods

4.4 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.

Domestic and foreign laws and regulations which relate to the Company's operations require the Company to adapt its internal regulations and procedures to the requirements of the legislator. Failure to comply with the applicable regulations may result in the imposition of financial or other penalties on the Company.

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

If unforeseen events occur, such as wars or terrorist attacks or epidemics, adverse changes in economic conditions and the financial market may occur, which may adversely affect the Company's financial condition. In addition, such random events as fires, floods and other extraordinary natural disasters may cause failures or destruction of material property belonging to Mabion S.A., as well as disruptions to the Company's operations, which may adversely affect the Company's financial results.

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.

Risk related to the coronavris (COVID-19) pandemic

As regards the coronavirus (COVID-19) epidemic threat, which started to increase with the beginning of 2020, there was a risk of delays in the schedule of work or suspension of work for an unspecified period of time due to the possible or actual restrictions indicated below:

- reduced staff availability (quarantine, childcare in case of school closures, risk of falling ill);
- limiting the mobility of the Company's employees - suspension of the participation of the Company's representatives in meetings and conferences, both foreign and domestic;
- suspension of meetings with external companies, including consultants;
- delays in deliveries resulting in the inability to conduct certain processes in the Company;
- the possibility of plant closure in order to limit the possibility of virus spread.

All the aforementioned phenomena may have a direct impact on the Company's financial situation. In order to prevent the aforementioned risk, the Management Board monitors the global situation on an ongoing basis, trying to adapt the Company's strategy to changes in the threats in the areas described above in advance.

With regard to the epidemic risk, the Management Board has taken steps to significantly reduce the risk both through the education of employees and the implementation of solutions to protect workers' health (e.g. a resolution was adopted on the introduction of countermeasures by the Management Board in connection with the entry into force of the Act of 2 March 2020 on special solutions related to the prevention, counteracting and combating of COVID-19, other infectious diseases and crisis situations caused by them (Polish Journal of Laws, item 374 of 2020).

The Management Board is monitoring the situation on an ongoing basis and in the event of significant new circumstances related to the coronavirus COVID-19 pandemic and affecting the Issuer's operations, the Company will introduce appropriate solutions, adapting to administrative decisions

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. Clinical development activities for oncological drugs are undertaken by more than 700 companies and are at a record high level, and the estimated expenditure will have a CAGR (until 2023) of 11-14%[40]. In addition, there is a rapid development in 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.

[40] Global Oncology Trends 2019, IQVIA Institute

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.

By the date of publication of this report, biosimilars to MabThera/Rituxan have been marketed in the EU by Celltrion and Sandoz, and Pfizer has received a positive CHMP opinion for its antibody. In the US, Celltrion and Pfizer have received a positive regulatory approval. In December 2019, Amgen submitted an application to the FDA for registration of a biosimilar rituximab.

The above mentioned activities of competitors do not affect Mabion's schedule. Even if the commercialisation of a biosimilar drug to MabThera/Rituxan is successful for several players, the analyses show that this market has a growth potential.

For the sustainable development of the market for biosimilar medicines, it is essential that more manufacturers emerge. Even within the EU, where the market penetration of biosimilar medicines is the highest, some countries still have low access to biosimilar treatments. Currently, demand for medicines for oncology and autoimmune diseases exceeds the production capacity of suppliers and is limited by the financial capacity of national health systems.

The market for biosimilar drugs is one with high entry barriers. These include very high requirements for clinical trials, particularly in the US and other developed countries, to prove that a medicine is biosimilar to the original medicine.

Partnering risk

In 2016, the Company signed a long-term cooperation agreement with Mylan. The agreement provides Mylan with exclusive rights to sell the drug under the working name of MabionCD20 in all EU and Balkan countries. In addition, under the agreement, Mylan supports the Company in the process of registration of MabionCD20 by the EMA. With respect to sales of the drug in the US market, Mylan is a potential partner for the Company, which has priority to conclude an agreement with the Company regarding the right to sell MabionCD20 on the US market. Mabion will be able to contact other potential partners, however the Company could commence cooperation with a specific partner other than Mylan only in the event that Mylan resigns its priority.

In July 2019, Mylan announced its intention to merge with Upjohn, a spin-off of the Pfizer Group. According to publicly available information, Pfizer will not contribute to the new entity's biosimilar drug development projects, which is important given that both Mabion and Pfizer are developing an oncological drug with rituximab as the active ingredient. In addition, from the information in the available materials it stems that Pfizer will focus on innovative projects, which may suggest that biosimilars will not be a key development area for the company. In August 2019, Mabion S.A. received information from Mylan's legal department that at that time, they did not anticipate any impact of the planned merger on the binding agreement (Development and Commercialization Agreement) for registration of MabionCD20 on the European market. This is confirmed by the fact that the cooperation between the Company and Mylan is conducted in accordance with the adopted assumptions, and working group meetings are held on a regular basis and in accordance with the needs of work related to the process of registration of MabionCD20 in the EMA.

However, it cannot be excluded that Mylan's position may change in the future. Mabion has no influence on the scope of cooperation of third parties and it may happen that the development strategy for medicinal products adopted by the new entity will be competitive in relation to the Company's offer. On 26 March 2020, Pfizer and Mylan announced that the completion of the merger will be delayed and is expected only in the second half of 2020. In their statement, the companies referred to "unprecedented circumstances related to the COVID-19 pandemic, including associated delays in the regulatory review process"[41].

[41] https://www.fiercepharma.com/pharma/pfizer-mylan-postpone-generics-merger-review-due-to-covid-19-delays

In addition, as a result of the change in Mabion's regulatory strategy introduced on 16 March 2020 and the withdrawal from the EMA of registration applications for MabionCD20, the introduction of MabionCD20 to the European market may be delayed in comparison to the original arrangements with Mylan. The existing agreement with the distribution partner provides for the possibility of termination after 2020 in the absence of drug registration by that time. In case of lack of registration of MabionCD20 by December 31, 2020, Mylan may terminate the contract, consequently, may require the Company to reimburse most of the advances obtained in Note 19 to the financial statements. In such a case, the Company will have to acquire a new partner or distribution partnersThe Company continues an ongoing close cooperation with Mylan representatives and exercises due care to ensure that its course is satisfactory to both the entities.

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 between USD 100 and 300 million. Guidelines relating to biosimilars are only now being formed and each case is analysed by market regulators individually, therefore, the scope of requirements relating to the technology, documentation, analytics and clinical development is not strictly specified. Therefore, the exact scope of research and development work cannot be determined and the development costs of the 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 characterise 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[42]. The Company' s goal was to market MabionCD20 as soon as possible after patent expiration, which would allow the Company to achieve a temporarily favorable competitive position.

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 has held scientific advice sessions to eliminate doubts and to refine the activities related to the preparation of registration documentation. However, the EMA has a number of tools at its disposal to ensure the regulator' s discretion and the possibility of adjusting the solution individually to the needs of a specific registration procedure. The Company has no influence on the EMA' s assessment of applications and responses. There are a number of possible events in the registration process - positive or negative decisions, obtaining a list of additional questions (once or more), filling in a round of oral answers (once or more), withdrawal of the application by the Company and its resubmission after supplementing, or other events not envisaged by the Company. The schedule of work on the part of the Company also depends to a large extent on the recommendations of the regulator, which the Company may receive during the aforementioned scientific advice sessions.

For the US market, the Company is actively pursuing a consultative process with the 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. However, there is a risk that after analysis of data presented by the Company in the consultation process, FDA will indicate the need for additional work to be carried out by the Company, which may affect the schedule of drug registration in the USA.

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.

[42] Global Data

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 and the quality control 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, including quality control of the product at intermediate and final stages, and stability and purity of the entire production process. The Quality Control Laboratories have been equipped in line with the highest pharmaceutical standards. A panel of validated analytical methods ensures maximum accuracy, precision, specificity and repeatability of the results. The panel is designed in accordance with the requirements of the regulator's guidelines, and enables reliable product control. A key parameter of analytical methods is their variability, which is influenced by a number of factors determined during the validation. Constant control of the method variability over time is critical in the case of tests in which the results are collected over years (e.g. product stability, biosimilarity and bioequivalence studies). Lack of reliable trend analysis of methods may adversely affect the final assessment of both the production processes and bioequivalence of the test and reference products. 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 manufacturing 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 production process specified in a technological procedure 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.

An extremely important factor in the Company's operations is maintaining appropriate conditions on the premises where the Company's products are being developed. All equipment and manufacturing facilities at both plants are kept in the qualified condition.

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 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 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 US markets, which involves the obligation to register such drugs with the EMA and Food and the FDA, respectively.

In developing its regulatory strategy for MabionCD20 on a 2x250L scale, the company has identified from the outset a number of risks that may affect the registration process and, consequently, the timing of MabionCD20's marketing in Europe. Such factors include regulatory issues (e.g. misinterpretation of guidelines), organisational issues (e.g. inability to respond to the regulator within a specific timeframe, lack of specific data and analytical or manufacturing results, etc.) or quality issues (failure to achieve specific quality parameters for the drug). Ongoing monitoring and preventive actions undertaken by the Company were aimed at minimising the risk factors indicated.

The original regulatory strategy assumed obtaining a marketing authorisation for a medicine manufactured in a small scale - step 1, and then, on the basis of a variation, a marketing authorisation for a large, commercial scale - step 2. At the same time, the Company carried out works related to the validation of a batch manufactured in the scale 2x2500L. On 16 March 2020, on the basis of opinions of external consultants and recommendations of the Company's Supervisory Board, the Management Board of Mabion S.A. decided to change its regulatory strategy. The basic change is to obtain approval for marketing of the drug in EMA directly for a large commercial scale as opposed to the previously planned 2-step strategy. In the opinion of the Company's Management Board, the change of the strategy is currently the most optimal path in terms of both cost and time of registration of the product coming from the large-scale process oand the possibility of commercialization of MabionCD20 in the European Union.

The scope and format of the new applications will first be consulted with representatives of the EMA as part of the scientific advice procedure, in order to adapt them to the Agency's expectations, which will streamline the registration procedure for the target large scale production process.

It should be highlighted, however, that although the registration process takes place in accordance with the adopted regulations and according to specific guidelines, the regulators (both the EMA and the FDA) have a number of tools at their disposal which provide them with considerable decision-making freedom and the possibility of individual adaptation of solutions to the needs

that occur, in the regulator's assessment, in a given registration procedure. The process of registration and authorisation of a medicine is a multi-stage process aimed at working out the final position of the regulator. Even if the regulator provides guidance and guidelines on the shape and scope of the data currently required, it cannot be ruled out that additional requirements for product approval may arise in the future.

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.

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.

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 recognised 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. The Company implements activities aimed at supporting the professional development of its employees, e.g. through their participation in the "Mabion Academy" project which covers internal and external training, support in undertaking doctoral studies, as well as including in the promotion procedure. The rules for obtaining the above-mentioned benefits are formalised, open and objective (e.g. promotion procedures, implementation of bonus schemes for many-year employees, implementation of loyalty programmes and bonus schemesIn addition, in 2018 the Company adopted the Incentive Scheme for persons of key importance to the Company, implemented over a period of up to 4 financial years, i.e. for the financial years 2018-2021. The aim 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, by means of a permanent relationship between the persons participating in the Incentive Scheme and the Company and its objectives.

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.

The initial deadline for the project was set for 31 December 2019. In June 2019, the Company applied to the NCBR to extend the project implementation by 9 months, i.e. until 30 September 2020. In December 2019, the NCBR agreed to introduce the above change, whose introduction is crucial for the implementation of development work (the necessity to comply with the regulator's guidelines and the time of ongoing experiments - additional analytical batches) and obtaining the planned milestones.

» *„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.

In 2018, the Company submitted an application to the NCBR to extend the first stage of the project by 10 months (from the assumed date of 31 December 2018 to 31 October 2019). The change results from the need to adjust the schedule of material progress to the ongoing research work. In July 2019, NCBR agreed to introduce the above change.

» *„The clinical development and registration of a humanised 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

In 2017, the Company decided to end the above mentioned project at its current stage of implementation due to the high scientific risk related to the implementation of research on a biopharmaceutical similar to Herceptin and the analysis of the competitive environment. From the received funding, the Company used funds in the amount of PLN 177 thousand. On 11 September 2019, the Company received information from the NCBR on the obligation to repay the amount of PLN 149 thousand and interest (calculated as for tax arrears from the date of transfer of funds, i.e. from 10.12.2014), as reimbursement of funding under the INNOMED project. Taking into account that the project covered by the subsidy ended without achieving the assumed objectives and planned indicators and the high probability of having to return the funds, the Company, in earlier reporting periods, created an appropriate provision fully covering the potential amount necessary to repay the funds with interest. On 19 September 2019, the Company paid the above liabilities in full.

On 11 March 2020, the Company received a letter from the NCBR stating that after the verification of the cash flows under the subsidy agreement, the amount of liability under the adjustment amounting to PLN 23,926.68 and interest (calculated as for tax arrears from the date of transfer of funds, i.e. from 10.12.2014) remained to be repaid. On 25 March 2020, the Company applied for cancellation of payment of interest and the principal amount or deferral of payment until the end of 2020. As at the date of publication of this report, the Company awaits the position of NCBR.

» *„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

In 2019, the Company fulfilled the financial condition resulting from the provisions of the project financing agreement, thanks to which it may start the project in its full scope. In 2019, the Company also started work related to the selection of contractors / suppliers of the first devices necessary to implement the project.

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

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.

With regard to the change in Mabion's regulatory strategy adopted on 16 March 2020 and the withdrawal of applications for registration of MabionCD20 from the EMA, the introduction of MabionCD20 to the European market may be delayed as compared to the original arrangements with Mylan. The existing agreement with the distribution partner provides for the possibility of termination after 2020 in the absence of drug registration by that time. In case of lack of registration of MabionCD20 by December 31, 2020, Mylan may terminate the contract, consequently, may require the Company to reimburse most of the advances obtained in Note 19 to the financial statements. In such a case, the Company will have to acquire a new partner or distribution partners.

The Company continues an ongoing close cooperation with Mylan representatives and exercises due care to ensure that its course is satisfactory to both the entities.

Possible delays in the implementation of the assumed schedule may delay Mabion's receipt of subsequent tranches of payments from the distributor. In addition, failure to apply for new EU aid may also expose Mabion to liquidity problems and the need to obtain an alternative source of funding.

The Company's management monitors current forecasts of the Company's liquid assets and liabilities based on projected cash flows. The risks associated with limited access to funding due to the global liquidity situation or the Company's financial position and the assessment of the ability to register the key drug, MabionCD20, cannot be excluded. The risk associated with the impossibility of changing the terms of the existing loan agreements, including the possibility of disbursement of individual tranches of financing, or changes in the terms of the agreement with Mylan, should be indicated here. In particular, the current situation caused by the pandemic and its impact on capital markets should be borne in mind, as it may result in significant limitations in terms of sources of financing, including equity 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 (LSEZ). 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 LSEZ 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 Applied corporate principles

In 2019, 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 2019, the Company did not apply two DPSN 2016 recommendations: VI.R.1., VI.R.2.

In 2018, the Company did not apply seven DPSN 2016 detailed principles: II.Z.2., III.Z.2., III.Z.3., III.Z.4., V.Z.6., VI.Z.1, VI.Z.2.

In 2019, three recommendations did not apply to the Company: I.R.2., IV.R.2., IV.R.3. as well as two detailed principles: I.Z.1.10., IV.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: At present, the Company does not have a separate policy of sponsorship and charity or other similar activities. The Company may only engage in thematic biotechconferences to a limited extent as a partner or sponsor, having first analysed the compliance with the adopted communication strategy and adequacy of the costs incurred. As part of the work on the implementation of internal regulations forming the anti-corruption system, the Company plans to include in the scope of the Anti-Corruption Code issues related to sponsorship and charity activities, in the event of a decision to carry out sponsorship activities in a specific scope.

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.

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.

The above 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.

The above 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.

The above 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.

The above 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.

The above 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. As part of the work on the implementation of internal regulations forming an anti-corruption system, the Company plans to include in the scope of the Anti-Corruption Code issues concerning conflicts of interest.

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

The above principle is not applied.

The Company's comment: In 2019, the Company did not have a remuneration policy, and remuneration for different Members of the Management Board was determined each time as a result of negotiations by the Supervisory Board, and in relation to the Supervisory Board, by the General Meeting. In accordance with the amended Act on Public Offering (...), in 2020 the Company will start to develop a remuneration policy that meets the statutory requirements, which will be presented to the General Meeting of the Company for adoption.

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.

The above principle is not applied.

The Company's comment: In 2019, the Company did not have a remuneration policy, and remuneration for different Members of the Management Board was determined each time as a result of negotiations by the Supervisory Board, and in relation to the Supervisory Board, by the General Meeting. In accordance with the amended Act on Public Offering (...), in 2020 the Company will start to develop a remuneration policy that meets the statutory requirements, which will be presented to the General Meeting of the Company for adoption.

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.

The above 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.

The above principle is not applied.

The Company's comment: The Rules and Regulations of the Incentive Scheme for 2018-2021 of Mabion S.A. do not provide for a minimum two-year period between the granting of the aforementioned financial instruments and the possibility of their realisation, therefore the above principle is not applied in the Company. At the same time, the Company emphasises that in accordance with the Rules and Regulations of the Incentive Scheme for 2018-2021 of Mabion S.A., the exercise of rights carried by A and B series subscription warrants by an eligible person and the acquisition of R and S series shares of the Company requires that the eligible person submit to the Company a declaration of commitment not to sell R and S series shares within one or three years, respectively, from submitting to the Company the declaration on taking up the shares in the exercise of rights from subscription warrants.

With regard to the above principle, on 18 November 2019 the Company decided not to apply it. Originally, the principle did not apply to the Company. In connection with the implementation, in November 2019, of the Incentive Scheme adopted by Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the introduction of the Incentive Scheme and the subscription by eligible persons for B series subscription warrants of the Company granted to such persons for 2018, the above principle began to apply to the Company. At the same time, as explained above, the Rules and Regulations of the Incentive Scheme for 2018-2021of Mabion S.A. do not provide for a minimum two-year period between the granting of the above financial instruments and the possibility of their realisation, therefore the above DPSN principle is not applied to the Company. The Company informed the EIB about the decision to abandon applying the rule in Current Report no. 1/2019 of 18 November 2019.

At the same time, in 2019 the Company started to apply principle I.Z.2. (A company whose shares participate in the exchange index WIG20 or mWIG40 should ensure that its website is alsoavailable in English, at least to the extent described in principle I.Z.1. This principle should also be followed bycompanies not participating in these indices if so required by the structure of their shareholders or the nature andscope of their activity).

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

6.1 The Company's share capital

As of the date of publication of this report, the Company's share capital amounts to PLN 1,373,027.20 and is divided into 13,730,272 shares with a nominal value of PLN 0.10 each, including:

- 450,000 A series registered preference shares,
- 450,000 B series registered preference shares,
- 450,000 C series registered preference shares,
- 450,000 D series ordinary preference shares,
- 100,000 E series registered preference shares,
- 100,000 F series registered preference shares,
- 20,000 G series registered preference shares,
- 2,980,000 H series ordinary preference shares,
- 1,900,000 I series ordinary preference shares,
- 2,600,000 J series ordinary preference shares,
- 790,000 K series ordinary preference shares,
- 510,000 L series ordinary preference shares,
- 360,000 M series ordinary preference shares,
- 340,000 N series ordinary preference shares,
- 300,000 O series ordinary preference shares,
- 1,920,772 P series ordinary preference shares,
- 9,500 S series ordinary preference shares.

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 of the Company is 15,300,272 votes.

On 2 April 2019, the Management Board of the Company adopted a resolution on conversion of 514,773 ordinary registered P shares into ordinary bearer P shares, issuing a collective certificate for the above shares and depositing it in a brokerage house, and on entering into an agreement with the National Depository for Securities (Krajowy Depozyt Papierów Wartościowych S.A.) on the registration of the above shares in the deposit of securities and applying for their admission and introduction to trading on the official stock exchange quotation market of the Warsaw Stock Exchange (Giełda Papierów Wartościowych w Warszawie S.A.). The resolution was adopted in accordance with the motion of a shareholder – Twiti Investments Limited – submitted pursuant to Article 334 § 2 of the Code of Commercial Companies. 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 P shares are not preference shares.

After the conversion, all P shares of the Company, i.e. 1,920,772 shares, are ordinary bearer shares. The Company informed about the event in its Current Report no. 7/2019 of 2 April 2019.

On 18 November 2019, the Company issued 9,500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2018. The subscription warrants were taken up on 18 November 2019, free of charge, by eligible persons, i.e. persons appointed by the Company's Supervisory Board. Each B series subscription warrant entitled to take up 1 S series ordinary bearer share of the Company at the issue price equal to the nominal value of shares of PLN 0.10 each. All eligible persons submitted declarations on taking up their S series shares of the Company on 18 November 2019. The issue of S series shares took place in performance of Resolution No. 25/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the issue, for the purpose of implementing the Incentive Scheme, of A and B series subscription warrants with the exclusion of the pre-emptive right of the existing shareholders, entitling to take up R series shares and S series shares, and on the conditional increase of the share capital through the issue of R series shares and S series shares, with the exclusion of the pre-emptive right of the existing shareholders, and the related amendment of the Company's Articles of Association. The S series shares were issued as part of a conditional share capital increase, therefore no allocation of shares took place. Due to the fact that the S series shares were issued as dematerialized shares and were subject to the application for admission to trading on the regulated market, the shares were released by recording them on the securities accounts of the eligible persons. The S series shares were released on 29 January 2020 (event after the balance-sheet date). A total of 9,500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were released. The Company informed about the event in Current Reports no. 33/2019 of 29 November 2019 and no. 8/2020 of 29 January 2020.

On 5 December 2019, the District Court for Łódź-Śródmieście in Łódź, 20th Commercial Division of the National Court Register (Court) registered the conditional increase in the Company's share capital by an amount not higher than PLN 40,283.50 on the basis of Resolution No. 3/XI/2019 of the Extraordinary General Meeting of the Company of 29 November 2019 on the conditional increase in the Company's share capital through the issue of T series ordinary bearer shares with the simultaneous full exclusion of the pre-emptive right of the existing shareholders of the Company, the issue of C series subscription warrants with the simultaneous full exclusion of the pre-emptive right of the existing shareholders of the Company, and the amendment of the Company's Articles of Association. The Company's share capital was conditionally increased by issuing not more than 402,835 ordinary shares to bearer, T series, with a nominal value of 0.10 PLN each, with a total nominal value not higher than PLN 40,283.50. The conditional share capital increase was effected in order to grant rights to take up T series shares to the European Investment Bank (EIB) - the holder of registered subscription warrants to be issued by the Company in performance of the Warrant Agreement concluded with the EIB on 31 October 2019. The subscription warrants may be issued not later than on 30 June 2020. The warrants will be issued free of charge. Each subscription warrant will entitle to take up 1 T series share at the issue price of PLN 0.10 per one T series share. The right to take up T series shares may be exercised until 29 November 2029. All T series shares may be paid up only with a cash contribution. The Company informed about the event in Current Reports no. 32/2019 of 29 November 2019 and no. 35/2019 of 6 December 2019..

On 17 January 2020 (event after the balance-sheet date) the National Depository for Securities (KDPW S.A.) (KDPW) made a conditional registration in the securities depository, under ISIN code PLMBION00016, of 514,773 P series ordinary bearer shares of the Company and 9,500 S series ordinary bearer shares of the Company. The condition for the registration of shares of each of the above mentioned series was their introduction to trading on the regulated market to which other shares of the Issuer marked with the above mentioned ISIN code were introduced. On 24 January 2020, the Board of the Warsaw Stock Exchange S.A. (WSE) adopted a resolution on the admission and introduction of the Company's P and S series shares to exchange trading on the WSE Primary Market. Pursuant to the resolution, the above mentioned shares of the Company were admitted to trading on the primary market and the WSE Board decided to introduce the above mentioned shares of the Company as of 29 January 2020 to trading on the primary market, provided that the KDPW registered the shares on 29 January 2020 and assigned them with code PLMBION00016. On 27 January 2020, the KDPW published an announcement on the registration of the above shares under the above code in the securities depository as of 29 January 2020. Thus, the condition for the introduction of the above shares to trading on the WSE primary market on 29 January 2020 was fulfilled. The Company informed about the above events in Current Reports no. 3/2020 of 17 January 2020, no. 5/2020 of 24 January 2020 and no. 6/2020 of 27 January 2020.

6.2 Shareholders of the Company holding significant blocks of shares

To the best knowledge of the Management Board of the Company, as at the date of approval of this report, i.e. 8 April 2020, the following shareholders held at least 5% of votes at the General Meeting of the Company.

Table 16: Shareholding structure.

No.	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.	Funds managed by Nationale-Nederlanden PTE S.A.***	938,031	938,031	6.84%	6.13%
7.	Other	4,779,558	4,779,558	34.83%	31.26%
	Total	**13,720,772**	**13,720,772**	**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 Extraordinary General Meeting of Mabion S.A. on 29.11.2019*

*** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 18.06.2019.*

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 publication of this report, i.e. 8 April 2020, members of the Company's Management Board and Supervisory Board hold the following shares in the Company:

Table 17. Shares held by managing and supervising persons.

Shares held as at the date of approving the report for 2019 (as at 8 April 2020)	
Management Board	
Sławomir Jaros	holds directly 4,043 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.03% of the Company's share capital and entitling to 0.02% of votes at the General Meeting.
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., a 66.67% participation in the share capital) he holds a total of 1,626,576 shares in the Company with a nominal value of PLN 0.10 each, constituting 11.85% of the Company's share capital and entitling to 13.85% of votes at the General Meeting.

As at the date of publication of this report, i.e. 8 April 2020, other managing and supervising persons do not hold any shares in the Company. Members of the Management Board and Supervisory Board of Mabion S.A. do not hold any shares in the Company's related entities.

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..

As regards the implementation of the Incentive Scheme for 2018, in February 2019 the Supervisory Board of Mabion S.A., after verifying whether the criteria specified in the Incentive Scheme are met, 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 eligible persons the right to take up a total of 9,500 B series subscription warrants for 2018.

As regards the implementation of the Incentive Scheme for 2019, in February 2020, the Supervisory Board, after verifying the fulfillment of the criteria, concluded that in 2019, with respect to A series warrants, the market objective constituting one of the conditions for the right to take up and exercise rights carried by A series warrants was also not fulfilled, while the condition for the right to take up and exercise rights carried by B series subscription warrants was met. Thus, the Supervisory Board granted the eligible persons the right to take up a total of 500 B series subscription warrants for 2019.

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. Każdy warrant subskrypcyjny serii A i serii B uprawnia do objęcia 1 akcji (odpowiednio serii R i serii S). 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.

On 18 November 2019, the Company issued 9,500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2018. All eligible persons subscribed for the subscription warrants free of charge on 18 November 2019 and also on 18 November 2019, they submitted declarations on taking up the Company's warrants for S series shares. Due to the fact that the S series shares were issued as dematerialized shares and were the subject of applying for admission to trading on a regulated market, the shares were released by recording them on the securities accounts of the eligible persons. The S series shares were released on 29 January 2020.

Until the date of publication of this report, the B series subscription warrants available under the Incentive Scheme for 2019 have not been issued.

Moreover, in February 2020 the Supervisory Board of Mabion S.A., by way of resolutions, adopted a list of persons eliigble to take up A and B series subscription warrants for 2020 together with the maximum number of warrants that each of these persons may take up, provided that the criteria set out in the Incentive Scheme are met. According to the resolutions, the eligible persons are entitled to take up a maximum of 28,500 A series warrants and 500 B series warrants in total for 2020.

6.5 Purchase of own shares

In 2019, the Company did not acquire or dispose of its own shares.

6.6 Holders of securities with special control rights

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. No other securities giving special control rights exist in the Company.

Tabela 18: Registered shares.

Series	Number of shares	Shareholder	Number of series shares held by the shareholder as at 8 April 2020
A	450,000	Celon Pharma S.A.	450,000
B	450,000	Polfarmex S.A.	450,000
C	450,000	Twiti Investments Limited	450,000
E	100,000	Celon Pharma S.A.	32,850
		Polfarmex S.A.	32,850
		Twiti Investments Limited	34,300
F	100,000	Celon Pharma S.A.	10,000
		Twiti Investments Limited	90,000
G	20,000	Twiti Investments Limited	20,000

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 Articles of Association of the Company do not provide for any limitations in trading in D, H, I, J, K, L, M, N, O, P and S series shares of the Company. The A, B, C, E, F, G series shares are registered shares. The shareholders entitled under registered shares have the priority right and the pre-emption right to purchase registered shares intended 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 which, if implemented in the future, could cause changes in the way the Company is controlled. The Artciles of Association of the Company contain provisions related

to the rules of disposal of priviledged registered shares of A, B, C, E, F and G series (pre-emption right and priority right of purchase of registered shares for other owners of registered shares of the Company), on the basis of which a registered share can be disposed of to people other than shareholders entitled under the registered shares only on the condition that those entitled from the pre-emption right and from the priority right of purchase will not execute 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

As of 1 January 2019, the composition of the Company's 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. The Company informed about the event in Current Report no. 63/2018 of 24 December 2018.

On 25 April 2019, Mr. Artur Chabowski tendered his resignation from the position of President of the Management Board of the Company. The resignation came into force on 30 June 2019. The Company informed about the event in Current Report no. 11/2019 of 25 April 2019.

As at 31 December 2019, the composition of the Company's Management Board was as follows:

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

On 16 March 2020, the Supervisory Board of the Company adopted a resolution on appointing Mr. Dirk Kreder as President of the Management Board of the first joint term of office of the Company. The Company informed about the event in Current Report no. 14/2020 of 16 March 2020.

As at the date of publication of this report, the composition of the Company's Management Board is as follows:

Mr. Dirk Kreder	–	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 exercises all rights to manage 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 (§ 27 of the Company's Articles of Association). The right to take a decision on the issue or purchase of shares is vested in the General Assembly (§ 17 of the Company's Articles of Association). The President of the Management Board alone or two Members of the Management Board acting jointly or one Member of the Management Board acting together with a proxy are authorised to make declarations of will and sign on behalf of the Company. The Management Board is obliged to conduct the Company's affairs and manage its assets with due diligence required in business transactions, observe the law, provisions of the Company's Articles of Association and resolutions adopted by the General Meeting and the Supervisory Board.

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 2019 to the Management Board Members for serving on the Company's Management Board.

Table 19. Remuneration of the Management Board Members.

Member of the Management Board	Gross remuneration due for 2019	Gross remuneration paid in 2019
Artur Chabowski	PLN 875,790.50	PLN 921,502.50
Jarosław Walczak	PLN 48,000.00	PLN 48,000.00
Sławomir Jaros*	PLN 686,769.81*	PLN 681,240.81**
Grabowicz Grzegorz***	PLN 483,266.65	PLN 442,866.65

* *including PLN 505,769.81 on account of the employment contract (basic salary plus other components);*
** *including PLN 496,240.81 on account of the employment contract (basic salary plus other components);*
*** *the total remuneration shown in the table obtained under the employment contract (basic 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 2019.

In 2019, the following bonuses were paid to the Management Board Members:

» On the basis of the resolution of the Supervisory Board of 12.02.2019, Mr. Sławomir Jaros was awarded a bonus of PLN 40,000 gross in connection with leveraging EU funds for the Company;

» On the basis of the resolution of the Supervisory Board of 12.02.2019, Mr. Artur Chabowski was awarded a bonus of PLN 100,000 gross in connection with leveraging EU funds for the Company;

» On the basis of the resolution of the Supervisory Board of 25 April 2019, Mr. Artur Chabowski was awarded a bonus of PLN 75,000 gross in connection with sending answers to the European Medicines Agency;

» On the basis of the resolution of the Supervisory Board of 25 April 2019, Mr. Sławomir Jaros was awarded a bonus of PLN 125,000 gross in connection with sending answers to the European Medicines Agency;

The above amounts are included in the summary presented in Table 19.

In addition, the following benefits were granted and paid in 2019 to Mr. Artur Chabowski:

» As compensation for the non-competition ban established for the period after the resignation from the position of President under the "non-competition agreement" (resolution of the Supervisory Board of 25 April 2019), a total of PLN 290 000 gross was paid out.

» Severance pay in connection with the resignation referred to above, in the amount of PLN 135,000 gross (resolution of the Supervisory Board of 31 March 2017 on determining the remuneration of the President of the Management Board).

The above amounts are included in the summary presented in Table 19.

In 2018, the Company introduced an Incentive Scheme for persons of key importance to the Company, the principles of which are described in sections 6.4 and 8.1 of this Report. In accordance with the resolutions of the Company's Supervisory Board of February 2019 and February 2020, the persons entitled to take up subscription warrants for 2018, 2019, and 2020 include Members of the Management Board of the Company:

» Mr. Sławomir Jaros - for 2018: granted 4,043 B series warrants and the right to take up a maximum of 5,644 A series warrants; for 2019: granted 213 B series warrants and the right to take up a maximum of 3,960 A series warrants; for 2020: the right to take up a maximum of 6,099 A series warrants and 213 B series warrants;

» Mr. Jarosław Walczak - for 2018: the right to take up a maximum of 1,411 A series warrants; for 2019: the right to take up a maximum of 990 A series warrants;

» Mr. Grzegorz Grabowicz - for 2019: the right to take up a maximum of 3,300 A series warrants, for 2020: the right to take up a maximum of 5,101 A series warrants.

A series subscription warrants for 2018 and 2019 were not granted due to failure to meet the market target in 2018 in 2019. However, in accordance with the Rules and Regulations of the Incentive Scheme, these warrants may be granted to eligible persons during the period of the Incentive Scheme together with A series warrants for the year in which the market target is met.

B series subscription warrants for 2018 were granted. On 18 November 2019, Mr. Sławomir Jaros took up, free of charge, 4,043 B series warrants and submitted a declaration on taking up 4,043 S series shares of the Company in the exercise of his rights carried by those warrants. Due to the fact that S series shares were issued as dematerialized shares and were subject to the application for admission to trading on the regulated market, the shares were released by recording them on securities accounts, which took place on 29 January 2020.

The B series subscription warrants for 2019 were granted under a resolution of the Supervisory Board in February 2020, but have not been issued until the date of publication of this report.

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

In the financial year 2019, the composition of the Company's Supervisory Board was as follows:

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

On 16 March 2020, Mr. Dirk Kreder tendered his resignation from the position of Member of the Supervisory Board of the Company in connection with the intention to appoint him as President of the Management Board of the first joint term of the Company. Furthermore, on the same day, Mr. Maciej Wieczorek tendered his resignation from the position of Chairman of the Supervisory Board of the Company. Mr. Maciej Wieczorek is still a Member of the Supervisory Board. At the same time, on 16 March 2020, the Supervisory Board of the Company adopted a resolution on the election of Mr. Krzysztof Kaczmarczyk as Chairman of the Supervisory Board. On the same day, Mr. Józef Banach tendered his resignation from the position of Deputy Chairman of the Supervisory Board. Mr. Józef Banach is still a Member of the Supervisory Board. At the same time, the Supervisory Board of the Company adopted a resolution on the election of Mr. Maciej Wieczorek as Deputy Chairman of the Supervisory Board. The Company informed about the event in Current Reports no. 14/2020 and 18/2020 dated 16 March 2020.

As at the date of publication of this report, the composition of the Company's Supervisory Board is as follows:

- Krzysztof Kaczmarczyk – Chairman of the Supervisory Board, Independent Member;
- Maciej Wieczorek – Deputy Chairman of the Supervisory Board;
- Józef Banach – 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 Kroński – Independent Member of the Supervisory Board.

The Company's Supervisory Board consists of five to nine members. 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 financial year 2019. Members of the Supervisory Board are appointed and dismissed by the General Meeting.

7.2.2 Powers 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 of a value exceeding PLN 250 thousand;

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

k) granting consent for the Company to enter into a significant agreement with a shareholder holding at least 5% of the total number of votes in the Company or an entity related to the Company, except for typical transactions concluded on arm's length as part of the Company's operating activity with entities belonging to the Company's capital group.

In addition to the activities listed above, the Supervisory Board should:

a) 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;

b) 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 2019 was as follows:

Table 20: Remuneration of the Supervisory Board Members.

Supervisory Board Member	Remuneration due for 2019, gross*	Remuneration paid for 2019, gross**
Józef Banach	PLN 55,000.00	PLN 54,000.00
David James	PLN 102,000.00	PLN 102,000.00
Krzysztof Kaczmarczyk	PLN 102,000.00	PLN 102,000.00
Robert Koński	PLN 54,000.00.00	PLN 54,000.00
Dirk Kreder	PLN 53,000.00	PLN 65,666.67
Jacek Nowak	PLN 55,000.00	PLN 54,000.00
Tadeusz Pietrucha	PLN 7,000.00	PLN 7,000.00
Maciej Wieczorek	PLN 55,000.00	PLN 55,000.00

* *The amount stated above is inclusive of the remuneration due in respect of the year 2019 for performing the function of Member of the Supervisory Board.*

** *The amount stated above is inclusive of the remuneration paid in the year 2019, including amounts due for 2018.*

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 2019.

In 2019, 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 2019, 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 2019, the Company did not grant any in-kind benefits to Members of its Supervisory Board.

In accordance with the Resolution of the Extraordinary 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/2017dated 16 February 2017.

In 2019, 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

In the financial year 2019, the composition of the Audit Committee was 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.

On 16 March 2020, Mr. Dirk Kreder tendered his resignation from the position of Member of the Supervisory Board of the Company. Therefore, as at the date of publication of this report, the composition of the Audit Committee is 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. Józef Banach – Member of the Audit Committee.

The Audit Committee operates in accordance with the provisions of the Act of 11 May 2017 on Statutory Auditors, Audit Firms and Public Supervision (hereinafter referred to in point 7.2.4 as "Act"), and its organisation and operation are specified in the rules of procedure adopted by the Supervisory Board.

In 2019, the Audit Committee held 3 meetings.

The criteria of independence within the meaning of the Act in the composition of the Audit Committee in 2019 were fulfilled by Mr. David James, Mr. Dirk Kreder, Mr. Krzysztof Kaczmarczyk and Mr. Józef Banach. These persons also met the independence criteria within the meaning of the Best Practice of WSE Listed Companies 2016.

Members of the Audit Committee have declared that they had 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 (until 16 March 2020)
Dirk Kreder (until 16 March 2020)	Jacek Nowak
Jacek Nowak	Józef Banach
Józef Banach	

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

Graduate of the University of Cambridge, certified auditor at the Polish Chamber of Chartered Accountants and ICAEW (Institute of Chartered Accountants in England and Wales). Currently International Liaison Partner, Grupa Strategia, Poland. He has 28 years of experience in audit and internal control. Member of the management boards of many companies and a start-up advisor in the CEE region for nearly fifty companies. Partner responsible for auditing the financial statements of over 100 companies and groups of companies from multiple sectors of the economy, both listed companies, private equity funds and family businesses. His portfolio includes over 80 due diligence analyses, he dealt with statutory, internal and forensic financial audits and provided business advisory services to many clients. He has worked in Poland, UK, 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 an original method of foreign language learning.

» **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 (until 16 March 2020)**

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 include 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, a statutory auditor or an audit firm carrying out the statutory audit of a public-interest entity, or any member of the network to which the statutory auditor or the audit firm belongs, shall not directly or indirectly provide to the audited entity, to its parent undertaking or to its controlled undertakings within the 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 Article 5(1), second paragraph, point e) of the above mentioned Regulation.

Services prohibited under Article 136.1 of the 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 2019 was audited by PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k. 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 2019, 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 2019. For more information on the audit firm, please refer to point 8.4.

2. Appointment and Remuneration Committee

On 22 September 2017, the Company's Supervisory Board, 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 powers specified in the adopted Rules of Procedure, pursuant to Article 390 of the Code of Commercial Companies.

In the financial year 2019 and until the date of publication of this report, the composition of the Appointment and Remuneration Committee 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 competence of the General Meeting includes 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 (CCC), 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 CCC) and right to vote at the General Meeting (Article 411 § 1 of the CCC).

   Voting rights from the existing Company shares are as follows:

a) two votes at the General Meeting are attached to each of the A, B, C, E, F, G series shares;

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

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 CCC). If within two weeks of the date of presenting the request to the Management Board the Extraordinary General Meeting is not convened, the Registration Court may authorise the shareholders who requested the Meeting to convene it (Article 400 § 3 of the CCC).

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

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

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

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

10) The right to 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 CCC).

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 CCC).

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 CCC).

13) The right to file a motion for checking the list of attendees to the General Meeting by a specially appointed committee comprising at least three persons. The motion may be filed by 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 CCC).

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 CCC).

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 CCC, 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 CCC (in the event of a merger of the Company), in Article 540 § 1 of the CCC (in the event of a division of the Company) and in Article 561 § 1 of the CCC (in the event of the Company's transformation) be made available on the Company's premises free of charge.

17) The right to 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 CCC).

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 CCC).

7.4 Principles for amending the Company's Articles of Association

The principles for amending the Company's Articles of Association are regulated by the Code of Commercial Companies. 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

In 2019, the Company did not have a separate, formal remuneration policy and the remuneration of each member of the Management Board was 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. In accordance with the amendment to the Act on Public Offering (...), in 2020 the Company will start developing a remuneration policy that meets the statutory requirements and will be presented to the General Meeting of the Company for adoption.

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 in 2019 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 is 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, respectively, up to 125,000 R series ordinary bearer shares and 11,000 S series ordinary bearer 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.

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

Each A series subscription warrant entitles 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 entitles 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 is PLN 91 per each R series share, and the issue price for holders of B series subscription warrants is PLN 0.10 per each S series share. R series shares and S series shares may be taken up only for cash contributions made in full before the shares are released.

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

In accordance with the aforementioned Resolution No. 25/VI/2018 of the Ordinary General Meeting of the Company, the ordinary bearer shares of series S and series R will be dematerialised and will be subject to application for admission to trading on the regulated market, therefore the shares shall be released by recording the shares on the securities accounts of the eligible persons.

In accordance with Resolution No. 3/II/2019 of the Supervisory Board of 12 February 2019, the Company did not issue A series warrants entitling it to take up R series shares due to failure to achieve the Market Target in 2018, within the meaning of § 5.3.i(a) of Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company.

In accordance with Resolution No. 4/II/2019 of the Supervisory Board of 12 February 2019, a list of persons eligible to subscribe for series B warrants, entitling to subscribe for S series shares, was established due to meeting the required criteria in 2018 within the meaning of § 5.3.ii of Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company.

The S series ordinary bearer shares were taken up by persons entitled to exercise their rights under B series subscription warrants granted to such persons for 2018 under the Incentive Scheme adopted by the Company. Six B series subscription warrants were subscribed for by all eligible persons on 18 November 2019. The deadline for exercising the rights carried by B series subscription warrants expires on 31 July 2022, with all eligible persons submitting declarations of subscription for S series shares to which they were entitled on 18 November 2019. The S series ordinary bearer shares were issued as part of a conditional share capital increase, therefore no allocation of shares took place. Due to the fact that the S series shares were dematerialized, the shares were released by recording them in the securities accounts of the entitled persons. The number of shares subscribed for was 9,500 S series ordinary bearer shares, taken up at PLN 0.10 each.

The value of the subscription, understood as the product of the number of securities offered and the issue price, totalled PLN 950. The S series ordinary bearer shares were taken up for cash contributions made in full before the shares were released.

In accordance with Resolution No. 2/I/2020 of the Supervisory Board of 30 January 2020, the Company did not issue A series warrants entitling it to acquire R series shares due to failure to achieve the Market Target in 2019, within the meaning of § 5.3.i(b) of Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company.

In accordance with Resolution No. 3/I/2020 of the Supervisory Board of 30 January 2020, a list of persons eligible (namely six persons) to subscribe for B series warrants, entitling to subscribe for series S shares, was established due to meeting the required criteria in 2019 within the meaning of § 5.3.ii of Resolution No. 24/VI/2018 of the Company's Ordinary General Meeting.

On 28 January 2020, the Management Board of Mabion S.A., acting pursuant to § 4.3 of the Rules and Regulations of the Incentive Scheme for 2018-2021, adopted a resolution on recommendations for the Supervisory Board concerning candidates for participation in the Incentive Scheme in 2020 to take up A and B series warrants.

The list of persons entitled to participate in the Incentive Scheme in 2020 and take up A and B series warrants was adopted by the Supervisory Board by virtue of Resolution No. 1/II/2020 of 27 February 2020.

Apart from the above, in 2019 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 under pensions and similar obligations

In 2019, 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 Lawsuits

In 2019, 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. with its registered office in Warsaw, ul. Polna 11, 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.

In previous years, Mabion S.A. used PwC services in the following scope:

» audit of the annual financial statements for 2018 and review of the interim condensed financial statements for the period from 1 January 2018 to 30 June 2018;

» audit of the annual financial statements for 2017 and review of the interim condensed financial statements for the period from 1 January 2017 to 30 June 2017;

» services related to the planned issue of the Company's shares on a stock exchange outside the territory of the Republic of Poland (in Europe or the United States), i.e. support for the Company in the preparation for the conversion of financial statements for 2016 and 2015 drawn up in accordance with the PSR into financial statements in accordance with IFRS, audit of the Company's financial statements for 2016 and 2015 drawn up in accordance with IFRS, preparation of the comfort letters in connection with the planned floating of the Company's shares on the above mentioned stock exchange, support and other services related to the preparation of the issuance documents necessary to issue shares on the above mentioned stock exchange;

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

Table 21. Remuneration due to PwC for services provided in 2018 and 2019.

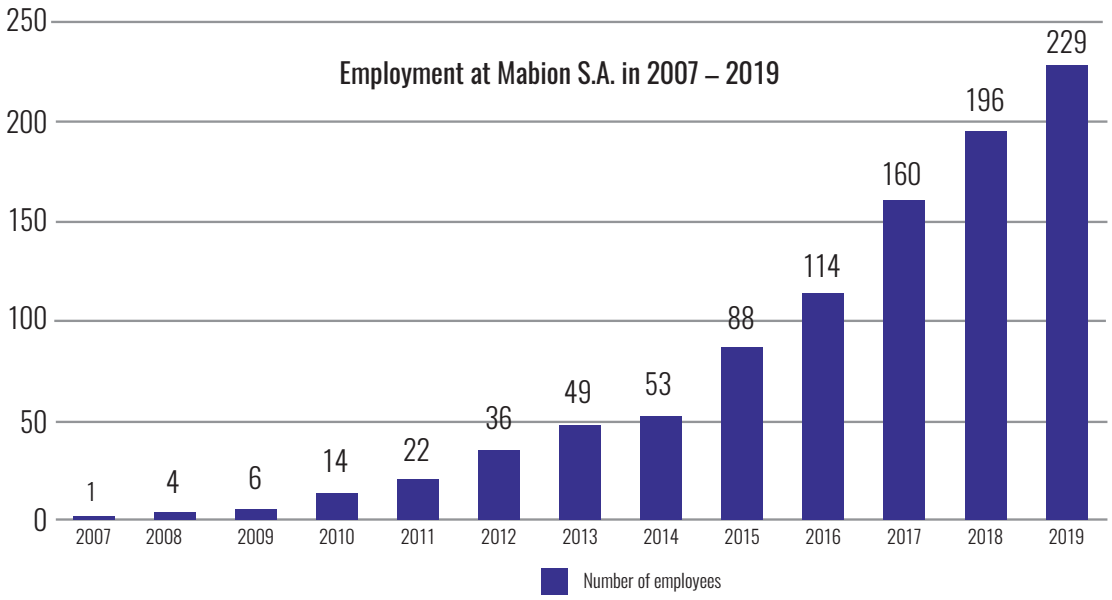
	2019	2018
Audit of the annual	185,000	185,000
Other assurance services, including the review of financial statements	60,000	60,000
Tax consultacy services	0	0
Other services	**0**	**0**
Reimbursement of expenses	**9,800 ***	**9,800**

* *Maximum amount of reimbursement in accordance with the agreement with PwC*

8.5 Employment

As at 31 December 2019, the Company employed 229 people, while the average employment in 2019 was 202.15 full-time equivalents.

Table 21. Employment at Mabion S.A. in 2007 – 2019.



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 products biosimilar to the original medicines available on the market (socalled reference medicines), applied in the treatment of cancer, metabolic and autoimmune diseases, including:

- MabionCD20 monoclonal antibody - a drug containing rituximab antibody, biosimilar to Mabthera/Rituxan produced by Roche. MabThera/Rituxan is widely used in the treatment of blood cancers (lymphomas, leukaemia) and rheumatoid arthritis;

- MabionMS monoclonal antibody - a medicine containing rituximab antibody, for use in the treatment of multiple sclerosis;

- MabionEGFR monoclonal antibody - an oncological medicine biosimilar to Erbitux (with Cetuximab as the active substance). The indication for Cetuximab is the treatment of patients with colorectal cancer with metastases.

- Monoclonal antibody Mabion_denosumab1 and Mabion_denosumab2 - a drug biosimilar to Prolia and Xgeva (with Denosumab as the active substance). The medicines are used to treat osteoporosis and prevent bone complications in patients with metastases of solid to bone tumors.

- Mabion_omalizumab monoclonal antibody - a biosimilar to Xolair (with omalizumab as the active substance). Xolair is used as an anti-asthmatic drug.

8.7 Environment protection

Topics 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:

- continuous improvement in the area of environmental protection;

- meeting the legal requirements which the Company is obliged to comply with;

- the availability of information and resources necessary to achieve the objectives and targets set;

- rational management of raw materials and materials;

- rational consumption 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.

A long-term goal of the Company is also to reduce electricity consumption. To this end, the Company has analysed energy efficiency, use and consumption based on current data and information to detect significant consumption points and identify opportunities to improve energy performance. The summary of these activities is included in a document titled "Energy Review of the plant and the development of a tool to monitor the energy target".

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: DSSOŚR-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.

The following agreements were in force in 2019 in Mabion S.A. as part of the waste management:

1. With EGOLIT Sp. z o. o. of 21.08.2015 along with Annex 3 to the Agreement, entered into on 14.01.2019. The Agreement concerns the collection, disposal or recovery of hazardous and non-hazardous industrial waste.

2. With ECO-ABC, of 15.05.2018, No. 37/JN/2018. The agreement concerns the collection and neutralization of solid medical waste. On 28.06.2019 r. ECO-ABC Sp. z o. o. terminated part of agreement No. 37/JN/2018 in the field of disposal and neutralization of liquid waste, due to the fact that the technology used to neutralize medical waste does not have sufficient power to burn liquid waste in a pyrolytic furnace.

3. 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).

As part of permanent cooperation, the Company transfers waste to the following companies:

1. EMKA S.A., ul. Jaktorowska 15A, Żyrardów – liquid medical waste.

2. PHU „TRANS-SUR" Bogdan Kier, ul. Strycharska 5/31, Łódź – packaging waste – secondary raw materials

The Company has been entered on the register of entities introducing products, products in packaging and managing waste (waste database) for waste generation. In April 2019, the Company updated its entry in the register with regard to the activities resulting from the Act of 13 June 2013 on Packaging and Packaging Waste Management.

In order to fulfil the obligation under the aforementioned Act, on 30 December 2019 the Company also signed, with INTERSEROH Organizacja Odzysku Opakowań S.A., agreement no. UM/2019/1244 on the takeover and fulfilment of the entrepreneur's

obligation to ensure recovery and recycling of packaging waste. Under the agreement, the Organization undertakes to perform the following activities for and on behalf of the Company:

» collecting packaging waste,

» recovering and recycling packaging waste,

» preparing and submiting an annual report on packaging and packaging waste management to the competent public administration,

» conducting public education campaigns.

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.

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.

The Company is at an advanced stage of a project consisting in the implementation of an Integrated Management System according to ISO 14001:2015 - Environmental Management System, ISO 45001:2018 - Occupational Health and Safety Management System, and 50001:2018 - Energy Management System in the plant located in Konstantynów Łódzki. The scope of the IMS covers all main and auxiliary processes comprising the Company's operations. Mabion S.A., as part of the project, cooperates with EcoMS Consulting Sp. z o. o., which, as a consulting company, helps to build the IMS.

In order to raise environmental awareness among employees and the local community, Mabion S.A. started an environmental education project. The project includes various activities that contribute to raising awareness and promoting pro-ecological behaviour and the principle of sustainable development.

In cooperation with the Foundation for Aluminium Packaging Recovery Recal, Mabion S.A. has become a Partner of the "Every Can Counts" Project, the aim of which is to reduce the consumption of raw materials and limit the negative impact on the environment by increasing the amount of segregated aluminium waste, which is 100% recyclable.

8.8 Social responsibility policy

1. EQUAL OPPORTUNITIES POLICY

Mabion pursues a policy of equal opportunities for all employees, in terms of:

- gender;
- race;
- ethnic origin;
- religion;
- views;
- disability;
- age;
- sexual orientation.

Both the scope of responsibilities and the level of remuneration are not differentiated depending on any of the above factors. The basis for the assessment of employees is competence, knowledge and regular evaluation of the results achieved. 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).

2. 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 recognised and rewarded based on merit (basic pay system, plus performance bonuses and motivational trips);
- may talk openly and improve the performance of the whole team;
- is treated fairly and respectfully;
- is not discriminated against (see point 1);
- feels supported in pursuing his or her personal priorities.

3. 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:

- equal treatment - the same procedures and criteria apply to all candidates;
- unchanging requirements for candidates - before the recruitment process begins, the requirements and criteria for candidates are defined which do not change during the recruitment and selection process;
- impartiality - each Mabion representative participating in the recruitment process acts in a way that eliminates any form of favouritism or discrimination against candidates;
- professionalism - people who take part in a recruitment process are properly prepared for it and keep the official tone of the conversation;
- transparency - the recruitment process is clear and documented, allowing candidates to receive reliable feedback on their application;
- respect for privacy - interviewers avoid questions about candidates' private life, family status and plans to start a family;
- respect for individuality - interviewers tolerate that candidates show other attitudes, behaviours, physical and mental characteristics than their own;
- easy access to job offers - advertisements are published in several ways (industry portals, Mabion website, recruitment portals) allowing a wider group of candidates to apply for a position of their choice.

4. 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.

5. 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. Work-life balance is one of the most important principles in the Company.

Projects are 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, since 2018, the employee motivation survey has been conducted.

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 policy of the Company 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 2019, the Company implemented its communication policy in many different dimensions, thus ensuring a broad channel for reaching recipients.

The Company carried out promotional and sponsoring 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;
- expert statements and comments of the Company's officials in Polish and international media, online interviews and teleconferences involving the Company's Management Board;
- meetings with academic students enabling to learn about the Company's industry and activities;
- participation in initiatives organised by universities and other institutions;
- participation in the "Łódź Business Run" charity event;
- preparing a film promoting the Company as an employer.

In addition, Company's representatives have appeared in the press dedicated to the financial sector and investors (e.g. Puls Biznesu), as well as in specialist industry magazines (e.g. biotechnologia.pl) and news magazines (Polish Press Agency).

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.

In 2019, the Company organised meetings with individual and institutional investors and participated in many numerous meetings with market analysts. Additionally, video conferences and chats with investors on current topics were held.

In connection with the implementation of the strategy of increasing the international visibility of the Company, its representatives took part, among other things, in:

- JP Morgan Healthcare Conference in San Francisco (7-10 January 2019);
- IFC Global Private Health Conference in Miami (27-28 March 2019);
- Innovation Conference 2019 Erste Group in Warsaw (25 April 2019);
- BIO International Convention in Philadelphia (3-6 June 2019);
- Jefferies Healthcare in New York (4-7 June 2019);
- CPhI in Frankfurt (4-7 November 2019);
- Jefferies Healthcare Conference in London (20-22 November 2019).

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 website includes:

- Information about the Company and its bodies;
- A calendar of the most important events in the Company;
- Corporate documents;
- Current and interim reports;
- Current share quotation of the Company;
- 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.

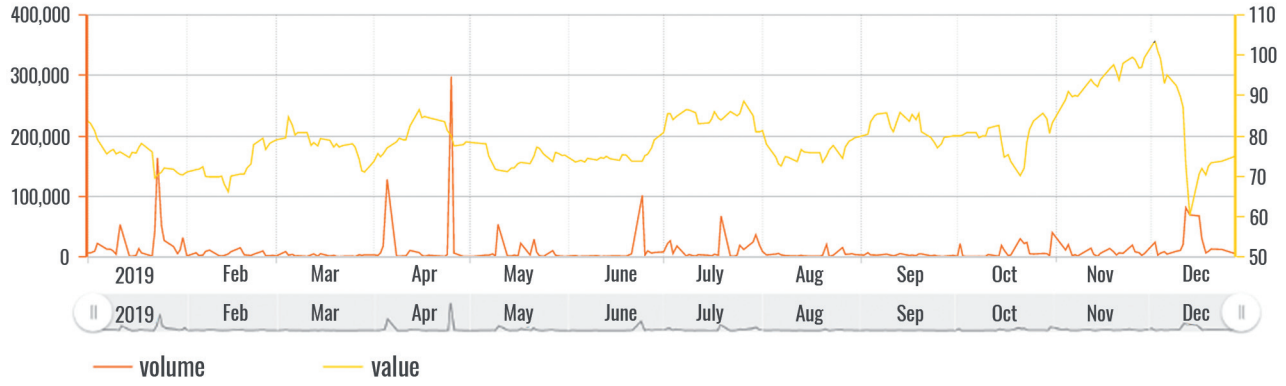
The information policy mainly involved the following areas:

- Registration procedures for MabionCD20 in the EMA;
- Dialogue with the US regulator - FDA;
- Company development plans.

Contact for investors: relacjeinwestorskie@mabion.eu.

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

Table 22: Mabion S.A. stock quotes on the Warsaw Stock Exchange (02.01.2019 – 31.12.2019) - chart.



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

Table 23: Mabion S.A. stock quotes on the Warsaw Stock Exchange (02.01.2019 – 31.12.2019 r.) – figures.

Start date:	2019-01-01
End date:	2019-12-31
Reference price:	PLN 86.60 (2018-12-28)
End price:	PLN 77.00 (2019-12-30)
Change:	-11.09%
Change:	PLN -9.60
Minimum:	PLN 60.20 (2019-12-13)
Maximum:	PLN 105.20 (2019-12-02)
Average:	PLN 79.37
Trading volume:	2,584,455 pcs.
Average volume:	10,463 pcs.
Turnover:	PLN 199.419 mln
Average turnover:	PLN 0.807 mln

The Management Board

Dirk Kreder
President of the Management Board

Jarosław Walczak
Member of the Management Board

Sławomir Jaros
Member of the Management Board

Grzegorz Grabowicz
Member of the Management Board

Konstantynów Łódzki, 8 April 2020

8th April, 2020

Oświadczenie

Niniejszym oświadczam, że z uwagi na pandemię koronawirusa COVID-19 powodującą ograniczenia w przemieszczaniu pomiędzy krajami UE jak również wewnątrz Państw Członkowskich UE nie udało się mi się w pełni zakończyć procedury uzyskania podpisu elektronicznego w terminie do zatwierdzenia Sprawozdania Finansowego za rok 2019, w związku z czym nie miałem możliwości podpisania sprawozdania finansowego w sposób przewidziany obowiązującą w polskim porządku prawnym ustawą o rachunkowości.

Ponadto oświadczam, że sprawozdanie Zarządu z działalności Spółki za rok 2019 zawiera prawdziwy obraz rozwoju i osiągnięć oraz sytuacji Spółki, w tym opis podstawowych zagrożeń i ryzyka.

Statement

I hereby declare that, due to the COVID -19 coronavirus pandemic causing restrictions on movement between EU countries as well as within an EU Member State, I have not been able to complete the procedure of obtaining electronic signature in time for the approval of the 2019 Financial Statements and, as a result, I have not been able to sign the accounts in the manner set forth in the Polish Accounting Act.

Moreover, I declare that the report on the Company's activity contains a true view of the development, achievements and situation of the Company, including the description of basic threats and risks.

Dirk Kreder – Prezes Zarządu Mabion S.A./

President of Management Board of Mabion S.A.