Mabion S.A.
Directors' Report for the year 2020

Konstantynów Łódzki, 30 April 2021

Mabion S.A. Directors' Report for the year 2020

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1 ORGANISATION 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:	Mariana Langiewicza 60, 95-050 Konstantynów Łódzki
Telecommunications numbers:	phone (+48 42) 207 78 90
E-mail address:	info@mabion.eu
Website	www.mabion.eu

1.2 Branches

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

Currently, the Company has two centres (plants) – the Research and Development Centre (Centrum Badawczo-Rozwojowe, CBR)[1] 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 2020, 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 Calendar

January	On 22 January 2020, a Type 3 BPD (Biosimilar Biological Product Development) meeting of the Company's representatives was held with the Food and Drug Administration (FDA) on the registration and marketing authorisation of MabionCD20 in the USA. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the USA. On 28 January 2020, the Company submitted answers to the list of questions receive in December 2019 as part of the medicine registration procedure for MabionCD20, for a small production scale. This made it possible to proceed with the Company's registration applications at that time.
February	On 7 February 2020, the Company received a positive decision of the Minister of Development on the amendment of permit no. 301 to conduct business activity in the Łódź Special Economic Zone (LSEZ) regarding the extension of the deadline for incurring investment expenditure. On 12 February 2020, the Company was informed of a positive decision of the District Governor of Pabianice changing the permit for the construction of a building as part of the investment entitled "Technological and Scientific Centre for Advanced Medical Biotechnology of Mabion S.A." ("Centrum Naukowo-Technologiczne zaawansowanej biotechnologii medycznej Mabion S.A.") in terms of increasing the volume of the building. On 26 February 2020, the Company's Management Board, together with a team of experts, participated in the Committee for Medicinal Products for Human Use (CHMP) meeting, presenting the issues indicated by the EMA in the invitation (oral explanation).
March	On 16 March 2020, the Supervisory Board appointed Mr. Dirk Kreder as President of the Management Board of the Company. On 16 March 2020, the Management Board of Mabion S.A. decided to change the regulatory strategy for registering MabionCD20 with the EMA. The most important consisted in a decision to obtaining marketing authorisation for the drug at the EMA directly for a large commercial scale as opposed to the previously planned 2-step strategy (small-scale marketing authorisation, and then on the basis of a variation, commercial scale authorisation). As a consequence, the Company withdrew its existing registration applications from the EMA, as confirmed by a notice posted on the EMA's website on 30 March 2020, and has taken the necessary steps to submit new registration applications with a view to marketing MabionCD20 on a commercial scale. On 16 March 2020, the Management Board of the Company, in consultation with the Supervisory Board, elaborated the Company's financing arrangements in light of MabionCD20's new regulatory strategy at the EMA. The Company received supporting documents from the Company's main (founding) shareholders, according to which the shareholders declared to inject capital in the Company, in 2020, in an amount not lower than PLN 15,000 thousand. On 16 March 2020, the Management Board provided information on the possible impact of the SARS-CoV-2 pandemic on the Company's operations.
June	On 23 June 2020, the Company received an inspection record confirming the Company's implementation of the condition of permit no. 301 of 12 April 2012 to operate within the Łódź Special Economic Zone (LSEZ) in terms of maintaining at least 100 employees in total in the Zone until 1 March 2020.

July	On 1 July 2020, the Company received a written response from the EMA as part of scientific advice (i.e. scientific consultation with EMA representatives) regarding the Briefing Package submitted by the Company and relating to the Company's individual proposed assumptions for the new registration process for MabionCD20 with the EMA. On 9 July 2020, the Company's Management Board, after internal analysis, consultation with external experts and the Supervisory Board, adopted a preliminary framework for the scope and schedule of work required to submit a new marketing authorization application (MAA) to the EMA for MabionCD20 manufactured on a commercial scale. On 15 July 2020, the Company entered into a borrowing agreement with Glatton Sp. z o.o. in the amount of PLN 15,000 thousand to refinance the revolving credit facility granted to the Company in 2018 by Santander Bank Polska S.A.
August	On 12 August 2020, the Company entered into borrowing agreements with Twiti Investments Ltd. and Glatton Sp. z o.o. up to a total of PLN 15,000 thousand, pursuant to the documents of support dated March 2020. On 28 August 2020, the Management Board announced that the Company had received a summary of the BPD Type 2 meeting with the FDA regarding the registration and marketing approval of MabionCD20 in the USA. The meeting was aimed at clarifying the details of the clinical development of MabionCD20 for the US market
September	On 14 September 2020, the Company entered into a Memorandum of Understanding with Vaxine Pty Ltd. based in Australia to work out arrangements in relation to the potential process development, manufacturing and commercialisation of Covax-19™, a potential vaccine for COVID-19 disease.
October	On 14 October 2020, the Company signed a letter of intent with IcanoMAB GmbH, based in Germany, regarding a potential collaboration to conduct development and production of the "IL-mAb" antibody being developed as a potential drug to treat COVID-19 infections. On 21 October 2020, the Company signed a Memorandum of Understanding with Taxon Therapeutics Ltd. based in Israel regarding the parties' intention to work out the terms of a potential long-term collaboration for the research, developmen, and commercialisation of MabionCD20 antibodies in specific clinical indications in the area of rare diseases. On 26-29 October 2020, the Company participated in the 6th edition of BIO-Europe 2020® – one of the most important international partnering events in the life science industry worldwide. On 29 October 2020, the Company entered into an agreement with Parexel International (IRL) Limited, based in Ireland, to conduct the final clinical trial of MabionCD20 prior to submission of a marketing authorisation application to the EMA (three-arm trial in patients diagnosed with rheumatoid arthritis). On 29 October 2020, the Company entered into an agreement with Vaxine Pty Ltd. to govern the transfer of biological materials from Vaxine to the Company for exploratory research in the Company's laboratories on a SARS-CoV-2 vaccine antigen.
November	On 30 November 2020, the Company entered into an agreement with Vaxine Pty Ltd. extending the expiry date of the Memorandum of Understanding for the Covax-19™ collaboration until 31 January 2021.
December	On 10 December 2020, the Company signed an annex to the PLN 15,000 thousand borrowing agreement with Glatton Sp. z o.o. extending the loan repayment date to 31 December 2021.

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. In addition, the GMP-certified manufacturing capacity available and the experience of the staff in the research and development, clinical and regulatory areas enable the Company to participate in the development of new recombinant protein vaccines related to the prevention of COVID-19 infection. In the area of therapeutic products, the strategic goal of the Company is to develop, manufacture and sell drugs used in the treatment of neoplastic, autoimmune, metabolic and neurological diseases. In the area of prevention of COVID-19 infection, the Company's strategic objective is to collaborate with the strategic partner in the development and production of new protein vaccines for use against the persisting COVID-19 pandemic. Biological medicines developed by the Company are targeted preparations 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 a possible lower 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 reference drug to MabThera/ Rituxan (Roche).

Biosimilar medicines

Biosimilar medicines form a dynamically developing area in the global pharmacy. According to the definition adopted by pharmaceutical regulators, a biosimilar is a biological medicine similar to another biological medicine that has already been authorised. In registration, a biosimilar product is compared and evaluated against a reference product. It should be as similar to it as possible and not show clinically significant differences. As shown in reports and analytical studies, the share of biosimilars in global sales increases year by year. This is mainly due to the increasing demand for biologic medicines and the expiry of patents on reference medicines.

Depending on the source and time frame, the cumulative annual growth rate (CAGR) for the biosimilars market in the years to come should oscillate within between 17.3% and 44%, with an estimated global market value in 2026 at USD 79.2 billion (according to Frost & Sullivan: "Access to New Therapy Areas to Drive Major Growth in the Global Biosimilars Market, 2020-2026"). Among the drivers boosting 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 smaller companies with a global reach) to the market, a favourable environment for this type of investment, as well as the expiry of patents for best-selling biological drugs (on average two such drugs per year will go off the patent cliff over the next five years). 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 IQVIA's October 2019 study, "The Impact of Biosimilar Competition in Europe", the cost range for developing a biosimilar is between USD 100,000 thousand and 300,000 thousand).

The European Medicines Agency (EMA), a body that coordinates the evaluation and supervision of medicinal products for human use throughout the 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.

In accordance with the Generics and Biosimilars Initiative's study ("Biosimilars market and opportunities in Europe", February 2019), it is expected that by 2024, the market will be worth USD 11.6 billion, with a 24.9% CAGR growth in 2019–2024[2]. According to Generics and Biosimilars Initiative ("Biosimilars market and opportunities in Europe", May 2019), due to its global leadership in the regulation and approval of biosimilar products, the European biosimilars market has been the largest to date, representing about 60 % of the global market for biosimilar products and growing steadily from year to year.

[2] „Biosimilar Market in Europe.." (February 2019)

In line with the reports produced in September 2018, October 2019, and December 2020 for the European Commission, entitled: "The Impact of Biosimilar Competition in Europe", 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 reports show, in seven therapeutic areas competition in biosimilar drugs has emerged, there is a consistent reduction in prices. Prescribing of biosimilars has already reduced spending on biological medicines in Europe by more than EUR 10 billion[3]. Increased competition resulting from the marketing of biosimilars affects not only the price of the reference medicine for a particular biosimilar, but often also the price of the whole class of products in a specific therapeutic group. For most therapeutic classes, there is often an increase in sales following the introduction of biosimilars to the market, due to the increased availability of therapies to patients.

In the past, the European biomedicines market was dominated by five biological medicines: MabThera, Herceptin, Enbrel, Remicade and Humira, which accounted for 75% of the European biomedicines market. Currently, due to expiring patents, there is an opportunity for biosimilar drugs to expand in this market. In some EU countries, access to biosimilar oncological therapies is still considerably limited, a couple of years after their market launch. Increasing availability of biosimilar medicines, and growing competition among their manufacturers, supports greater savings to be achieved in the healthcare systems of individual European countries in the long term.

In June 2018, the US regulator took steps to facilitate the development of biosimilar drugs on the US market. The actions taken primarily concerned changes in the regulatory approach and consisted in adapting it to the real possibilities of manufacturers of drugs to obtain biosimilarity to an original medicine. This move was aimed at reducing barriers to the development of biosimilar medicines in the US market and achieving significant savings in the health system. However, these assumptions did not turn out to be entirely accurate, and the slower market penetration of biosimilars in the US than in Europe is largely due to ongoing patent disputes between drug manufacturers. It is estimated that over the next decade, the US healthcare system will save approximately USD 54 billion as a result of the introduction of biosimilar medicines[4].

MabionCD20

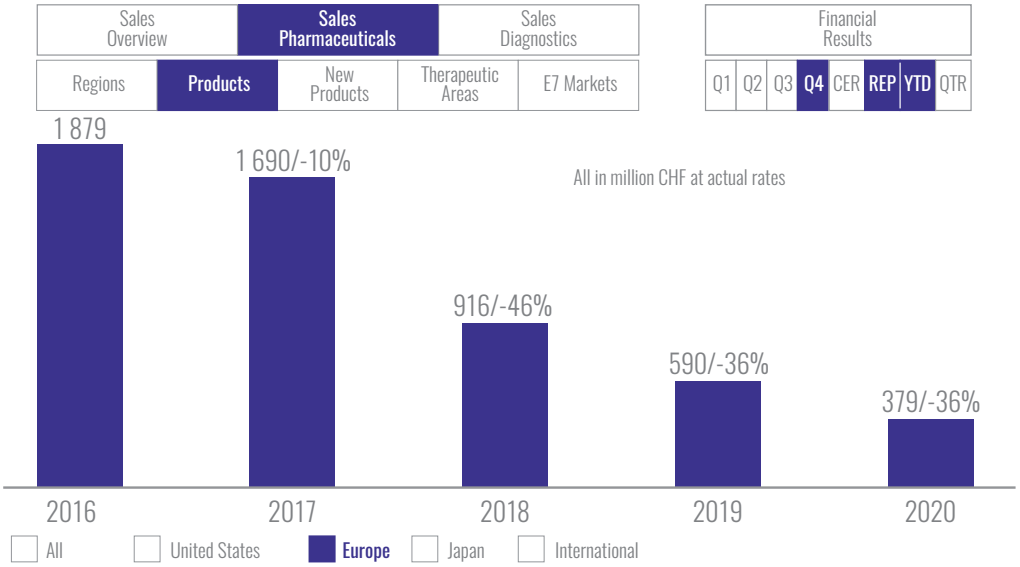
The drug under the working name of MabionCD20 is the Company's most advanced project. In 2018, the Company elaborated the results of a clinical trial which confirmed the efficacy of the therapy, and submitted applications for registration of the drug in European Union countries. In 2019, the registration 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 originator 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.

[3] Sustainability of Biosimilars in Europe: A Delphi Panel Consensus with Systematic Literature Review, 17 November 2020
[4] IMS; Biosimilars Council; Rémuzatet al. (2017); European Medical Journal ;L.E.K. interviews, research and analysis

Table 1: Sales of MabThera/Rituxan in Europe in 2016–2020 (source: https://www.roche.com/investors/rofis.htm)



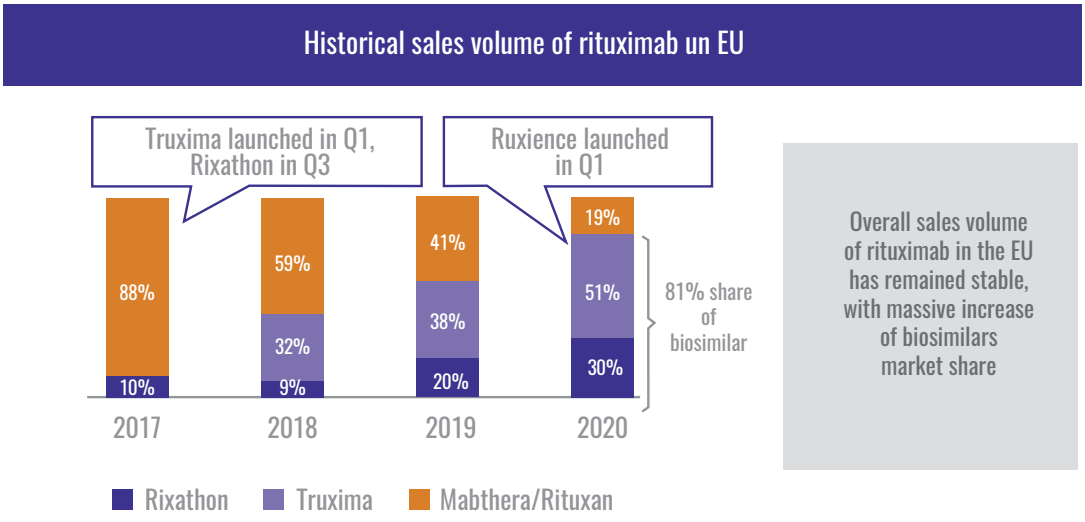
In its financial statements for 2020, Roche reports that its global sales of MabThera/Rituxan amounted to CHF 4.2 billion, a drop of 35% YoY.

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[5].

The following summary shows the historical values of the rituximab market for both originator and biosimilar drugs and the cumulative forecast for sales volume growth from 2020 to 2024, taking into account the two most important indications, which are non-Hodgkin's lymphoma (NHL) and rheumatoid arthritis (RA).

Table 2. Historical sales of medicines with rituximab as the active substance in Europe (source: Roche, Celltrion, L.E.K)



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

Table 3. Sales forecast for medicines with rituximab as the active substance (sources: Roche, Celltrion, L.E.K).

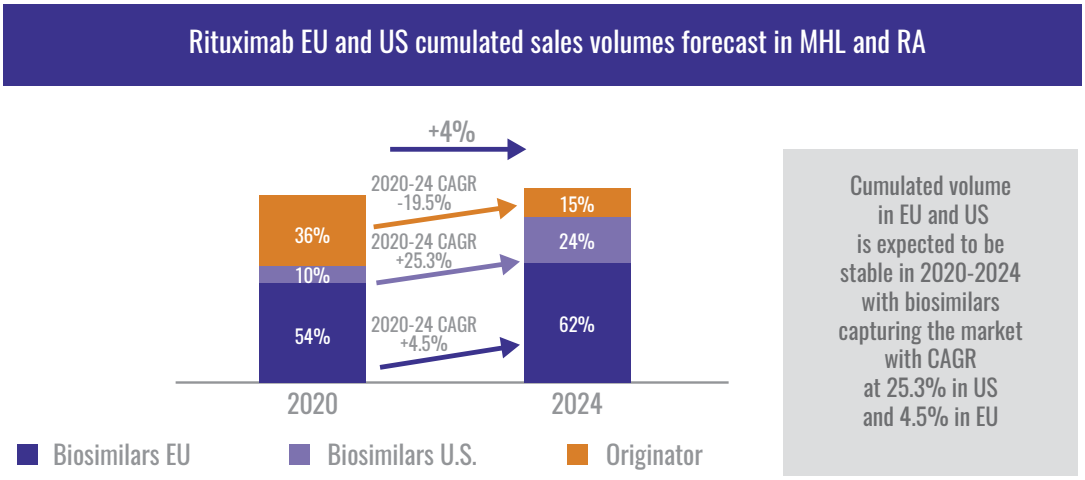


Table 4. Market size forecast for biosimilar medicines with rituximab as the active ingredient – as percentage (sources: Roche, Celltrion, L.E.K).

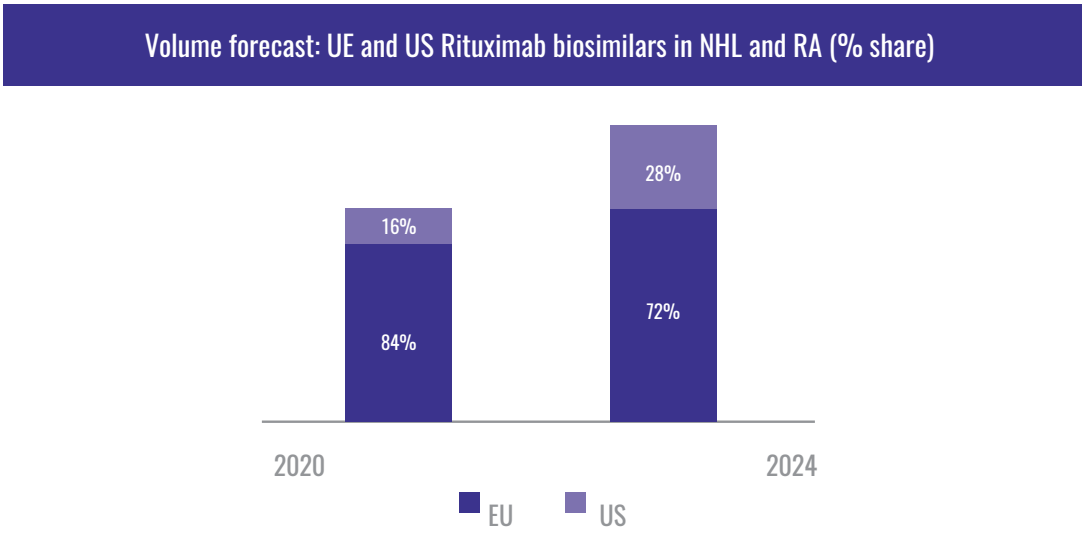
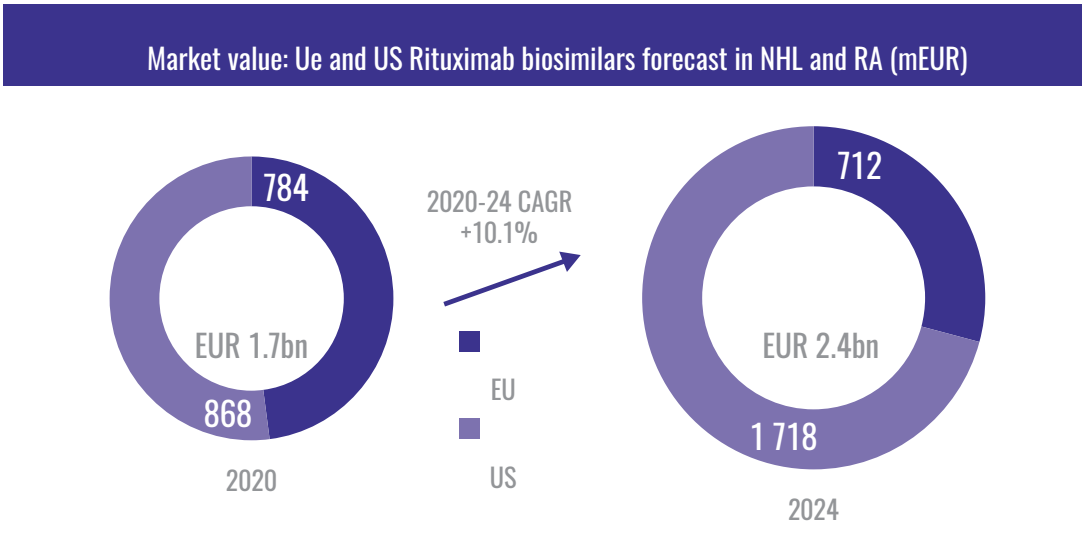


Table 5. Market size forecast for biosimilar medicines with rituximab as the active ingredient in EUR million (sources: Roche, Celltrion, L.E.K).



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.

COVID-19 vaccines

The COVID-19 vaccine market is growing rapidly. Currently, the types of vaccines being developed can be classified into one of four basic groups: genetic, protein, vector and inactivated/attenuated. A detailed description of the groups together with information on the companies developing each product is presented in the table below.

Table 6. COVID-19 vaccine market (sources: Mabion, L.E.K, WHO).

	COVID-19 vaccine types		selected developing entities (approved, Ph3 or Ph 2)
Increasing novelty	genetic vaccines	vaccines that deliver one or more of the coronavirus's own genes into our cells to provoke an immune response	moderna, Pfizer BIONTECH, CUREVAC, Zydus dedicated to life
	peptide and protein-based vaccines	vaccines that contain coronavisus proteins but no genetic material	NOVAVAX, COVAXX, gsk, CLOVER, DYNAVAX
	viral vector vaccines	vaccines that contain viruses engineered to carry coronavirus genes	AstraZeneca, THE GAMALEYA NATIONAL CENTER, janssen
	inactivated or attenuated vaccines	vaccines created from weakened coronavirus or coraonaviruses that have been killed with chemicals	sinovac, 国药山西 SINOPHARM, BHARAT BIOTECH

One of the main problems in the fight against the COVID-19 pandemic is the availability of vaccines. The current global demand exceeds supply by far and we are therefore faced with a situation of permanent vaccine shortages and instability of supply. In addition, current knowledge suggests that multiple vaccines may be required in the future due to the higher mutagenicity of the SARS-Cov-2 virus than previously thought. A similar situation exists in the anti-flu vaccine market, where almost every year a new version of the vaccine has to be developed taking into account the most recent mutations of the virus. According to Coherent Market Insights' report, the global COVID-19 vaccine market is valued at USD 14.5 billion in 2021 and is expected to grow at a CAGR of 30.9% between 2021 and 2027 to reach USD 73.2 billion by 2027.

Mabion, with its state-of-the-art GMP-certified manufacturing facilities And a unique, in Poland, experience in the development of technologically advanced biological drugs is a natural partner for global companies developing protein vaccines, both in terms of clinical and regulatory development as well as large scale manufacturing of the product.

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 patent protection for the above mentioned invention under the PCT procedure. 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 (July 2020) published by Fortune Business Insights, the multiple sclerosis medicine market will feature a CAGR of 7.1% and will be worth USD 40.66 billion by 2027.[6] This is due to the enormoous and still growing demand for therapies in this indication. According to According to ["Atlas of MS"] research carried out by the Multiple Sclerosis International Federation and published in September 2020, currently about 2.8 million people around the world live with MS.[7]

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.

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[8].

2.3 Regulatory environment

Registration of a biosimilar medicine in the European Union and the United States requires meeting a number of quality, efficacy and safety standards. The analytical, pre-clinical and clinical testing programme must be aligned with the stringent and sometimes contradictory guidelines recognised by the European and US registration authorities (EMA and FDA), which, in addition to the standard regulations relevant to the development of originator biological drugs, also include stringent provisions for comparative testing with the reference product. The last year has not brought fundamental changes to the regulation of trials and data to be submitted for registration of a biosimilar drug, but - particularly in the area of clinical trials - additional restrictions and limitations have been imposed due to the outbreak of the COVID-19 pandemic, which may cause delays in the implementation of the research programme.

Guidelines of the European Medicines Agency (EMA) of 2020

In the wake of the outbreak of the COVID-19 pandemic in early 2020, the EMA has published a series of guidelines aimed at streamlining the conduct of R&D during the current epidemiological threat and accelerating the registration of new drugs and

[6] https://www.fortunebusinessinsights.com/industry-reports/multiple-sclerosis-drugs-market-100386
[7] https://www.nationalmssociety.org/About-the-Society/News/Updated-Atlas-of-MS-Shows-Over-2-8-million-People
[8] GlobalData, Multiple Sclerosis: Dynamic Market Forecast to 2026, November 2018

vaccines targeting the SARS-CoV-2 virus. Border closures, material supply disruptions and potential threats to patient life and health have had a particularly negative impact on the conduct of large, multi-centre clinical trials such as Mabion's planned bridging trial MabionCD20-003RA. The recommendations issued by the Agency enabled the plan for the further clinical development of MabionCD20 to be quickly adapted to the current situation by selecting an appropriate population, a logistically safe location, and appropriately equipped clinical sites. The guidelines also made it easier to put in place additional procedures to guarantee maximum safety for trial participants. The most important documents published by the EMA in response to the COVID-19 pandemic are:

» *"Guidance on the management of clinical trials during the COVID-19 (coronavirus) pandemic"*

The document includes recommendations for protocol changes and deviations that may occur as a result of unexpected events related to the existing COVID-19 pandemic, including the need for medical staff to limit patient visits or quarantine. It lists specific solutions to ensure the safety of participants and the highest quality of data collection in ongoing trials, as well as those at the planning or commencement stage. The MabionCD20-003RA bridging study protocol, initiated in 2020, includes, inter alia, recommendations for remote visits and mandatory testing of patients for coronavirus. The guidelines saw two further editions in 2020, with the latest version (v.3) published in April.

» *"Points to consider on implications of Coronavirus disease (COVID-19) on methodological aspects of ongoing clinical trials"*

This guideline, adopted by the EMA in June 2020, describes the methodological aspects of conducting clinical trials during a pandemic, including the processes of data collection, analysis, and interpretation.

» *"Guidance for medicine developers and other stakeholders on COVID-19"*

The main guideline for fast track development and registration of drugs and vaccines against COVID-19, issued in July 2020. It allows pharmaceutical companies to explore abbreviated registration procedures and the Agency's requirements for these urgently needed products.

» *"Detailed guidance on ICSRs in the context of COVID-19"*

A detailed guideline providing recommendations for the processing and submission of individual clinical safety reports (ICSRs) related to medicinal products used to treat or prevent SARS-CoV-2 infection.

» *"Guidance on remote GCP inspections during the COVID-19 pandemic"*

This document concerns the organisation of remote GCP inspections during the COVID-19 pandemic. It aims at providing guidance on the steps to follow during remote clinical trial inspections (GCP).

Apart from the above guidance, the EMA also issued a call for pooling of European resources to fund and conduct trials of potential medicines and vaccines for COVID-19, and together with other regulatory agencies signed a declaration on prioritisation of such trials.

In addition to the documents produced in response to the problems generated by the COVID-19 pandemic, the EMA has also published other guidelines closely related to the R&D activities of the Company.

In February 2020, an addendum to the 1998 ICH guideline E9 (R1) "Statistical Principles for Clinical Trials" was released, which clarifies and expands the methods for conducting and interpreting statistical analysis of clinical trial results. The addendum, entitled *"ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials Step 5"*, governs the principles of the "intent-to-treat" (ITT) analysis, in which patients are examined according to a randomisation code, regardless of the treatment actually received. Furthermore, the document addresses the issues of compensating for missing data and defining populations for the final analysis (so-called analysis sets). The availability

of such guidelines reduces discretion in designing and analysing the results of clinical trials, including trials of biosimilar medicines, and thus mitigates the risk of significant methodological errors when compiling registration dossiers.

In April 2020, the EMA issued a notice to companies involved in the clinical development of medicinal products regarding the validation and qualification of computerised systems used in clinical trials (*"Inspections Office, Quality and Safety of Medicines Department Notice to sponsors on validation and qualification of computerised systems used in clinical trials"*). The main motivation underlying this document were the numerous instances of the negative impact of an inadequately prepared IT system on the quality and integrity of clinical data, observed during recent GCP inspections. The notice provides a brief elaboration of the related guidelines and regulations, as well as recommendations to avoid common mistakes made by sponsors.

In October 2020, the EMA published the document: *"European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance"*, which is intended to make it easier for applicants to obtain scientific advice from the Agency on the development of a medicinal product, as well as a review of a proposed clinical trial protocol. It contains information on the scope and format of the consultation and the content of the relevant application that the company seeking advice must submit.

In November 2020, a guideline titled: *"Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells"* was issued, providing guidance on the development and evaluation of medicinal products containing genetically modified cells. The document addresses non-clinical aspects, quality, safety and efficacy of genetically modified cells and their use in medicinal products.

Guidelines of the US Food and Administration Agency (FDA) of 2020

As the European regulatory agency, the FDA responded to the problems and risks associated with the COVID-19 pandemic by issuing numerous procedures and guidelines for the pharmaceutical industry and clinical sites. These documents were designed to minimise the risks associated with research work during a pandemic by providing ready-made solutions and recommendations acceptable to the authority. The central focus of these guidelines was to mitigate potential risks to clinical trial participants and to ensure that data are collected, processed, and analysed correctly. It also describes remote methods of communication with the office and the rules for organising meetings. The most important recommendations are included in the following documents:

- *"Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards"*
- *"Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency Guidance for Industry"*
- *"Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing"*
- *"Resuming Normal Drug and Biologics Manufacturing During the COVID-19 Public Health Emergency"*

In order to help the pharmaceutical industry rapidly develop potential therapeutic drugs and vaccines for COVID-19, the FDA has proposed a special mode of pre-IND meetings where companies can agree with the agency on the further development path of the most promising molecules/preparations and establish the exact requirements that must be met for their registration and post-approval efficacy/safety monitoring. Such meetings are described in the guideline entitled *"COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products"*. Additionally, in response to the ongoing health crisis, the FDA has posted answers to questions (Q&A) on its website about the potential impact of the SARS-CoV-2 pandemic on the organisation of routine meetings with pharmaceutical companies.

In June 2020, the FDA has developed a dedicated regulatory process for accelerated registration of vaccines to prevent SARS-CoV-2 infection. The rules governing the pre-clinical and clinical trials on such vaccines, as well as the requirements to be met in order to obtain marketing authorisation for them, are set out in the document entitled: *"Development and Licensure of Vaccines to Prevent COVID-19"*.

In February 2020, the FDA has published special guidance for companies planning to register a biosimilar drug in some of the reference drug's therapeutic indications (*"Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed Guidance for Industry"*). US regulations already allowed certain nosological units to be omitted from a biosimilar application. Now, the regulatory pathway and the Agency's scope of requirements have been carefully described in a dedicated document, making it easier to enter the procedure with trials covering only one indication.

In the same month, the US regulatory agency issued the seventh version of its electronic regulatory submission manual, entitled: *"Providing Regulatory Submissions in Electronic Format--Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications Revision 7"*. According to the manual, all applications listed under section 745A(a) of the Federal Food, Drug and Cosmetic Act (FD&C Act), including NDAs and BLAs, should be submitted in a standard format strictly defined by the FDA (eCTD). The requirement also applies to an application for registration of a biosimilar medicine and is an essential condition for starting its evaluation.

Also in February 2020, a guideline entitled *"Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics"* was published, intended to facilitate pharmaceutical companies' non-clinical evaluation of the immunotoxic potential of drugs and biologics. The detection of drugs that may have toxic effects on the immune system at an early stage of development is particularly important in the context of the ongoing pandemic.

A series of recommendations for inclusion criteria in trials relating to cancer drugs (including monoclonal antibodies such as MabionCD20) were published by the Agency in July 2020 (*"Cancer Clinical Trial Eligibility Criteria"*). As such trials involve a high level of risk for both sponsors and patients, the FDA decided to propose specific patient eligibility rules to safely test new therapeutic agents on a representative population suffering from a given cancer. Separate recommendations were made for paediatric patients, those with HBV/HCV/HIV infection, those with CNS metastases and those with key organ failure.

In July 2020, the FDA issued guidance on the content of the summary of product characteristics and patient information regarding the safety of use in pregnancy and during breastfeeding, and potential reproductive effects (*"Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry"*). The guidelines govern both the content and format of information presentation, with an emphasis on clear communication of risks to the users.

In August 2020, a guideline was published, entitled *„Drug-Drug Interaction Assessment for Therapeutic Proteins Guidance for Industry"* aimed at helping sponsors of investigated drugs to determine the need for drug-drug interaction studies for therapeutic proteins by ensuring a systematic risk-based approach.

In September 2020, the FDA has issued a special procedure in response to numerous cases where potentially carcinogenic nitorosamines have been detected in popular drug products: *"Control of Nitrosamine Impurities in Human Drugs Guidance for Industry"*. The guideline describes the steps which manufacturers of active substances and drug products should take to detect and prevent unacceptable levels of nitrosamines. The guideline also describes the conditions which may cause such contamination.

In October 2020, a document entitled *"Providing Regulatory Submissions in Electronic Format - Standardized Study Data"* was issued, setting out the requirements for electronic submission of applications for registration of new medicinal products (specifying the format of the dossier) in NDA, ANDA, BLA, INDs applications. The BLA is submitted for biosimilar medicines, among others.

A major problem with many clinical trials is that only a carefully selected group of patients is included, which poorly reflects the target population receiving the medicinal product once it is authorised. In November 2020, the FDA attempted to improve this situation by issuing a special guidance (*"Enhancing the Diversity of Clinical Trial Populations--Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry"*) that calls for the diversity of patients participating in clinical trials to be increased by broadening the inclusion criteria and implementing an appropriate enrollment strategy. The guidelines underline

that a broad demographic and clinical diversification of trial participants underpins the correct assessment of the benefit-risk ratio of new therapies, including drugs for oncology, rare diseases and orphan diseases.

In November 2020, an additional Q&A list on the development of biosimilar medicines and the implementation of the provisions of the BPCI Act was published – *"Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act Guidance for Industry"*. The Q&A raise the issue of "interchangeable" status, which allows a reference medicine to be replaced by a biosimilar in a pharmacy without the doctor's consent, and the issue of marketing exclusivity after authorisation.

In December 2020, a guideline entitled *"Best Practices in Developing Proprietary Names for Human Prescription Drug Products"* was released, in which the FDA describes best practices to help minimise medication errors associated with legal names and otherwise avoid the adoption of proprietary names that contribute to violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations.The document also describes the framework used by the FDA to evaluate proposed proprietary names, which is also available for sponsors to use before submitting names for FDA review.

2.4 Information on operations of the Company

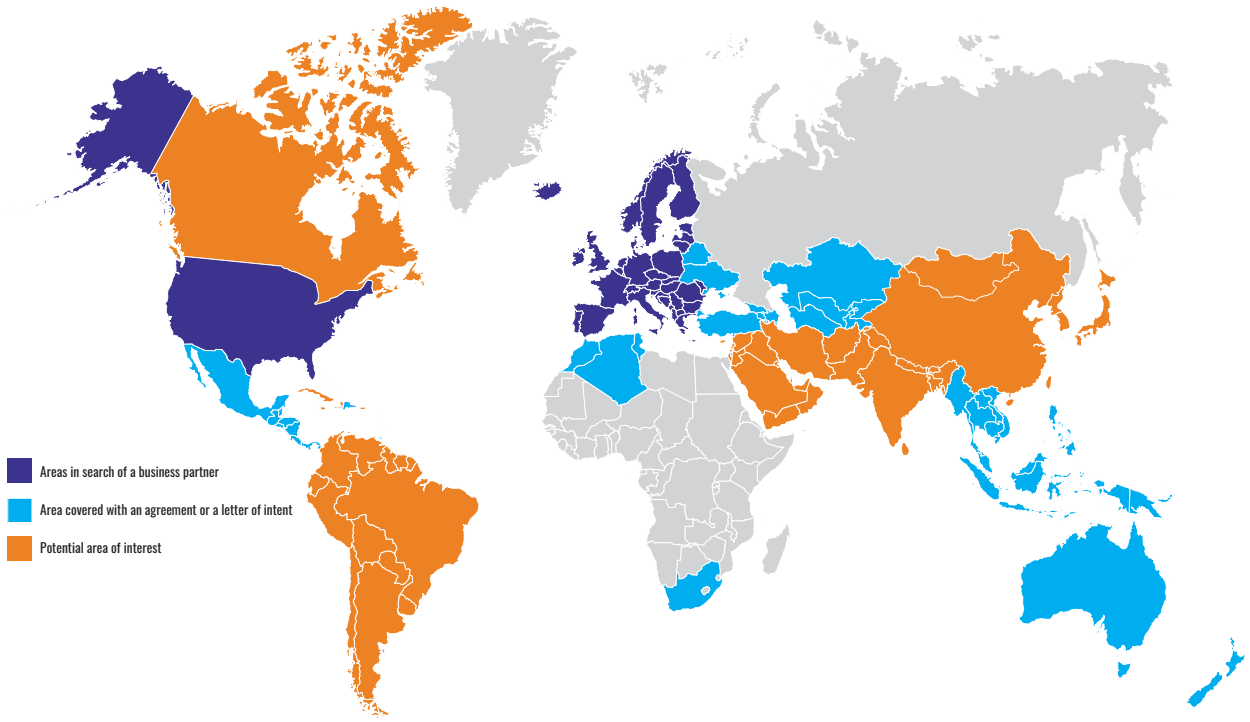
The Company's core business in the future will be the development, manufacture and sales of the medicines which are currently at various stages of development. In 2020 – as in the previous years – the Company did not generate any sales revenues from core activities, focusing on the work related to the registration procedure for MabionCD20, the development of its own projects as well as the identification of possible partnership projects. The Company has the capability and resources to conduct R&D and manufacturing in the development of biological drugs, vaccines and innovative therapies in response to the SARS-CoV-2 pandemic.

In 2020, 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. Searching for a partner is a complicated process, 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 negotiating the appropriate provisions of partnering agreements on both sides, that is elements naturally occurring in business negotiations.

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



2.5 Sourcing information

The Company carries out development work in the field of manufacturing of biotechnological medicines. The degrees of development of various projects differ. In 2020, work was conducted on all possible product development levels, from 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 release procedures of the Quality Control Department, which often require using appropriately characterised reagents or outsourcing analyses to appropriately certified bodies.

In 2020, 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 12.69%.

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 2020, 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 2020, the Company did not enter into any significant agreements concerning its operating activities, except for the agreement indicated below.

Agreement to conduct the last clinical trial before submitting the marketing authorisation application for MabionCD20 to the EMA

On 29 October 2020, the Company entered into an agreement with Parexel International (IRL) Limited, based in Ireland ("Parexel"), on conducting a three-arm, double-blind, randomised clinical trial of MabionCD20 in parallel groups in patients diagnosed with (moderate to severe) rheumatoid arthritis. The purpose of the trial is to determine the similarity in selected clinical parameters between MabionCD20 manufactured on a commercial scale, and MabThera registered in the EU and Rituxan authorised in the US ("Agreement"). Parexel is a leading global CRO Clinical Research Organization) which organises and conducts clinical trials on behalf of other entities. The scope of activities commissioned to Parexel under the Agreement includes, inter alia, verification of the clinical trial protocol, submission of applications for approval to conduct the trial in individual countries, recruitment of clinical sites and patients, supervision of the trial, regular review and analysis of data, preparation of trial-related documentation and reports for the drug registration procedure, including the final integrated clinical study report (CSR).

The above trial is a bridging clinical trial carried out to obtain the data necessary to submit a new marketing authorisation application (MAA) to the European Medicines Agency (EMA) for MabionCD20 manufactured as part of a large-scale, commercial production process. The Company has consulted with the EMA on this approach and data scope as part of the scientific advice procedure in the second quarter of 2020. The information received, combined with the answers obtained separately as part of consultations with the US regulator, will also serve the Company in its application process before the US Food and Drug Administration (FDA). The Company is in the process of consulting the proposed approach with the US regulator. Under the assumptions of the agreement, the cost of the tasks covered by this agreement with the CRO will amount to approximately EUR 5,400 thousand net (excluding the cost of logistics and purchase of the reference drugs, MabThera and Rituxan) and they are expected to be completed by mid-2022. The timing of the clinical trial has been consulted with Parexel and takes into account the precautionary approach given the current COVID-19 pandemic. Either party may, for the reasons set out in the Agreement or without cause upon written notice, terminate the Agreement. However, the Company has stipulated that the above assumptions may change in the future due to the fact that they are based on a number of factors that may affect the implementation timeframe, including factors beyond the Company's control such as the pace of clinical trial recruitment. The Company is currently engaged in ongoing consultations with both the EMA and the FDA and aims to harmonise the approach of the two regulators in relation to the trial, therefore recommendations from the above agencies may influence the Company's assumptions. At the same time, the Company has advised that the assumptions made and actions taken do not guarantee product registration.

The Company informed about the Agreement conclusion in its Current Report No. 41/2020 dated 29 October 2020.

2.7.2 Other agreements relating to operating activities

On 31 January 2019, the Company entered into an agreement with IMA Sp.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 1,830 thousand. Due to the nature of the order and the need to involve multiple parties in the execution of the subject matter of the agreement, the agreement was not performed on time (November 2019). At the end of January 2020, the line was subjected to the acceptance process at the manufacturer's headquarters in Italy, but the manufacturer did not meet all the criteria and final acceptance was not granted. Due to the COVID-19 pandemic, re-testing and acceptance was suspended. Currently, the Company has sent an enquiry to the contractor asking about the possibility of agreeing a new date for tests to be carried out at the manufacturer's headquarters or remotely, and as at the date of publication of this report, the Company is awaiting a response. The Company does not recognise any risk regarding the performance of this agreement.

2.7.3 Agreements relating to loans and borrowings received in 2020

On 17 July 2018, the Company entered into an agreement with Santander Bank Polska S.A. (formerly: Bank Zachodni WBK S.A.) an agreement for a revolving credit facility to finance the Company's operating activities, for a period of two years from the date of the agreement. The amount of the Loan granted was PLN 30,000 thousand, whereas the disbursement of PLN 15,000 thousand took place after meeting the formal and legal conditions and the establishment of collaterals. An amount beyond the PLN 15,000 thousand could be disbursed after the Company has received a positive decision of the European Medicines Agency concerning the registration of MabionCD20. The interest rate on the Loan is variable and based on WIBOR 1M plus the Bank's margin determined on arm's length. The termination date of the agreement and repayment of the loan was 17 July 2020 and on that date, the loan was repaid in its entirety (i.e. the amount of PLN 15,000 thousand corresponding to the used tranche of the loan).

On 21 October 2019, the Company 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 30,000 thousand. 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 the Financing Agreement. It bears interest at a fixed interest rate not exceeding 2.7% per annum. The Agreement stipulates certain restrictions, 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. A breach of the Company's obligations specified in the Financing Agreement will entitle the EIB to demand immediate repayment of the loan.

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. By the date of publication of this report, the specified conditions enabling the disbursement of funds have not been met. The Company, after changing its strategy for the registration process, has taken actions aimed at changing the conditions provided for in the binding agreement.

As at 31 December 2020, the Company did not use the facility granted by the EIB.

On 15 July 2020, the Company entered into a borrowing agreement with Glatton Sp. z o.o. – a related party and shareholder of the Company– for the amount of PLN 15,000 thousand to refinance the revolving credit facility granted to the Company in 2018 by Santander Bank Polska S.A. The borrowing agreement entered into force on 16 July 2020. The Company's Supervisory Board approved the conclusion of the Borrowing Agreement. The Borrowing constitutes additional financing not included in the financing declared on 16 March 2020 by the main shareholders of the Company. The interest rate on the Borrowing has been agreed on an arm's length basis as a variable interest rate based on WIBOR 3M plus a margin. The collateral for the repayment of the borrowing consists of: mortgage on real property located in Konstantynów Łódzki up to the amount of PLN 45,000 thousand (first rank entry in the mortgage register) with priority right over other possible mortgage creditors, and statement on submission to execution in the form of notarial deed. Subject to the mortgage referred to above, the nominal value of the collateral in favour of the Lender will, in total, equal or exceed at least 150% of the Borrowing amount.

As at 31 December 2020, the Company has utilised the entire amount of PLN 15,000 thousand as part of the limit granted under the above-mentioned borrowing agreement. Pursuant to the borrowing agreement, the Company was obliged to repay the borrowing by 31 December 2020, with the parties allowing for the possibility of extending the aforementioned term. On 10 December 2020, the parties concluded an annex to the agreement, according to which the borrowing repayment date was extended to 31 December 2021.

On 12 August 2020, the Company entered into borrowing agreements with Twiti Investments Ltd. and Glatton Sp. z o.o. up to a total of PLN 15,000 thousand. The conclusion of the agreements represented the implementation of the Company's shareholders' declaration of 16 March 2020 regarding the recapitalisation of Mabion S.A. The borrowings could be disbursed by the lenders to the Company borrower n tranches, in amounts and on dates agreed by the parties in separate disbursement schedules, with the lenders required to disburse each tranche upon written request by the borrower. The interest rate on the borrowings, the same for each of the Agreements, was agreed on an arm's length basis as a variable interest rate based on WIBOR 3M plus a margin. The borrowings were to be repaid by conversion into U shares or in cash no later than 31 March 2021.

As at 31 December 2020, the Company has utilised the entire amount of PLN 15,000 thousand as part of the limit granted under the above-mentioned borrowing agreements. The principal receivable under both of the above borrowings was repaid in Q1 2021 by way of conversion into U series ordinary bearer shares issued by the Company pursuant to a resolution of the Extraordinary General Meeting of 23 February 2021. To this end, the Company performed a contractual set-off of the claim against Glatton Sp. z o.o. for payment of the issue price for the U series shares subscribed for by Glatton Sp. z o.o. as part of the issue with the claim of Glatton Sp. z o.o. under the said borrowing agreement, and a contractual set-off of part of the claim against Twiti Investments Limited for payment of the issue price for the U series shares subscribed for by Twiti Investments Limited as part of the issue with the claim of Twiti Investments Limited under the said borrowing agreement.

2.7.4 Agreements relating to loans or borrowings terminated or dissolved in 2020

In the financial year 2020, no loan or borrowing agreements were terminated or dissolved.

2.7.5 Agreements relating to borrowings granted

In the financial year 2020, 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 45,000 thousand, was in force. The surety concerned a revolving credit agreement dated 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 a related entity, governing the rules of payment for the surety. As the loan granted by Santander has been repaid, the surety agreement ceased to be in force on 16 July 2020.

2.7.7 Transactions with related parties

The Company's transactions with related parties are presented in Notes 20 and 24 of the financial statements.

In 2020, 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

European Medicines Agency (EMA) registration procedure for MabionCD20 manufactured on a small scale

On 13 January 2020, as a result of telephone consultations with the EMA, the Company planned 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 applications at a meeting of the Committee for Medicinal Products for Human Use (CHMP), most likely on 24–27 February 2020.

On 28 January 2020, the Company received confirmation from a company contracted to deposit answers, that the Company's answers had been successfully submitted to the electronic system of the EMA. The answers concerned both authorisation applications – the basic application and the application in which the list of indications for the product did not include rheumatoid arthritis (duplicate application). Submitting the answers allowed the EMA to continue its assessment of the applications. Given that the regulator has a number of tools at its disposal to ensure its discretion and the ability to tailor a solution to the needs of a given registration procedure, the Company stressed that informed that it had no influence on the assessment of the EMA, and there were a number of possible further 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 that stage by the Company.

On 13 February 2020, the Company received from the EMA a list of issues to be presented at the CHMP meeting on 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).

Then, on 16 March 2020, the Management Board of Mabion S.A. decided to change the regulatory strategy for MabionCD20 in the EMA and to obtain a direct marketing authorisation for the drug manufactured as part of a large-scale, commercial production process. As a result of the above, the Company withdrew the existing registration applications and terminated the registration procedure for MabionCD20 manufactured on a small scale described above, which is discussed in more detail further on in this section.

The Company informed about the above events in Current Reports no. 2/2020 of 13 January 2020, no. 7/2020 of 28 January 2020, no. 11/2020 of 13 February 2020, and no. 13/2020 of 26 February 2020.

Consultation with the Food and Drug Administration (FDA)

On 22 January 2020, a Type 3 BPD (Biosimilar Biological Product Development) meeting of the Company's representatives was held with the Food and Drug Administration (FDA) on the registration and marketing authorisation of MabionCD20 in the USA. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the USA. During the meeting, a productive discussion was held on the data needed to apply for registration of 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. The Type 3 BPD meeting was a stage of implementation of activities aimed at obtaining registration of MabionCD20 in the USA, but its completion does not guarantee that these actions will have a positive result.

On 14 February 2020, the Company received from the FDA a summary of the meeting described above. The Company has analysed 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 the drug in the USA.

On 28 August 2020, the Management Board announced that the Company had received a summary of the next meeting with the FDA – a BPD Type 2 meeting regarding the registration and marketing approval of MabionCD20 in the USA. The meeting was aimed at clarifying the details of the clinical development of MabionCD20 for the US market. The Company has received

confirmation from the Agency of a number of the Company's proposed clinical programme parameters, including the ability to use the substantial data packages generated for the EU approval of MabionCD20. This confirms the earlier consultation in which the Agency suggested that there was no need for a completely separate development programme to authorise MabionCD20 in the US. In addition, the Company has started to review with the Agency the feasibility of a novel regulatory strategy to allow for an earlier initial application for registration than originally anticipated and proposed by the Agency. The Company has accepted the Agency's suggestion to clarify the details of this approach at a further separate meeting, which has been set for 15 April 2021. The arrangements are non-binding on the Agency. 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 above events in Current Reports no. 4/2020 of 22 January 2020, no. 12/2020 of 14 January 2020, and no. 32/2020 of 28 August 2020.

Permit to operate in an economic zone

On 7 February 2020, the Company received a decision of the Minister of Development on the amendment of permit no. 301 (granted in 2017) to conduct business activity in the Łódź Special Economic Zone ("Zone"). By virtue of the above mentioned decision, at the request of the Company the deadline for incurring investment expenditure of at least PLN 20,000 thousand 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, was extended from 31 December 2019 to 30 June 2021. The request for the above change resulted from the change in the schedule of the Company's commencement of the investment. At the same time, the investment completion date planned for 31 December 2021 did not change.

On 23 June 2020, the Company received an inspection record concerning the Company's implementation of the condition of permit no. 301 of 12 April 2012 on maintaining the employment in the Zone of at least 100 employees in total from 2 March 2017 to 1 March 2020. On the basis of the inspection activities carried out, it was found that this condition was fulfilled. The remaining conditions of the above-mentioned permit are: incurring investment expenditure specified above within the Zone and completing the investment by 31 December 2021.

The Company informed about the events in Current Reports no. 9/2020 of 7 February 2020 and no. 26/2020 of 23 June 2020.

The Company informed about the events in Current Reports no. 9/2020 of 7 February 2020 and no. 26/2020 of 23 June 2020.

Change of construction permit for Scientific and Technological Centre

On 12 February 2020, the Company was informed of a decision of the District Governor of Pabianice changing the permit (granted in November 2018) for the construction of a building as part of the investment entitled "Technological and Scientific Centre for Advanced Medical Biotechnology of Mabion S.A." with the necessary infrastructure in Konstantynów Łódzki. 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.

Change in regulatory strategy for MabionCD20 at EMA

On 16 March 2020, the Management Board of Mabion S.A. decided to change the regulatory strategy for registering MabionCD20 with the EMA. The basic change aimed at obtaining marketing authorisation for the drug at the EMA directly for a large commercial scale as opposed to the 2-step strategy pursued previously (obtaining marketing authorisation for a small scale production process, and then on the basis of a separate variation, a marketing authorisation for large commercial manufacturing). The Company's Management Board made this decision on the basis of the opinion of external consultants received on 16 March 2020 and on the recommendation of the Company's Supervisory Board. The change of the strategy involved withdrawing the small-scale registration applications submitted in June 2018 and in May 2019.

On 30 March 2020, the EMA website published information confirming the withdrawal of registration applications by the Company. The confirmation ended the registration procedure. 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. However, the Company, given its hitherto interactions with the Agency, decided that the data would be revised in the new application concerning large-scale, commercial production, and therefore the applications for the small-scale manufacturing process were withdrawn.

The Company's intention was that the new application, which will be assessed by the Agency in terms of the target scale, would be submitted after the validation and biosimilarity data for the product from the large scale production are available, however, the scope and format of the application were to be consulted in the first place with EMA representatives under the Scientific Advice procedure, in order to adapt them to the Agency's expectations and streamline the future registration process. For procedural and formal reasons, the Company could not proceed with the previously submitted applications supplemented by additional large-scale data. In the opinion of the Company's Management Board, the decision changing the regulatory strategy for MabionCD20 was therefore 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 decision did not affect the original schedule of work on the large-scale manufacturing and bridging trial validation as well as work on registering MabionCD20 in the US market. 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.

On 30 March 2020, the Agency published a "Questions and Answers" document ("Q&A") containing a short summary of the ended registration procedure. The details (European public assessment report, EPAR), in line with the EMA regulations, were published by the regulator on 24 June 2020. The EPAR was based on the latest CHMP-approved version of the assessment report (version concerning the Day 195 of the registration procedure, that is November 2019), which identified more unresolved issues than those pending at the time of withdrawal of the application, and therefore the report did not reflect the most current status of the ended 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 informed about the above events in Current Reports no. 15/2020 of 16 March 2020 and no. 19/2020 of 30 March 2020.

Arrangements for financing the Company' s activities and the conclusion of borrowing agreements with the Company' s major shareholders

On 16 March 2020, the Supervisory Board of Mabion S.A. 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 15,000 thousand in 2020. The capital injection, in accordance with the Shareholders' declaration of 16 March 2020, was to take place in tranches, in response to the Company's financial needs. The recapitalisation of the Company could 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 would enable effective implementation of the new strategy of registration of MabionCD20 with the EMA. In the opinion of the Company's Management Board, it could have been possible to obtain external debt financing thanks to the strong support received by the Company from its major shareholders. In addition, the Company did 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.

On 12 August 2020, pursuant to the supporting documents indicated above, the Company entered into borrowing agreements with Twiti Investments Ltd. and Glatton Sp. z o.o. (Lenders) up to a total of PLN 15,000 thousand. Details of the borrowings

obtained are presented in section 2.7.3 of this report. The principal receivable under both of the above borrowings was repaid in Q1 2021 by way of conversion into U series ordinary bearer shares issued by the Company pursuant to a resolution of the Extraordinary General Meeting of 23 February 2021. To this end, the Company performed a contractual set-off of the claim against Glatton Sp. z o.o. for payment of the issue price for the U series shares subscribed for by Glatton Sp. z o.o. as part of the issue with the claim of Glatton Sp. z o.o. under the said borrowing agreement, and a contractual set-off of part of the claim against Twiti Investments Limited for payment of the issue price for the U series shares subscribed for by Twiti Investments Limited as part of the issue with the claim of Twiti Investments Limited under the said borrowing agreement. On 14-15 April 2021, the Company made a payment in respect of the remaining unpaid liabilities under the above agreements, including interest on borrowings granted by Twiti Investments Limited and Glatton Sp. z o.o.

The Company informed about the above events in Current Reports no. 16/2020 of 16 March 2020, no. 31/2020 of 12 August 2020, no. 20/2021 of 8 March 2021 and no. 23/2021 of 15 March 2021.

Information on the impact of the SARS-CoV-2 coronavirus pandemic on the Company' s operations

On 16 March 2020, in connection with the epidemic emergency introduced in Poland and the SARS-CoV-2 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. 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). At the time of publication of the current report, this work was proceeding smoothly, according to the schedules, and there were no delays in delivery of components, materials, machinery or equipment. However, it could not be excluded that such delays would occur in the future. The Management Board of the Company had also recognised the risks associated with the liquidity disruption in the markets resulting from the spread of SARS-CoV-2 virus 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. The Management Board emphasised that at the time of submitting the Current Report, it had not received any information from the above-mentioned authorities concerning the shift in the processes in progress. The Management Board also highlighted that the continuing pandemic, including, among others, the reduction of passenger traffic could 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 Company's Management Board stated that it would monitor the situation on an ongoing basis, and the Company complied with all applicable administrative decisions.

The impact of the spread of the SARS-CoV-2 virus on the operations of Mabion S.A. was reported by the Company in Current Report No. 17/2020 of 16 March 2020. For information on the current impact of SARS-CoV-2 on the Company's operations, please refer to section 2.8.4 of this report.

Adoption of a resolution on the continued existence of the Company pursuant to article 397 of the CCC

On 15 June 2020, the Ordinary General Meeting of Mabion S.A. adopted Resolution No. 18/VI/2020, according to which, in connection with the occurrence of the circumstances provided for in Article 397 of the CCC, the General Meeting of the Company decided on the continued existence of the Company. Pursuant to Article 397 of the Commercial Companies Code, "[i]f the balance sheet drawn up by the management board shows a loss exceeding the aggregate of the supplementary and the reserve capitals and one third of the share capital, the management board shall immediately convene the general assembly so that a resolution on the continued existence of the company can be adopted". Due to the fact that as at 31 December 2019 the

Company has met the aforementioned prerequisite, the Management Board of the Company has included in the agenda of the forthcoming General Meeting an item providing for the adoption of a resolution concerning the Company's continued existence, at the same time justifying that the main reason for the negative financial result for the financial year 2019 is the lack of realised sales revenue, the high costs of research and development, as well as the general and administrative expenses incurred and their increase resulting from growth and changes in the structure of employment. The Ordinary General Meeting of Mabion S.A. decided on the continued existence of the Company. The Company informed about the event in Current Report no. 23/2020 of 15 June 2020.

Scientific Advice consultations with EMA

On 1 July 2020, the Company received a written response from the EMA as part of the Scientific Advice procedure (i.e. scientific consultation with EMA representatives regarding the Briefing Package submitted by the Company in April 2020). The document contains the Agency's response to the Company's specific assumptions regarding the new registration process for MabionCD20. In particular, it refers to the scope of data to be included in the new registration application, as well as the actions proposed to generate such data. In the Company's opinion, consultation with the EMA allows it to significantly reduce regulatory uncertainty and risk, as well as to optimise the timing and effort required for the submission of a Marketing Authorisation Application (MAA) and for its regulatory review. However, the Company points out that due to the specific responsibilities of the regulatory authorities, the content of the document is subject to interpretation, which poses some risk of discrepancies in interpretation. The Company informed about the event in Current Report no. 28/2020 of 1 July 2020.

Initial assumptions for the registration application to be submitted to the EMA for MabionCD20 manufactured on a commercial scale

On 9 July 2020, the Company's Management Board, after internal analysis, consultation with external experts and the Company's Supervisory Board, adopted a preliminary framework for the scope and schedule of work required to submit a new marketing authorization application (MAA) for the product. As of the date of Current Report no. 29/2020, validation of the large-scale manufacturing process of MabionCD20 based on three validation batches has been completed. The initial analytical testing proved that the manufactured batches met the requirements for all drug substance (DS) level analysed quality attributes. In addition, the Company has commenced product stability testing and plans to commence biosimilarity and bioequivalence tests in the near future. In line with the assumptions adopted, in order to expand the analytical data presented in the registration application, the Company is considering the production of additional batches so that the marketing authorisation application will ultimately be based on data from at least four to five batches of the product manufactured as part of a large-scale production process. In the Company's view, providing a broad package of analytical data would significantly mitigate regulatory risk. Apart from generating a package of analytical data, it is the Company's intention to conduct, for the purposes of the registration dossier, also a clinical trial which, in the Company's opinion, is required to demonstrate comparability and, at the same time, will allow to mitigate the aforementioned risks and thus reduce the cost and duration of the preparation stage for the registration process. The Company has developed a draft protocol for the bridging trial (3-arm clinical trial, scope: safety and pharmacokinetics, indication: rheumatoid arthritis) which will aim to confirm biosimilarity between MabionCD20 and MabThera and Rituxan.

The trial design and scale indicated above may be subject to modification as a result of consultation with the EMA/FDA.

Based on the above assumptions, the Company estimated in July 2020 that the work to obtain the data required for the new marketing application, including the bridging trial, would be completed before or in early 2022. This timeline has changed to mid-2022 due to the conclusion of an agreement with Parexel International (IRL) Limited (CRO) in October 2020 to conduct the aforementioned trial, which is discussed further in section 2.7.1 of this report. According to the Company's best estimates, the planned activities will entail net expenditures of approximately PLN 75,000 thousand – 85,000 thousand over the assumed period, of which approximately 70% will be R&D costs (estimates include the bridging clinical trial). Under the assumptions of the agreement, the expected cost of work related to the clinical trial under the agreement signed with the CRO is EUR 5,400 thousand net (approximately PLN 24,500 thousand) – excluding, among other things the costs of logistics and purchase of the reference drugs, MabThera and Rituxan. Other expenses represent production and maintenance costs (additional validation batches), regulatory process

costs (including fees to the EMA) and QA/QC expenses. The assumed estimates do not take into account the costs of day-to-day operations and capital expenditure associated with increasing production capacity. The Company does not exclude the possibility of modifying the aforementioned assumptions should circumstances require it. Indeed, the Company's objective is to respond quickly and decisively to any needs arising from the registration process in order to mitigate regulatory risk while keeping the cost of the process at a level that can be financed by the Company and to carry out the product registration procedure as fast as possible. The above assumptions may be subject to change in the future due to the fact that they are based on a number of factors that may affect the timeframe, including factors beyond the Company's control such as the speed of clinical trial recruitment. The Company is currently engaged in ongoing consultations with both the EMA and the FDA and aims to harmonise the approach of the two regulators in relation to the trial, therefore recommendations from the above agencies may influence the Company's assumptions. At the same time, the assumptions made and actions carried out do not guarantee the registration of the product.

The Company informed about the event in Current Report no. 29/2020 of 9 July 2020.

Borrowing agreement with Glatton Sp. z o.o.

On 15 July 2020, the Company entered into a borrowing agreement with Glatton Sp. z o.o. – a related party and shareholder of the Company– for the amount of PLN 15,000 thousand to refinance the revolving credit facility granted to the Company in 2018 by Santander Bank Polska S.A. with respect to the portion of the loan used by the Company in the amount of PLN 15,000 thousand. The borrowing agreement with Glatton Sp. z o.o. entered into force on 15 July 2020. The Company's Supervisory Board approved the conclusion of the Borrowing Agreement. Under the borrowing agreement, the Company was required to repay the borrowing by 31 December 2020. However, on 10 December 2020 the parties concluded an annex to the agreement, according to which the borrowing repayment date was extended to 31 December 2021. Details of the borrowing obtained are presented in section 2.7.3 of this report.

The Company informed about the above events in Current Reports no. 30/2020 of 15 July 2020 and no. 46/2020 of 10 December 2020.

Conclusion of a memorandum with Vaxine Pty Ltd. for a possible collaboration in the development, manufacture and commercialisation of a potential vaccine for Covid-19 disease

On 14 September 2020, the Company entered into a Memorandum of Understanding ("MoU") with Vaxine Pty Ltd. based in Australia ("Vaxine") to work out arrangements in relation to the process development, manufacturing and commercialisation of Covax-19™, a potential vaccine for COVID-19 disease caused by the Sars-Cov-2 virus ("Product"), with particular focus on the Polish and European Union markets. Vaxine is an Australian biotechnology company focusing on the development of innovative vaccines against seasonal and pandemic influenza, COVID-19, hepatitis B and Japanese encephalitis. According to the MoU, the parties' objective was to negotiate and conclude, if deemed appropriate by the them, agreements relating to the manufacturing of the Product by Mabion, the process work to be performed and the commercialisation of the Product by Mabion in agreed markets, and prior to concluding the agreements, to conduct mutual due diligence and to cooperate in arranging future government or EU funding or reimbursement.

The Company stipulated that the MoU was of an intentional and non-binding nature and that its conclusion did not prejudge the conclusion of the agreement or the parties' future cooperation. In line with the original wording of the memorandum, either party could terminate the MoU if the parties had not entered into the relevant agreements by 30 October 2020 or in the event of an adverse due diligence outcome (in the opinion of the party concerned). On 29 October 2020, the parties to the memorandum extended the expiry date of the MoU to 30 November 2020, which was subsequently extended to 31 January 2021 on 30 November 2020. The expiry of the MoU at the end of January 2021 was not tantamount to the termination of the talks by the parties.

During the period of validity of the Memorandum, the parties worked on agreeing the terms of the possible agreements referred to above, as a result of which in January 2021 the Company prepared and sent to the partner a cooperation offer fulfilling the

provisions of the memorandum. Despite the expiry of the offer, Vaxine Pty Ltd. has not taken any further steps in relation to the above offer. Therefore, having regard to the purpose of the MoU as set out above, the Company assumed that the other party to the MoU did not consider it appropriate to enter into agreements relating to the Covax-19™ with Mabion, which was permissible under the MoU, and accordingly, on 3 March 2021, the Company announced the termination of its relationship with Vaxine.

On 29 October 2020, the Company and Vaxine entered into an agreement governing the transfer of biological materials from Vaxine to the Company for exploratory research in the Company's laboratories on a SARS-CoV-2 vaccine antigen. The agreement in question expired due to Vaxine's failure to fulfil the purpose for which it was concluded, which is described below.

The Company informed about the above events in Current Reports no. 34/2020 of 14 September 2020, no. 42/2020 of 29 October 2020, no. 45/2020 of 30 November 2020 and no. 15/2021 of 3 March 2021.

Signing a letter of intent with IcanoMAB GmbH to conduct development and production of the "IL-mAb" antibody being developed as a potential drug for the treatment of COVID-19 infections

On 14 October 2020, the Company signed a letter of intent with IcanoMAB GmbH, based in Germany "IcanoMAB", regarding a possible collaboration to conduct CMC development work and pharmaceutical GMP (Good Manufacturing Practice) compliant production of the human IL-1R7 mAb antibody being developed by IcanoMAB as a potential drug to treat patients with COVID-19 infection. The letter of intent provided the basis for further negotiations between the parties with a view to concluding a final agreement, including the financial terms of cooperation between the parties. Under the letter of intent, the agreement was to be entered into until 31 March 2021, provided that entry into force of the agreement and collaboration will occur if and when IcanoMAB secures funding for the development programme for the above antibodies. The Company also stipulated that the letter of intent is non-binding in nature and therefore its signing does not imply the commencement of cooperation, and the parties have the right to terminate negotiations at any time without concluding the final agreement. Moreover, the Company confirmed that the possible establishment of cooperation will not negatively influence the implementation of the Company's current projects, and in particular that the development and commercialisation of MabionCD20 will remain the Company's priority.

Due to the failure to provide relevant financial support within the timeframe originally assumed, the letter of intent between the parties expired as at the end of March 2021. The expiry of the letter of intent is not tantamount to the termination of talks by the parties. The parties are continuing discussions on the terms and conditions of possible cooperation.

The Company informed about the event in Current Report no. 37/2020 of 14 October 2020.

Signing of a preliminary agreement with Taxon Therapeutics Ltd. regarding cooperation in the research, development, and commercialisation of MabionCD20 antibody drug in specific clinical indications in the area of rare diseases.

On 21 October 2020, the Company signed a Memorandum of Understanding ("MoU") with Taxon Therapeutics Ltd. based in Israel ("Taxon") regarding the parties' intention to work out the terms of a potential long-term collaboration for the research, development, and then worldwide commercialisation of medicinal products based on a monoclonal antibody recognising the CD20 receptor on human B lymphocytes ("Products") in specific clinical indications in the area of rare diseases. Taxon Therapeutics is an Israeli biotechnology company focusing on drug development for rare conditions for which there are currently no registered medicines. The company is active in the orphan drugs segment. Taxon is interested in developing the Products, registering and commercialising them on an exclusive basis worldwide, in one or more indications where reference medicines containing rituximab as their active substance (i.e. antibodies that recognise the CD20 receptor) are not currently registered in any market. To this end, Taxon is prepared to cooperate with the Company and conduct the pre-clinical and clinical trials required to register the Products for the above indications, which will be specified by the parties at a later date. In accordance with the MoU, the activities for which Taxon will be responsible, including all research and development of the Products in the relevant indication, will be funded by Taxon. The company shall contribute its assets in the form of anti-CD20 antibody manufacturing technology, quality and regulatory documentation, as well as the therapeutic product for clinical development and, in the event of commercialisation, the Company will act as the sole manufacturer.

The Company stipulated that the MoU was of an intentional and non-binding nature and that its conclusion did not prejudge the conclusion of the agreement or the parties' future cooperation. Whether the cooperation is established depends on the positive conclusion of negotiations, including the elaboration of terms and conditions of cooperation satisfactory to the parties, in particular the scope of activities of individual parties and financial conditions, and on the conclusion of a final cooperation agreement. Moreover, Mabion confirmed that the possible establishment of the cooperation described above will not negatively influence the implementation of the Company's current projects, and in particular the Company assured that the development and commercialisation of MabionCD20 will remain its priority. Signing of the aforementioned MoU also does not affect the negotiations with the German company IcanoMAB GmbH regarding cooperation to carry out joint development and production of the "IL-mAb" antibody being developed as a potential drug for COVID-19 infections.

Under the MoU, if the parties do not enter into the final agreement within 4 months of signing the MoU, the memorandum will expire unless the parties agree otherwise. At the date of publication of these statements, although the MoU had expired, further discussions and negotiations are taking place on the terms and conditions of cooperation between the parties.

The Company informed about the event in Current Report no. 40/2020 of 21 October 2020.

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

Adoption of a long-term strategy for financing the Company's activities; the issue of U shares

On 27 January 2021, the Management Board of Mabion S.A., on the basis of an in-depth analysis of the Company's needs and estimated benefits, adopted a new long-term strategy for financing the Company's activities. The strategy covers the Company's overall capital needs which has to be fulfilled in order to carry out all activities which, in the opinion of the Company's Management Board, are necessary to complete the registration of MabionCD20 with the EMA and to start selling MabionCD20, which will allow the Company to generate operating cash flows. The arrangements for the Company's financing strategy were positively reviewed by the Company's Supervisory Board on the same date.

The financial strategy provided for parallel processes: the initiation of activities to attract a strategic investor, and two share issues of the Company. As part of the strategy, the following directional funding decisions were taken, and then the following activities were carried out to implement them:

1) decision to initiate the search for a strategic investor for the Company.

In order to effectively carry out this process, on 27 January 2021 the Company signed an agreement with the financial advisor Rothschild & Co. The scope of the advisor's responsibilities includes, inter alia, searching for a potential strategic investor, advising on the structure of a potential transaction, support in drafting transaction documentation and in negotiations with the potential strategic investor. As at the date of publication of Current Report no. 3/2021 and as at the date of publication of this report, no decisions have been made regarding the type of investor, the expected level of capital commitment, or the transaction formula. These decisions will be made in the course of a process designed to select the most beneficial way for the Company to achieve its long-term business objectives.

2) decision to conduct an offering of the Company's shares in the first quarter of 2021 under the "accelerated bookbuilding" procedure, addressed to eligible investors who are shareholders of the Company and who are qualified investors or who acquire shares with a total value of at least EUR 100 thousand, as indicated by the Company's Management Board.

In order to put the above decision into effect, the Company's Management Board convened an Extraordinary General Meeting for 23 February 2021, which adopted Resolution no. 4/II/2021 on increasing the Company's share capital by an amount not less than PLN 0.10 and not more than PLN 243,055.40 by way of an issue of at least one and not more than 2,430,554 U series ordinary bearer shares with a par value of PLN 0.10 each.

The purpose of the U series share issue was to generate the necessary financing for the Company's working capital, in particular for the development of MabionCD20 and activities aimed at carrying out the registration procedure at the EMA as soon as possible.

On 3 March 2021, the Company's Management Board adopted a resolution on determining the principles of the offering, the principles of bookbuilding, subscription, taking up and allotment of U shares, and the principles of conducting the bookbuilding process for these shares, adopting models of agreements for taking up U shares (subscription agreements for U shares) and consenting to the conclusion by Mabion S.A. of a placement agreement for the purposes of the offering and subscription of U shares.

On 4 March 2021, the Company and mBank S.A. ("Offering Manager") entered into a conditional share placement agreement ("Placement Agreement") and commenced a book-building process by way of a private placement of up to 2,430,554 U series ordinary bearer shares ("U Series Shares", "New Issue Shares") issued by the Company ("Offering"). Pursuant to the Placement Agreement, the Offering Manager has undertaken to provide services to the Company for the purposes of the placement of the New Issue Shares on the terms and conditions set out therein, in particular to exercise due diligence to solicit potential investors and to ensure that such investors subscribe for and pay for the shares. The Placement Agreement contained standard conditions precedent to the Offering Manager's obligations included in agreements of this type, such as conditions relating to the occurrence of force majeure events and the occurrence of a material adverse change in the Company's condition. As part of the Placement Agreement, the Company has undertaken that, without the consent of the Offering Manager, it will not issue, sell, or offer shares during the period of 120 days following the date of the first listing of the rights to the U Series Shares ("Rights"), except for standard exemptions and the issue of up to 10,500,000 V series ordinary shares of the Company assumed pursuant to section 3 referred to below. Additionally the following shareholders of the Issuer – Twiti Investments Limited, Polfarmex S.A. and Glatton sp. z o.o. – have undertaken not to sell or offer the shares acquired by them in the Offering of New Issue Shares during the period of 120 days from the date of the first listing of the Rights without the consent of the Offering Manager. However, this obligation does not apply to transfers within a given shareholder group, transfers required by law or pursuant to competent authorities' decisions as well as to possible sale of the Company's shares to a strategic investor as part of the contemplated process of attracting such an investor.

The book-building process was carried out from 4 to 9 March 2021. Following the completion of the accelerated book-building process for the U Series Shares on 9 March 2021, the Company's Management Board resolved that the issue price of the U Series Shares shall be PLN 55.00 per New Issue Share and the Company shall make offers to investors to acquire a total of 2,430,554 U Series Shares. The issue of the U Series Shares was effected upon the execution of agreements for the taking up of all the U Series Shares and upon payment in full of the contributions to cover the U Series Shares (no allotment of shares within the meaning of the Commercial Companies Code was necessary). The process of concluding the take-up agreements for the U Shares was completed on 12 March 2021. Contributions for the U Series Shares were made in full by 15 March 2021. 2,430,554 U Shares were taken up. Under the Offering, the U Series Shares were taken up by 65 investors.

The U shares were offered by way of private placement within the meaning of the Act of 15 September 2000 – Commercial Companies Code in a public offering on the basis of the exceptions from drawing up and publishing a prospectus referred to in Article 1(4)(a) and (d) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market and repealing Directive 2003/71/EC (the "Prospectus Regulation"). The New Issue Shares have been offered exclusively to: (a) qualified investors as referred to in Article 1(4)(a) of the Prospectus Regulation; or (b) investors who acquire securities with an aggregate value of at least EUR 100 thousand per investor as referred to in Article 1(4)(d) of the Prospectus Regulation, including Eligible Investors (as defined in Resolution No. 4/II/2021 of the Extraordinary General Meeting of the Company of 23 February 2021). The Company's Shareholders meeting the criteria indicated in the aforementioned Resolution No. 4/II/2021 of the Extraordinary General Meeting of the Company ("Eligible Investors"), who participated in the book-building process, were entitled to priority take-up of the New Issue Shares under the principles set out in the Resolution. Pursuant to the Resolution, upon meeting the requirements set forth therein, the Eligible Investors were entitled to priority take-up of the New Issue Shares in a number allowing them to maintain a share in the total number of votes at the General Meeting of the Company not lower than the share held at the end of the day on the date of adoption of the Resolution. Moreover, under the terms of the Resolution, the Eligible

Investors, being Qualified Investors, holding, at the end of the preference day, shares in the Company with an aggregate nominal value of at least 0.5% of the Company's share capital, were given a pre-emptive right to acquire U Series Shares before the other investors.

The issue price of the New Issue Shares was determined by the Company's Management Board based primarily on the results of the book-building process among institutional investors and taking into account all circumstances with a bearing on the determination of the issue price, including in particular the macroeconomic and economic environment, the current situation on the capital markets at the time of the book-building process for the New Issue Shares, the Company's financial standing at the time of the public offering of the New Issue Shares, current events and their impact on the Company's business prospects, as well as based on the recommendations of the Offering Manager engaged in the book-building process for the New Issue Shares.

As part of the issue of the U Series Shares, the Company entered into agreements with investors to take up all (i.e. 2,430,554) S series ordinary bearer shares of the Company. The required cash contributions to cover all U Series Shares were made in entirety, whereby the Company made: (i) a contractual set-off of the entire claim against Glatton sp. z o.o. for payment of the issue price of the U Series Shares against Glatton Sp. z o.o.'s claim under the borrowing agreement concluded with the Company on 12 August 2020, up to a total of PLN 4,999. 995.00; and (ii) a contractual set-off of a part of the claims against Twiti Investments Limited for payment of the issue price of the U Series Shares against the claims of Twiti Investments Limited under the borrowing agreements concluded with the Company on 12 August 2020 and 5 February 2021 up to the total amount of PLN 11,199,980.00, whereby the remaining part of the issue price of the U Series Shares subscribed for by Twiti in the amount of PLN 4,999,995.00 was paid by Twiti in cash.

The Company's share capital increase through the issue of U Series Shares was registered with the National Court Register on 2 April 2021.

Immediately after the issue was placed, the Company took steps to apply for the admission and introduction to trading on the regulated market of the Warsaw Stock Exchange ("WSE") the rights to 2,430,554 U series shares ("RTS"). On 19 March 2021, the National Depository for Securities (Krajowy Depozyt Papierów Wartościowych S.A., "KDPW") issued a statement on conditional registration in the depository of securities, under ISIN PLMBION00057 code, of 2,430,554 rights to U series ordinary bearer shares with a par value of PLN 0.10 each. The condition for the registration of the rights to U series shares was their admission to trading on the regulated market. On 23 March 2021, the WSE's Board adopted a resolution on the admission and introduction to trading on the WSE's Main Market of rights to U series ordinary bearer shares of the Company, pursuant to which the Board stated that 2,430,554 rights to U series ordinary bearer shares of the Company, with a par value of PLN 0.10 each, are admitted to trading on the primary market as of the date of registration of these rights to shares by the KDPW. At the same time, the WSE Board decided to introduce, as of 25 March 2021, the above mentioned RTS to trading on the primary market, provided the KDPW's registration of the RTS on 25 March 2021 at the latest and assigned it with code "PLMBION00057". Additionally, the WSE's Board has decided to list the RTS in the continuous trading system under the abbreviated name "MABION-PDA" and the designation "MABA". On 23 March 2021, the KDPW published a notice on the registration, as of 24 March 2021, in the depository of securities under ISIN PLMBION00057 code, of 2,430,554 rights to U series ordinary bearer shares of the Company with a par value of PLN 0.10 each. Thus, the condition for the introduction of the RTS to trading on the WSE primary market on 25 March 2021 was fulfilled.

Then, the Company took steps to apply for the admission and introduction of 2,430,554 U series shares of the Company to trading on the regulated market. On 14 April 2021, the KDPW issued a statement on the conditional registration in the securities depository under ISIN code PLMBION00016 of 2,430,554 U series ordinary bearer shares of the Company. The condition for the registration of the U shares was their introduction to trading on the regulated market. On 14 April 2021, the WSE's Board adopted a resolution on the admission and introduction to trading on the WSE's Main Market of U series shares of the Company, pursuant to which the Board stated that 2,430,554 U series ordinary bearer shares of the Company, with a par value of PLN 0.10 each, are admitted to trading on the primary market. At the same time, the WSE's Board decided to introduce, as of 19 April 2021, the above mentioned Company's shares to trading on the primary market, provided that the KDPW has registered these shares on 19 April 2021 and assigned it with code PLMBION00016. On 15 April 2021, the KDPW published a notice on the registration, as of 19 April 2021, in the depository of securities under ISIN PLMBION00016 code, of 2,430,554 U series

ordinary bearer shares of the Company with a par value of PLN 0.10 each. Thus, the condition for the introduction of the shares to trading on the WSE primary market on 19 April 2021 was fulfilled.

The U series shares were registered with the KDPW in connection with the closure of the accounts maintained for the aforementioned rights to shares. On 14 April 2021, the WSE' s Board adopted a resolution on determining the last day of listing, on the WSE Main Market, the rights to U series shares of the Company, pursuant to which it determined that 2,430,554 rights to U series ordinary bearer shares of the Company, designated by the KDPW with the code PLMBION00057, will be listed on 16 April 2021 for the last time. The admission of shares and the rights to U series shares to trading on the regulated market did not require the Company to make a prospectus, or any other information or offering document within the meaning of the relevant legal regulations, available to the public.

3) decision on the intention to make a prospectus-based offer of the Company's shares within the meaning of the relevant legislation.

To implement the above decision, concurrently with the issue of U shares, the Company started preparations related to the prospectus and the offering of the Company's shares on the basis of the prospectus, the parameters of the offering, and its schedule. The prospectus-based issue, subject to the approval of the prospectus by the Polish Financial Supervision Authority and the fulfilment of other legal requirements, is planned to be carried out in no less than several months.

On 22 February 2021, the Company's Management Board convened an Extraordinary General Meeting for 22 March 2021 to adopt a resolution on increasing the Company's share capital by an amount not less than PLN 0.10 and not more than PLN 1,050,000 by way of an issue of at least one and not more than 10,500,000 V series ordinary bearer shares with a par value of PLN 0.10 each.

On 16 March 2021, the Management Board of the Company announced the cancellation of the Extraordinary General Meeting of the Company which was to be held on 22 March 2021. The decision of the Management Board of the Issuer to cancel the General Meeting resulted from the need to verify available sources of funding necessary to cover financing needs, inter alia, following the successful issue of U shares and the conclusion of a framework agreement together with the first order for contractual services with Novavax, Inc. regarding the COVID-19 vaccine programme. The Management Board pointed out that raising funds from the issue of U series shares and the conclusion of an agreement with Novavax Inc. will enable the Company to potentially access additional, not yet fully available sources of financing, including potential debt financing from Polski Fundusz Rozwoju S.A. (PLN 30,000 thousand), a granted and unused subsidy from the European Regional Development Fund (approximately PLN 63,000 thousand) and potentially a loan from the European Investment Bank (up to a total of EUR 30,000 thousand, i.e. approximately PLN 138,000 thousand), with which the Company continues its talks. In the financing strategy initially adopted in January 2021, the Company did not take into account the potential operating flows related to the collaboration with Novavax, Inc. which, if a certain scenario is materialised (including the initial stage currently being implemented, i.e., inter alia: effective technology transfer, production of one technical batch and one test batch, followed by another stage of continued collaboration on a commercial basis), may bring additional operating flows to the Company. Accordingly, decisions on updating the Company's initially adopted financial strategy, including a decision on whether or not to carry out the subsequent share issue referred to in point 3, will be made following detailed analyses, taking particular account of the factors mentioned above.

In line with the assumptions adopted in January 2021, actions 1)-3) referred to above, depending on their success, was aimed at providing the Company with the financing necessary to complete the registration process and commercialisation of MabionCD20. In addition, the Company holds letters of support received from the Company's key shareholders referred to in the financial statements for 2020, whose contents indicate that these shareholders are willing and able to continue their financial support for the Company's day-to-day operations in the near future covering a period of at least another 12 months from the date of signing of these financial statements.

At the same time, in January 2021 the Company informed that it also does not exclude the use of other sources of financing such as external debt financing, grants, subsidies from EU funds, earmarked funds for the implementation of new projects, or other sources depending on the needs and capabilities of the Company. As at the date of the current report and the date of publication of this report, the Company's Management Board is in the process of negotiating agreements with several biotechnology companies that could potentially bring the Company profits from cooperation in the area of development and production of biological drugs or vaccines. The Company is also continuing talks with the European Investment Bank to align the terms of the financing agreements with the current regulatory strategy for MabionCD20.

The Company informed about the above events in Current Reports no. 3/2021 and no. 4/2021 of 27 January 2021, no. 11/2021 of 22 February 2021, no. 12/2021 of 23 February 2021, no. 19/2021 of 4 March 2021, no. 20/2021 of 8 March 2021, no. 21/2021 of 9 March 2021, no. 23/2021 of 15 March 2021, no. 25 of 16 March 2021, no. 26/2021 and no. 27/2021 of 22 March 2021, no. 28/2021 and no. 29/2021 of 23 March 2021, and no. 31/2021 of 2 April 2021.

Conclusion of a borrowing agreement with Twiti Investments Limited

On 5 February 2021, the Company entered into a borrowing agreement with Twiti Investments Ltd. – a related party and shareholder holding 17.33% of the Company's share capital ("Lender"), for the total amount of up to PLN 10,000 thousand. The Company's Supervisory Board approved the conclusion of the Borrowing Agreement. The borrowing may be disbursed in tranches, in amounts and on dates agreed by the parties in a separate disbursement schedule, with the Lender required to disburse each tranche upon written request by the Company. The borrowing agreement does not specify the purpose of the funds, and it was the Company's intention to use the funds raised to cover current expenses. The interest rate on the Borrowing has been agreed on an arm's length basis as a variable interest rate based on WIBOR 3M plus a margin. The remaining principal receivable under both of the above borrowing was repaid in part of approx. PLN 2,000 thousand in March 2021 by way of conversion into U series ordinary bearer shares issued by the Company pursuant to a resolution of the Extraordinary General Meeting of 23 February 2021. To this end, the Company performed a contractual set-off of part of the claim against Twiti Investments Limited for payment of the issue price for the U series shares subscribed for by Twiti Investments Limited as part of the issue with the claim of Twiti Investments Limited under the said borrowing agreement. On 15 April 2021, the Company settled the remaining unpaid liabilities under the above-mentioned agreement, i.e. the amount of PLN 2,300 thousand of principal and interest, and therefore the borrowing was repaid in full as used. The borrowing represented a further step in the implementation of the declaration of support for the Company by key shareholders made to the Company in letters of support. The Company informed about the events in Current Reports no. 5/2021 of 5 February 2021, no. 20/2021 of 8 March 2021, and no. 23/2021 of 15 March 2021.

Adoption of resolutions on the continued existence of the Company pursuant to article 397 of the CCC and on extending the Company's scope of business

On 23 February 2021, the Extraordinary General Meeting of Mabion S.A. adopted Resolution No. 3/II/2021, according to which, in connection with the occurrence of the circumstances provided for in Article 397 of the CCC, the General Meeting of the Company decided on the continued existence of the Company. Pursuant to Article 397 of the Commercial Companies Code, "[i]f the balance sheet drawn up by the management board shows a loss exceeding the aggregate of the supplementary and the reserve capitals and one third of the share capital, the management board shall immediately convene the general assembly so that a resolution on the continued existence of the company can be adopted". Due to the fact that as at 30 September 2020 the Company has met the aforementioned prerequisite, the Management Board of the Company has included in the agenda of the forthcoming General Meeting an item providing for the adoption of a resolution concerning the Company's continued existence, pointing to circumstances indicating material uncertainty that may cast significant doubt upon the Company's ability to continue as a going concern, at the same time justifying that the main reason for the negative financial result for the financial year 2020 is the lack of realised sales revenue, the high costs of research and development, as well as the general and administrative expenses incurred and their increase resulting from growth and changes in the structure of employment. The Extraordinary General Meeting of Mabion S.A. unanimously decided on the continued existence of the Company.

On 23 February 2021, the Extraordinary General Meeting of Mabion S.A. also adopted Resolution No. 5/II/2021 on amending the Company's Articles of Association by changing the Company's scope of business. As a result of the Company's analysis of opportunities to increase the efficiency of its operations using its resources, particularly within its available transport network, the Company has considered additional operations through the provision of new services. The change concerned the extension of the Company's scope of business to include freight transport by road (PKD 49.41.Z) and other postal and courier activities (PKD 53.20.Z), which will allow the Company to undertake operations in additional and complementary areas, and thus will not have a material impact on the Company's main business; therefore, the General Meeting resolved to implement the change without redeeming the shares of shareholders who do not agree to such change. The amendment of the Company's Articles of Association in the above scope was registered with the National Court Register on 2 April 2021.

The Company informed about the event in Current Reports no. 12/2021 of 23 February 2021 and no. 31/2021 of 2 April 2021.

Conclusion of a framework agreement with the first order for contractual services with Novavax, Inc. for the COVID-19 vaccine programme

On 3 March 2021, the Company entered into a framework agreement ("Framework Agreement") with Novavax, Inc. of the United States ("Novavax"), pursuant to which the Company, with Novavax's participation, will undertake activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate antigen under the working name of NVX-CoV2373 and conduct technical trial runs of the process on a commercial scale at the Company's facility. The Framework Agreement shall be in force until 31 December 2023.

With the conclusion of the Framework Agreement, the parties agreed on the scope and budget of the work contracted to the Company to carry out the technology transfer and technical batch production of the NVX-CoV2373 protein antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order includes technology transfer from Novavax to the Company. In addition, it includes: qualification of analytical methods after the transfer, including implementation of the transferred methods and documentation related to the manufacturing process into the Company's quality system, production of one technical batch and one test batch, being a confirmation of repeatability in batch production, of the product in the Company's plant. The Company estimates that no significant expenditure is required to complete the first order. The production of the technical batch will be funded by the non-refundable consideration the Company will receive from Novavax in connection with the first order.

It is the intention of the parties to the Framework Agreement that, if the manufacturing collaboration continues, the Company's facility may be integrated into the Novavax manufacturing chain for the commercial production of the active substance of the vaccine for Novavax. This will require additional agreements on technical, financial, quality and timing issues.

The Framework Agreement does not specify minimum order quantities, but defines the scope of work established under the first order. At the same time, Novavax retains the right to terminate the Framework Agreement in whole or in part, at any time without giving a reason. Moreover, pursuant to the Framework Agreement, the Company's undertaking of potential cooperation with other entities in the area of COVID-19 vaccine manufacturing will require prior approval from Novavax.

Based on the Framework Agreement, at this stage it is too early to determine the target scale of the cooperation initiated with Novavax and the target scope of work that will ultimately be performed, and thus to estimate the impact of the cooperation with Novavax on the Company's financial results. Such an estimate will be possible once the partners have agreed on the terms of the commercial agreement. In the opinion of the Management Board, the Company has the right team, production experience, knowledge and technology together with the production line to carry out the work commissioned by Novavax. Based on the conditions set out in the Framework Agreement, in the opinion of the Management Board the work performed by the Company will have a moderately positive impact on the Company's results as well as support the implementation of the Company's strategic plans.

Novavax is a biotechnology company focused on delivering new products that use its proprietary, innovative, patented recombinant nanoparticle vaccine technology to prevent a wide range of infectious diseases.

On 25 March 2021, the Company received the first payment from Novavax, Inc. as part of the fulfilment of the aforementioned order placed under the framework agreement.

The Company informed about the events in Current Reports no. 15/2021 of 3 March 2021 and no. 30/2021 of 25 March 2021.

Conclusion of an agreement with Polski Fundusz Rozwoju S.A.

On 3 March 2021, the Company entered into an agreement with Polski Fundusz Rozwoju S.A. ("PFR") regarding the entry conditions for PFR's investment of up to PLN 40,000 thousand ("PFR's Investment" and "Agreement") for the purpose of increasing the Company's production capacity, in particular for the Company's potential broader cooperation with Novavax, Inc. regarding serial production of the vaccine for COVID-19, which is currently pending registration with the European Medicines Agency. More information on signing a framework agreement with Novavax, under which the Company, with the participation of Novavax, will undertake activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate under the working name of NVX-CoV2373 and conduct technical trial runs of the process on a commercial scale at the Company's facility, are presented above in this section.

The parties' intention is to implement the PFR Investment in the form of (i) an interest-bearing three-year loan (or bond issue) granted to the Company up to the amount of PLN 30,000 thousand ("Debt Investment") and (ii) subscription for the Company's shares up to the amount of PLN 10,000 thousand under the issue of U series shares made pursuant to the resolution of the Extraordinary General Meeting of the Company dated 23 February 2021 ("Equity Investment"). The Equity Investment has been completed in line with the intention of the parties. The Debt Investment in turn, pursuant to the Agreement, is conditional upon the Company's execution of a manufacturing agreement with Novavax, Inc. providing for certain net revenues to the Company from the performance of the agreement and, in addition, the Debt Investment will be implemented if the conditions precedent are met including, among other things, the raising of additional financing from the issuance of the Company's U shares (the condition was met in March 2021), the preparation and agreement by the parties as to the terms of the transaction documentation and the establishment or filing of applications for the establishment of potential collateral. The Company has stipulated that the agreement is non-binding in nature, does not create obligations for any of the parties thereto and that the PFR's Investment is conditional and requires the negotiation and execution of appropriate transaction documentation.

The Company informed about the event in Current Report no. 16/2021 of 3 March 2021.

Mabion signs an annex to the cooperation agreement with Mylan Ireland Ltd.

On 29 April 2021, the Company signed an annex ("Annex") to the cooperation agreement ("Agreement", "Development and Commercialization Agreement"), of which the Company informed in Current Report no. 31/2016 of 8 November 2016. Under the Annex, the parties decided to continue cooperation, but the territorial scope of the agreement will change. Mylan will remain Company's non-exclusive distribution partner for MabionCD20 in selected countries in regions such as, in particular, Australia, Nowa Zelandia, Meksyk, Ameryka Środkowa, południowa Afryka, południowo-wschodnia Azja. At the same time, it was decided that Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries, as well as Mylan's priority right to enter into a commercialization agreement for MabionCD20 in the United States (USA), shall expire. The change in the scope of cooperation with Mylan will enable the Company to acquire a new partner or partners interested in commercializing MabionCD20 on the European and American markets and to establish cooperation taking into account the potential of MabionCD20 and the current market conditions. Importantly, the Annex in force does not affect the activities currently carried out by the Company in order to obtain the marketing authorisation for MabionCD20 from the European Medicines Agency, or their schedule. At the same time, the parties have agreed that the Company will reimburse to Mylan part of the advances, in an amount lower than the advance payments received by the Company under the Agreement before the date of the Annex, constituting repayable advances for distribution rights, which is tantamount to the final settlement of all payments made so far between the Parties. Owing to the Annex, the Company has obtained the necessary flexibility in the commercialization of MabionCD20 in its key markets in Europe and in the United States (USA).

The Company informed about the above event in Current Report no. 35/2021 of 29 April 2021.

2.8.3 Other events

On 15 June 2020, the Ordinary General Meeting of the Company (OGM) adopted Resolution No. 28/VI/2020 on increasing the Company's share capital by not less than PLN 0.10 and not more than PLN 190,728.10 up to not less than PLN 1,373,027.30 and not more than PLN 1,563,755.30 through the issue of not less than 1 but not more than 1,907,281 U series ordinary bearer shares with a par value of PLN 0.10 each. The decision to proceed with the aforementioned issue was taken by the Management Board of the Company on 18 May 2020. The Supervisory Board of the Company adopted a positive opinion on the above decision. The purpose of the issue was to raise additional financing for the Company's working capital and, in particular, to accelerate the ongoing development of MabionCD20 and to achieve the assumed milestones aimed at submitting the marketing authorisation application for MabionCD20 to the EMA as soon as possible. The issue of U shares was to be effected in the form of a private placement, within the meaning of Art. 431.2.1 of the Commercial Companies Code, conducted by way of a public offering which is exempt from the requirement to publish a prospectus, within the meaning of applicable laws, or another information or offering document for the purposes of such an offering, and in particular the selection of investors to whom the offers to acquire the shares were to be made with account taken of the book-building process or another process aimed at attracting possible buyers of the shares. Pursuant to the resolution of the OGM, share subscription agreements could be concluded no later than 6 months as of the date of the resolution, i.e. no later than 15 December 2020. Due to the expiry of the deadline specified in Resolution No. 38/VI/2020, the planned issue did not take place.

As a result of the above, resolution of the OGM nr 29/VI/2020 of 15 June 2020 on the conditional increase of the share capital by issuing D series registered subscription warrants fully allocated to the European Investment Bank (EIB), in order to comply with the agreements concluded with the EIB in 2019 (financing agreement and warrant agreement) and issuing V series ordinary bearer shares, did not enter into force.

The Company informed about the above events in Current Reports no. 21/2020 of 18 May 2020 and no. 23/2020 of 15 June 2020.

On 31 March 2021, the Company has received a lawsuit filed by Altiora d.o.o., based in Zagreb ("Altiora"). As set out in the statement of claim, Altiora seeks an award against the Company of the amount of EUR 359 thousand in respect of the remuneration charged by Altiora in connection with one of the agreements between the parties concerning the performance of clinical trials ("Master Service Agreement" of 18 July 2013, hereinafter "Agreement") which, according to the statement of claim and the opinion of Altiora, is still in force.

In the opinion of the Company, the disputed value is not significant and, moreover the agreement is not strategically important to the Company as there are other CRO companies that can provide such services. Possible litigation costs have been appropriately recognised in the financial statements of the Company drawn up as at 31 December 2020, therefore the litigation is not expected to have a negative financial impact on the Company.

The Company contests the claim both in principle and in amount. The Company is of the opinion that the action filed against it is groundless and the claims submitted therein have no legal or factual basis. The Company intends to file a response to the lawsuit, in which it shall present claims and evidence together with allegations proving that the lawsuit is groundless. The Company also intends to take its own claims held against Altiora for compensation for damages caused by the improper performance of the Agreement to court

2.8.4 Atypical factors and events

In the opinion of the Company, in the financial year 2020 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 8. Selected financial data of Mabion S.A.

	in PLN thousand		in EUR thousand	
Selected financial data	**2020**	**2019**	**2020**	**2019**
Net income from sales	0	0	0	0
Operating profit (loss)	-54,653	-63,272	-12,215	-14,708
Profit (loss) before tax	-55,772	-63,738	-12,465	-14,817
Net profit (loss)	-55,772	-63,738	-12,465	-14,817
Net cash flows from operating activities	-35,239	-36,287	-7,876	-8,435
Net cash flows from investing activities	-3,005	-6,613	-672	-1,537
Net cash flows from financing activities	12,669	12,452	2,832	2,895
Total net cash flows	-25,575	-30,448	-5 716	-7,078
	12.31.2020	**31.12.2019**	**12.31.2020**	**31.12.2019**
Total assets	78,321	113,545	16 972	26,663
-/Cash and cash equivalents**	2,395	27,970	519	6,568
Liabilities and provisions for liabilities	155,709	135,125	33,741	31,731
Long-term liabilities	51,138	48,743	11,081	11,446
Current liabilities	104,571	86,382	22,660	20,285
Equity	-77,388	-21,580	-16,770	-5,068
Share capital	1,373	1,373	298	322
Number of shares (in pcs)	13,730,272	13,730,272	13,730,272	13,730,272
Weighted average number of shares (in pcs)	13,721,917	13,721,917	13,721,917	13,721,917
Net profit (loss) per ordinary share	-4. 06	-4.64	-0.91	-1.08
Book value per share	5.71*	8.27*	1.24	1.94
Dividend declared or paid per share	0	0	0	0

* *Total assets/Weighted average number of shares*
** *Part of 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 2020: PLN 4.6148, 31 December 2019: PLN 4.2585). 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 (2020: 4.4742, 2019: 4.3018).

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 2020 and drawn up for the financial year from 1 January to 31 December 2020:
  - statement of comprehensive income;
  - statement of changes in equity;
  - cash flow statement;

and

  - additional information containing a description of the adopted accounting principles and other explanatory information.

The financial statements cover the annual reporting period from 1 January to 31 December 2020 and the comparative period from 1 January to 31 December 2019.

The financial statements have been drawn up on the historical cost basis except for derivative financial instruments, available-for-sale financial assets which have been 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 (presented in more detail in Note 3 to the financial statements). 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 2020, the Company generated a cumulative loss which resulted in negative equity. On 23 February 2021, the Extraordinary General Meeting of the Company adopted Resolution No. 3/II/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 31 August 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 2020, the same accounting principles (policies) as in the financial statements for the year 2019 were applied. There were no changes in the rules for measuring assets and liabilities and financial result in 2020.

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 2020.

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

In 2020, 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 2020 amounted to PLN 56,413 thousand. Their volume was mostly influenced by the costs of development work, which in 2020 amounted to PLN 35,726 thousand, and the costs of general administration, which amounted to PLN 20,499 thousand. The loss on operating activities for 2020 stood at PLN 54,653 thousand and was by PLN 8,619 thousand lower than in 2019. The Company's net loss during the 12 months of 2020 amounted to PLN 55,772 thousand.

The Company's balance-sheet total at the end of December 2020 amounted to PLN 78,321 thousand and decreased by PLN 35,224 thousand in relation to the end of December 2019. At the end of 2020, a significant share in the total assets, i.e. PLN 66,546 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 2020 amounted to PLN 2,395 thousand and came from funds obtained under borrowings, grants, and VAT refund.

In turn, on the equity and liabilities side of the Company at the end of 2020, there is a clear decrease in the value of equity, by PLN 55,808 thousand in relation to the end of December 2019, 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 regards short-term liabilities, there is a visible increase in liabilities from shareholder borrowings (Twiti Investments Ltd. and Glatton Sp. z o.o.) – the Company entered into borrowing agreements to refinance the revolving credit facility granted to the Company in 2018 by Santander Bank Polska S.A. and in connection with the implementation of the Company's shareholders' declaration of 16 March 2020 regarding the recapitalisation of Mabion S.A. 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 under an agreement with other possible distribution 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 2020 and 2019, the Company did not carry out 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 2020 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 2020, Mabion S.A. did not recognised any sales income related to products from core operations.

3.6 Issues of securities

Mabion S.A. has an 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. As part of the Incentive Scheme, the Company issues periodically S series shares 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.

As part of the Incentive Scheme, on 29 January 2020, an issue took place, i.e. pursuant to Article 451 § 2 of the Commercial Companies Code, 9,500 S series ordinary bearer shares with a nominal value of PLN 0.10 each, issued by the Company on 18 November 2019, were recorded in the securities accounts of the eligible persons in connection with the exercise by the eligible persons of their rights under the B series subscription warrants granted to those persons as part of the Incentive Scheme for 2018.

Then, as part of the Incentive Scheme, on 23 June 2020, the Company issued 500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2019. 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 on 23 June 2020. The S series shares (500 pcs) 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 released on 18 February 2021 (event after the balance-sheet date). A total of 500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were released.

On 23 February 2021 (an event after the balance-sheet date), the Extraordinary General Meeting of the Company adopted resolution on increasing the Company's share capital by not less than PLN 0.10 and not more than PLN 243,055.40 up to not less than PLN 1,373,077.30 and not more than PLN 1,616,132.60 through the issue of not less than 1 but not more than 2,430,554 ordinary bearer shares with a par value of PLN 0.10 each. Then, as a result of the accelerated book-building process carried out as part of the offering of new issue shares by way of private subscription within the meaning of Article 431 § 2.1 of the Commercial Companies Code, on 15 March 2021 agreements were concluded for the taking up of all 2,430,554 U series ordinary bearer shares of the Company at the issue price of PLN 55 per share. The Company's share capital increase through the issue of U Series Shares was registered with the National Court Register on 2 April 2021. For further information on the issue of U shares, please refer to section 2.8.2. Significant events and factors after the end of the financial year [of this report].

3.7 Financial instruments used

In 2020, 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 2020, 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 planned 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.

As the level of the Company's equity at 31 December 2019, as well as at 31 March 2020, showed a loss in excess of the sum of the supplementary capital and reserves and one-third of the share capital, at the Ordinary General Meeting of Mabion S.A. convened for 15 June 2020, Resolution no. 18/VI/2020 was adopted on the continued existence of the Company pursuant to Article 397 of the Commercial Companies Code. As at 30 June 2020 and 30 September 2020, the Company also reported a loss in excess of the sum of the supplementary capital and reserves and one-third of the share capital and at the Extraordinary General Meeting of Mabion S.A. convened for 23 February 2021, Resolution no. 3/II/2021 was adopted on the continued existence of the Company pursuant to Article 397 of the Commercial Companies Code.The Company's key distribution partner is Mylan (Viatris Group), 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, 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 in Europe with the European Medicines Agency ("EMA") using small batch production. On 29 April 2021, the Company signed an annex to the cooperation agreement with Mylan, under which the parties decided that the Company will reimburse to Mylan part of the advances, in an amount lower than the advance payments received by the Company under the agreement in force before the date of the Annex, constituting repayable advances for distribution rights stated in Note 19 to the financial statements.

On 24 October 2019, the Company entered an agreement with the European Investment Bank ("EIB") for a loan amounting in total to EUR 30,000 thousand 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, with the release of tranche A 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 amount of the loan is EUR 30 million and 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.

On 15 July 2020, the Company entered into a borrowing agreement with Glatton Sp. z o.o. in the amount of PLN 15,000 thousand to refinance the revolving credit facility granted to the Company in 2018 by Santander Bank Polska S.A. The funds received were used to repay the entire debt under the aforementioned loan on 17 July 2020. The borrowing constitutes additional financing obtained from a shareholder and is not part of the financing previously declared by the major shareholders of the Company.

On 12 August 2020, the Company entered into borrowing agreements with Glatton Sp. z o.o. and Twiti Investments Ltd. implementing the support documents received on 16 March 2020 from the major shareholders. As at the date of the financial statements, the Company has utilised the entire amount of PLN 15,000 thousand as part of the limit granted under the borrowing agreements. On 5 February 2021, the Company entered into a subsequent borrowing agreement with Twiti Investments Ltd. for a total amount of up to PLN 10,000 thousand, of which PLN 3,500 thousand has been drawn down as at the date of publication of the financial statements.

On 27 January 2021, the Company's Management Board, on the basis of an in-depth analysis of needs and estimated benefits, adopted a new long-term strategy for financing the Company's activities. The strategy adopoted covers the Company's overall capital needs which has to be fulfilled in order to carry out all activities which, in the opinion of the Company's Management Board, are necessary to complete the registration of MabionCD20 with the EMA and to start selling MabionCD20, allowing the Company to generate operating cash flows. The arrangements for the Company's financing strategy were positively reviewed by the Company's Supervisory Board.

The financial strategy consists of parallel processes: commencement of activities aimed at acquiring a strategic investor and two issues of the Company's shares.

The funds raised from the issue of U series shares and the fact of concluding an agreement with Novavax Inc. enabled the Company to potentially access additional, not yet fully available sources of financing, including potential debt financing from Polski Fundusz Rozwoju S.A. (PLN 30,000 thousand), a granted and unused subsidy from the European Regional Development Fund (approximately PLN 63,000 thousand).

In the hitherto financing strategy, the Company did not take into account the potential operating flows related to the collaboration with Novavax, Inc. which, if a certain scenario is materialised (including the initial stage currently being implemented, i.e., inter alia: effective technology transfer, production of one technical batch and one test batch, followed by another stage of continued collaboration on a commercial basis), may bring additional operating flows to the Company. The Company's current financial position is neither based on nor dependent upon the success of this project.

The Management Board of the Company assumes that the actions described above, depending on their success, should provide the Company with the financing necessary to complete the registration process and commercialisation of MabionCD20 and the tasks related to the cooperation with Novavax.

The final decisions to update the Company's hitherto financial strategy, including whether or not to carry out a further share issue, will be taken after detailed analyses with particular regard to the factors listed above.

The change in the terms of the currently binding debt financing agreements and further leveraging of financing available on the market, including financing available from EU projects and projects supporting research and development, and exclusive agreements with future distribution partners or 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. Following the analysis, no material indications of uncertainty as to the going concern were identified. The Company is actively monitoring the environment for the prospect of obtaining new funding opportunities with which it will be able to cover expenses related to its core R&D and investment activities. In particular, current activities are focused on including support from the National Centre for Research and Development in the planned bridging clinical trial.

In connection with the WHO (World Health Organization) announcement of the COVID-19 coronavirus pandemic worldwide, additional financial risks have been identified in relation to the liquidity disruption in the markets resulting from the spread of the 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 the 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.

The above-mentioned risks in individual areas remain particularly relevant in view of the third wave of the epidemic. To prevent or minimise the above-mentioned risks, the Company's Management Board has continuously monitored and continues to monitor both the global situation and the course of cooperation with counterparties as well as the Company's internal situation, trying to adapt the Company's plans and strategy to the epidemic situation and the risks and their evolution occurring in the areas described above. In the event of significant new circumstances related to SARS-CoV-2 coronavirus pandemic and affecting the operations, the Company will introduce appropriate solutions, also complying with all applicable administrative decisions.

Financial resource management in 2020

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 2020.

As at 31 December 2020, the Company's equity has a negative value of PLN 77,388 thousand, while the general debt due to long-term and short-term liabilities (supplies and services, and borrowings) amounts to PLN 155,709 thousand.

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 future cash flows.

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

» 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;

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

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

may be derived from:

» granted EU assistance funds;

» aid from EU funds;

» loans provided by banks;

» funds obtained under leases;

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

» borrowings from shareholders;

» future share issues.

» joint ventures with industry and business partners

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.

In April 2021, the Management Board received, from Polfarmex S.A. (6 April 2021), Glatton Sp. z o.o. (27 April 2021) and Twiti Investments Ltd. (23 April 2021), the major (founding) shareholders ("Shareholders") of the Company, support documents pursuant to which the Shareholders declared their financial support for the Company for a period of at least 13 months from the date of the support document.

In the Company's opinion, the declaration of the major shareholders regarding the recapitalisation confirms and provides important support in terms of the possibility to implement the adopted registration strategy for the key project. At the same time, in accordance with the long-term financing strategy for the Company's activities as adopted on 27 January 2021, the Company is taking steps to attract a strategic investor and also does not exclude conducting a prospectus-based share offering within the meaning of the relevant legislation. The Company's Management Board assumes that these actions, depending on their success, will provide the Company with the financing necessary to complete the registration process and commercialisation of MabionCD20.

The risk related to limited access to funding due to the global liquidity situation or the Company's financial position and the assessment of the potential for registration of the key drug MabionCD20 cannot be excluded. One should indicate here the risk related to the impossibility of changing the terms of the existing loan agreements, including with regard to the possibility of releasing individual financing tranches. In particular, the current situation resulting from the pandemic and its impact on capital markets should be borne in mind, as this may cause significant restrictions on sources of funding, including equity funding.

3.11 Dividend policy

In the financial year 2020, the Company did not pay out 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.

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 for 2010–2020 (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 medicines which are 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.

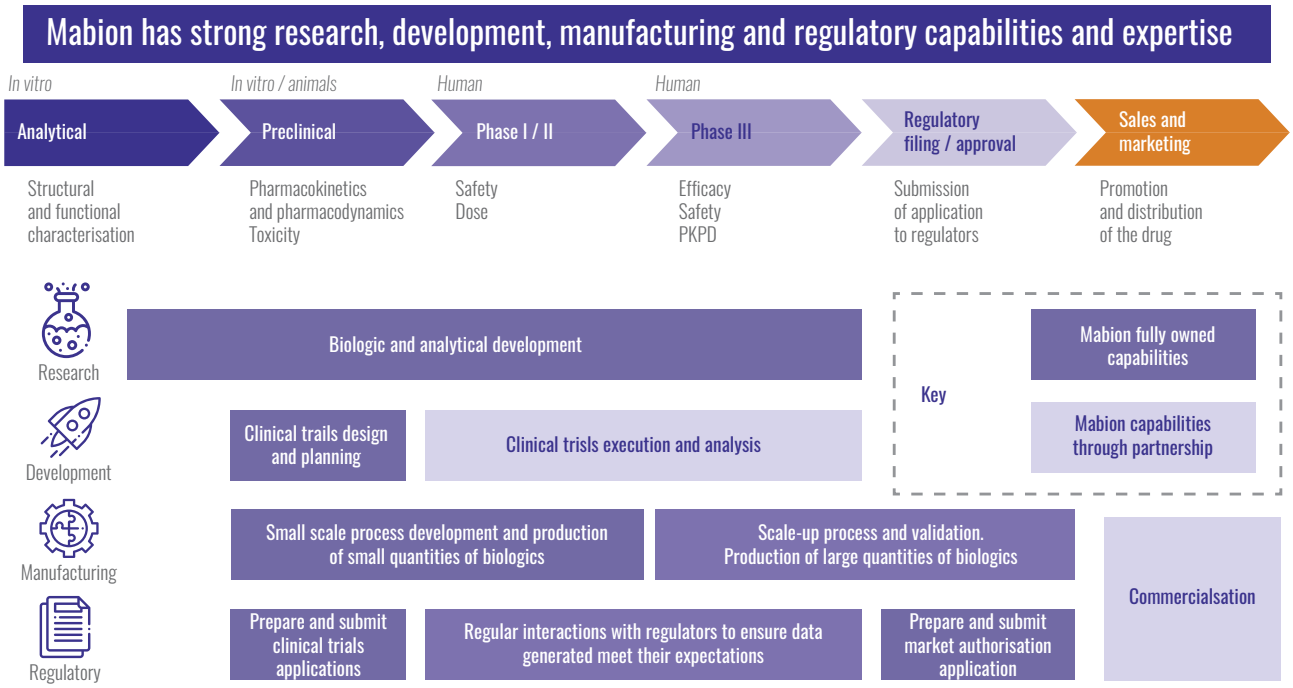
The technology of manufacturing therapeutic monoclonal antibodies is a relatively new area of medical biotechnology explored by the largest global pharmaceutical concerns, an area which has been dynamically developing over the last 20 years. The process of manufacturing therapeutic preparations – one of the most eminent achievements of modern biotechnology, enables the manufacture of targeted medicines which selectively interfere with cancer cells, ensuring higher 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 neoplastic 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.

In cooperation with a prospective strategic investor, and aided by external consultants, the Company intends to go through the registration process of a therapeutic monoclonal antibody according to the centralized procedure within the whole EU area, where the system for the registration of biosimilars is well regulated. The Company also has an important goal of introducing the medicine to the American market.

The work carried out to date on the MabionCD20 project has enabled the Company to acquire competencies unique on the Polish market in the development, clinical and regulatory development, and production of highly specialised protein drugs. This enables the Company to diversify its business by offering services under the CDMO (Contract Development and Manufacturing Organization) model. Using its competences, the Company becomes a natural partner for other entities at all stages of the process of development and production of biological medicines. The Company's detailed competences in this field are summarised below.

Table 9. Key competences of Mabion S.A.



4.2 Implementation of the development strategy

The Mabion'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) in the fields of oncology, autoimmunity, neurology and metabolic diseases.

The Company analyses on an annual basis the development plan for medicinal products and modifies it according to needs, 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.

In 2019, following a review and update of the medicines development strategy,, 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 classified scientific and research projects in three groups of projects, i.e. active projects, new projects which were to be launched in 2019, and partner projects. In 2020, the adopted development strategy was maintained.

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 2020:

» Reference drug Prolia[9] and Xgeva[10] (based on denosumab) – work on the construction of a biosimilar antibody coding vector and the creation of a reference material bank continued.

» Reference drug Xolair[11] (based on the omalizumab antibody) – work continued on establishing a reference material bank.

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, or rare diseases.

As part of the partnership projects, the Company has undertaken the following activities:

» Signing a letter of intent with IcanoMAB GmbH regarding potential collaboration to conduct CMC (Chemistry, Manufacturing and Controls) type development and manufacturing of a human IL-1R7 mAb antibody under development by IcanoMAB as a potential drug to treat patients with COVID-19 infection (October 2020),

» signing of a Memorandum of Understanding with Taxon Therapeutics Ltd. regarding cooperation in the research, development, and commercialisation of MabionCD20 antibody drug in specific clinical indications in the area of rare diseases (October 2020);

» entering into a framework agreement together with the first order for contractual services with Novavax, Inc. under which the Company, with Novavax's participation, will undertake activities related to the transfer of the manufacturing process technology and antigen analytics of the vaccine candidate for COVID-19 under the working name of NVX-CoV2373 and will carry out technical trial runs of the process on a commercial scale at the Company's facility (March 2021).

Detailed information on the above projects can be found further on in this report.

[9] Reference drug Prolia – main indication: osteoporosis in postmenopausal women at high risk of fractures, 2019 sales value close to USD 2.7 billion (based on Amgen, Letter to Shareholders 2019, up 17% on 2018). Prolia goes off the cliff in Europe in 2022 (except in France, Italy, Spain and the UK where the patent expires in 2025), and in the US – in 2025. Several entities are currently working on a biosimilar version of this drug.

[10] Reference drug Xgeva – indication: prevention of bone complications (pathological fractures, need for bone irradiation, spinal cord compression or need for bone surgery) in adults with bone metastases of solid tumours. Sales in 2019 are worth over USD 1.9 billion (based on Amgen, Letter to Shareholders 2019, up 8% on 2018). Xgeva goes off the cliff in Europe in 2022 (except in France, Italy, Spain and the UK where the patent expires in 2025), and in the US – in 2025. Several entities are currently working on a biosimilar version of the drug.

[11] Reference drug Xolair - indications: asthma, chronic idiopathic urticaria - 2019 sales value amounted approximately to USD 3.1 billion (based on data from Roche and Novartis annual reports). The patent protection expired in 2017. Several entities are currently working on a biosimilar version of the drug - including Celltrion and Biosana Pharma.

Table 10. Mabion S.A. product strategy – a summary.

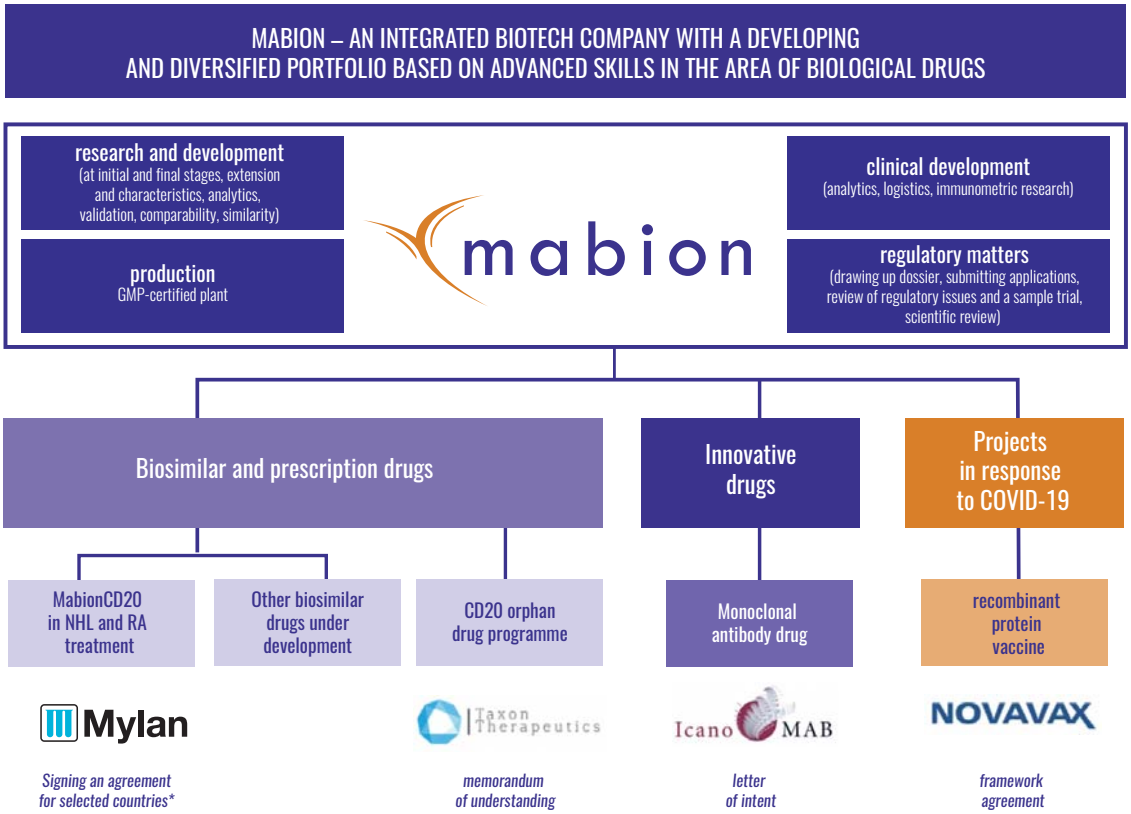


Table 11: R&D portfolio of Mabion S.A.

Diversified Mabion's R&D portfolio with a wide range of assets to be commercialized						
Mabion's role	molecule/drug	clinical indication	characteristics	status	commercialisation approach	partner
integrated developer and asset manufacturer	rituximab (MabionCD20)	oncology (NHL) and autoimmunology (RA)	biosimilar drug in approved therapies	at the registration stage in the EU and at the phase I clinical trial stage in the USA	active business development in the EU and US partnered for selected countries*	asset ready to partner in the EU and US Mylan
strategic co-manufacturer	rituximab (MabionCD20)	rare diseases (autoimmunology)	innovative therapy	product ready for the clinical stage	active business development	Taxon Therapeutics
strategic co-manufacturer / CMDO	vaccine	COVID-19	innovative therapy	framework agreement and first order for contracted services signed	memorandum of understanding	NOVAVAX
integrated developer and asset manufacturer	rituximab (MabionMS)	CNS disease (multiple sclerosis)	innovative therapy	product ready for the pre-clinical and clinical stage	partnering	partnering-capable asset
integrated developer and asset manufacturer	rituximab (MabionEGFR)	oncology (colorectal carcinoma, squamous cell carcinoma of the head and neck area)	biosimilar drug in approved therapies	cell line optimisation	active business development	partnering-capable asset
integrated developer and asset manufacturer	denosumab, omalizumab	autoimmunological diseases, metabolic diseases and oncology	biosimilar drug in approved therapies	active development of relevant cell lines	pre-commercial stage	possible partners identified
strategic co-manufacturer	mAb	TBA	innovative therapy	in negotiation	pre-commercial stage	Icano MAB

** incl. Australia, New Zealand, Mexico, Central America, South Africa, Southeast Asia*

MabionCD20 project

The Company's priority and most advanced project is MabionCD20, a proposed biosimilar to the reference drug MabThera/Rituxan (rituximab) (Roche). In 2018, the Company published the results of a clinical trial that confirmed the efficacy and safety of the therapy. The Company is preparing to submit a marketing authorisation application for MabionCD20 to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

With regard to the registration procedure at the European Medicines Agency, initiated in 2018 (the primary application submitted by the Company in June 2018 and in May 2019 (the second application, so-called duplicate application aimed at obtaining an additional trade name for which the list of indications for the product would be limited and would not include rheumatoid arthritis), in early 2020 the assessment of the marketing authorisation applications (MAA) continued. In January 2020, the Company submitted responses to the EMA's list of questions received in December 2019, following which, in February 2020, the Company received from the EMA a list of outstanding issues for presentation at the Committee for Medicinal Products for Human Use (CHMP) meeting held on 24-27 February 2020. On 26 February 2020, the Company's Management Board, together with a team of experts, participated in the CHMP meeting, answering the questions included by the EMA in the invitation (oral explanation).

Subsequently, on 16 March 2020, on the basis of the opinion of external consultants and the recommendation of the Supervisory Board, the Company's Management Board decided to change the strategy for the submission of the application for MabionCD20 for the European market. The main change is to seek marketing authorisation for a drug manufactured on a target, commercial scale (5000L), which will be submitted to the EMA in the future. Before the change, a two-step strategy was followed, involving first obtaining marketing authorisation for a product manufactured at clinical scale (500L) and then, on the basis of a subsequent application, obtaining marketing authorisation for a product manufactured at the target, i.e. commercial scale (5000L). The change in regulatory strategy has resulted in the withdrawal of registration applications for the clinical scale product (500L). The applications were withdrawn on 16 March 2020.

In H1 2020, the Company consulted with EMA representatives under the Scientific Advice procedure regarding the scope of data required for the future registration application. The aim was to align them with the Agency's expectations and to streamline the registration procedure for a data-based application for a large-scale product. In April 2020, the Company filed a Briefing Package with the EMA and in July 2020, the Company received a written response to the specific assumptions regarding the new registration process, in particular the scope of data to be included in the new application, as well as the actions required to generate the above data, as proposed by the Company.

In July 2020, following internal analysis, consultation with external experts and the Company's Supervisory Board, a preliminary framework was adopted on the scope and timing of the work required for the new registration application. The new registration application, in which the target (commercial) manufacturing scale of MabionCD20 will be the subject of EMA evaluation, will be submitted after completion of process validation and acquisition of analytical similarity data for the reference drug and comparability data for the process on the scale of 500L at which the drug was tested in previous clinical trials. Apart from generating a package of analytical data, it is the Company's intention to conduct, for the purposes of the registration dossier, also a smaller-scale bridging clinical trial, which, in the Company's opinion, is required to demonstrate comparability and, at the same time, will allow to reduce the regulatory risks and thus reduce the cost and duration of the preparation stage for the registration process. The Company has developed a draft protocol for the bridging trial (3-arm clinical trial) using MabionCD20 versus MabThera (the European reference product) and Rituxan (the US reference product).

With regard to the analytical data package, validation of the commercial-scale (5000L) MabionCD20 manufacturing process was completed in June 2020, based on three validation batches. Preliminary analytical testing demonstrates that the batches produced meet the assumptions for all quality attributes analysed at the DS (drug substance) level. In addition, the Company has launched product stability tests, and has planned tests for analytical similarity to the reference drug and comparability to MabionCD20 originating from the clinical scale (500L). In order to extend the analytical data presented in the registration application, in November this year, the Company conducted a Media Fill[12] test and also started to produce a post-validation

[12] The Media Fill test is carried out regularly to validate the process of aseptic filling of the product into glass vials of 10 ml and 50 ml. The process simulates sterile product filling using a fertile culture medium.

batch of MabionCD20 so that the application could be based on data from more than 3 batches of the product manufactured on a large scale. In the Company's view, providing a broad package of analytical data will significantly mitigate regulatory risk. Already at this stage, the existing large-scale analytical data indicate a reproducible quality and high degree of biosimilarity, both to the reference products and to the product previously used for clinical trials. In the Company's opinion, this similarity is a significant step that allows the Company to waive, for the purposes of registration with the EMA, additional, clinical trials beyond the trial that the Company plans to conduct in the rheumatoid arthritis patient population, based on a product originating from a commercial manufacturing scale.

With respect to the bridging trial in rheumatoid arthritis, in addition to the development of the trial protocol, the Company has undertaken a number of activities to develop the internal quality system required for the initiation of the clinical trial, including a number of procedures to allow for adequate control of the clinical trial, conducting a risk analysis taking into account both the potential risks specific to research in immunological diseases, observations from previous clinical work, as well as the current situation related to the coronavirus pandemic. The documents necessary for the launch of clinical trials were also drawn up, including the IMPD (Investigational Medicinal Product Dossier) and the IB (Investigator's Brochure). An important stage of the work was also the tender procedure and the work related to the selection of a CRO company Clinical Research Organization), to co-lead the clinical trial, which resulted in a contract with one of the most experienced CROs on the market, Parexel. In parallel, advanced work has been carried out leading to the development of a logistical plan for the clinical trial, work on the feasibility study of the clinical trial at selected clinical sites is being finalised, and a tender procedure has been conducted and suppliers of reference drugs (namely MabThera and Rituxan) for the trial have been contracted. Also, quality audits and qualification of the two selected suppliers were carried out.

In March 2021, the Company received recommendations from the EMA on the details of the RA clinical trial and began to implement these in the clinical trial protocol.

In July 2020, the Company also successfully completed a routine inspection of the GLP (Good Laboratory Practice) quality system of the Mabion's facility at 17 Fabryczna St. in Łódź, where analyses of pharmacokinetics, pharmacodynamics, and immunogenicity characteristics of the clinical trial will be conducted. The analytical procedures developed at the GLP-certified facility will ensure the Company's independence from external entities in terms of characterisation of the key endpoints of the bridging trial.

The Company's objective is to respond quickly and decisively to any needs arising from the registration process in order to mitigate regulatory risk while keeping the cost of the process at a level that can be financed by the Company and to carry out the product registration procedure as fast as possible. In the opinion of the Company's Management Board, the change in the regulatory strategy was 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 above assumptions may be subject to change in the future, in particular due to the fact that they are based on a number of factors that may affect the timeframe, including factors beyond the Company's control such as the speed of clinical trial recruitment. Moreover, the assumptions made and actions performed do not guarantee the registration of the product with the EMA.

With respect to the activities carried out to authorise the drug under the working name of MabionCD20 for marketing in the United States, according to the summary of the BPD (Biosimilar Biological Product Development) Type 2 meeting with the US Food and Drug Administration (FDA) held in June 2018, the FDA has allowed for the use of data possessed by the Company to support 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 recognised that with respect to the studies already performed in Europe based on the reference drug MabThera, which the Company will seek to use in the application process at the FDA, there is a need to perform a clinical bridging trial. The bridging trial should be three-armed and include the reference products - US Rituxan, European MabThera and MabionCD20 manufactured as part of a commercial, large-scale manufacturing process. A three-arm analytical research will also need to be performed. In this way, the bridging trial data obtained will be available for the Company to use in the application process, in package with other data obtained separately for the US market. The details of the strategy to build a 'clinical data bridge' are under continuous discussion with the Agency.

In January 2020, the Company held a BPD Type 3 meeting with the FDA to seek confirmation of the regulatory strategy. During the meeting, there was a productive discussion on the data needed to include in the registration application in the US for all indications of the reference medicine. In February 2020, the Company received, from the FDA, a summary of the meeting and thoroughly analysed the document and the conclusions and guidelines contained therein, and evaluated their impact on the actions planned by the Company so far to register and admit the drug to trading in the USA. As interpreted by the Company, the FDA confirmed the possibility of filing an application for MabionCD20 and the validity of the presented approach.

Then, as part of continued discussions regarding the application programme, the Company prepared and sent to the FDA both a set of additional questions clarifying the clinical parameters to be tested and detailed comparative analyses of MabionCD20 with reference drug Rituxan. In addition, the Company has requested a further (BDP Type 2) meeting with the regulator, which was held remotely in August 2020. According to FDA guidelines, Type 2 BDP meetings address specific issues for which the FDA provides directional recommendations, while Type 3 BDP meetings involve a comprehensive, in-depth analysis of a package of complex data. The Type 2 BDP meeting in August 2020 was aimed at clarifying the details of the clinical development of MabionCD20 for the US market. In line with the summary of the meeting, the Company has received confirmation from the Agency of a number of clinical programme parameters proposed by the Company, including the possibility of using a significant portion of the data already generated to authorise MabionCD20 in the EU, as well as data from a planned bridging trial in RA patients for a commercially manufactured drug. This confirms the earlier consultation in which the Agency suggested that there was no need for a completely separate development programme to authorise MabionCD20 in the US. However, the Company stipulates that the data obtained from the bridging clinical trial for the registration application with the EMA will be of supportive nature for the application process before the FDA, which means that the data does not exhaust all of the Agency's expectations for the full range of data. The detailed scope is still being discussed with the Agency.

In addition, the Company has started to review, with the Agency, the feasibility of a novel regulatory strategy to allow for an earlier initial application for registration than originally anticipated and proposed by the Agency, only for the indication of rheumatoid arthritis. The Company accepted the Agency's suggestion to clarify the details of such an approach at the next meeting (scheduled for 15 April 2021) and has started the process of further consultation of the strategy with the Agency. The current arrangements are non-binding on the Agency.

The US registration and marketing authorisation process for MabionCD20 is a complex process and it cannot be excluded that additional FDA approval requirements may arise in the future based on continuous communication with the Agency and review of documentation.

With respect to the ongoing activities aimed at the registration and marketing authorisation of MabionCD20, the Company emphasises that in order to commence the clinical bridging trial necessary for the authorisation of MabionCD20 in the EU in the first instance, the Company, based on the trial protocol, must obtain approvals from the relevant authorities and bioethics committees. At the same time, the Company must ensure that sufficient funds are allocated, which is a prerequisite for the commencement of the trial and thus determines its timing. Funds for the implementation of the above may come from a partner, European Union funds, or other sources. Apart from the European market, the Company is also interested in commercializing the drug in other markets, including the USA.

To sum up, in the research and development work on MabionCD20, the following activities were successfully carried out in 2020 and until the date of publication of this report:

» a preliminary 5000L characterisation study of the active substance was performed for 4 batches (technical batch and 3 validation batches), confirming its equivalence to the active substance obtained at the 500L scale (MabionCD20 5000L vs. MabionCD20 500L); the similarity of MabionCD20 to the reference drug was also confirmed (MabionCD20 vs. MabThera);

» production of MabionCD20 in four batches was completed (sterile filling of the technical batch and three validation batches for direct packagings of two sizes was carried out: 10 ml and 50 ml);

- production of a post-validation 5000L batch of MabionCD20 has commenced;
- a continuous process of stability testing for MabionCD20 on a scale of 500L was conducted;
- stability study of the active substance and the finished product obtained from 3 validation batches on a 5000L scale was commenced;
- optimisation of analytical methods was started with the aim of expanding the set of analyses performed in-house as part of analytical similarity studies with the reference drug and comparability studies of MabionCD20 obtained at the 5000L and 500L scales;
- analytical similarity study plans have been developed for the European reference drug (MabThera) and the US reference drug (Rituxan) and the comparability of MabionCD20 obtained at the 5000L scale against the 500L scale product;
- re-validation of the aseptic filling process was carried out on an automatic filling line using the Media Fill test for mixed fillings (10 ml and 50 ml);
- physicochemical, biological and microbiological analyses of one technical batch and three validation batches were conducted according to the developed MabionCD20 manufacturing process control strategy;
- optimisation of the analytical methods has been performed and, in the case of the pharmacodynamics characterisation method, it will need to be validated on samples from clinical trial patients with the selected disease entity, while in the case of the pharmacokinetics and immunogenicity characterisation methods, the validation process will take place entirely on material from clinical trial patients;
- new operational GCP procedures were developed for the launch and conduct of the clinical trial, CRO oversight and safety monitoring during ongoing trials;
- work on the feasibility study of the clinical trial has started at selected clinical sites, in accordance with the agreement signed with the CRO – Parexel;
- in April 2020, the Company submitted an enquiry file ("Briefing Package") as part of the EMA's Scientific Advice, to which it received a response in July 2020; the answers confirmed the Company's proposed scope of trials necessary for the registration of MabionCD20 manufactured on a 5000L scale with the EMA;
- in September 2020, the Company held consultations (under the national Scientific Advice procedure) with the German Paul-Ehrlich-Institut (PEI) to clarify the details of the study for the registration of the 5000L-scale produced MabionCD20 with the EMA; Following these arrangements, it was decided, inter alia, to change the assumptions of one of the analytical methods. Upon receiving the first results of this method, the Company is planning another analytical Scientific Advice with the EMA to confirm the Company's new assumptions for the method and its potential for use in biosimilarity and bioequivalence tests.
- in January 2020, the Company participated in a meeting with the FDA and then in May 2020, it sent a set of further questions to the FDA clarifying the clinical parameters, as well as detailed comparative analyses; The Company has proposed additional bridging trial options due to restrictions caused by the SARS-CoV-2 coronavirus pandemic. A Type 2 BDP meeting with the FDA was held on 11 August 2020.
- the clinical trial protocol was updated in line with the EMA's comments contained in the Scientific Advice documentation and in line with suggestions from meetings with the FDA;
- in December 2020, enquiries were sent to the EMA and FDA regarding details of the planned clinical trial in RA. In March 2021, the Company received recommendations from the regulator on the details of the RA clinical trial and began to implement these in the clinical trial protocol.

MabionMS

With regard to the MabionMS (multiple sclerosis, MS) innovative therapy project, the Company has so far submitted 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 applied 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 for the extension of patent protection under the PCT procedure for the above-mentioned invention, and in March 2019 it withdrew the original European application in order to benefit from the protection afforded by the international application (which also covers the European territory) and to avoid a potentially dangerous situation in which the patent office could bring an accusation of attempting to double patent the same scope of protection.

In July 2020, the Company filed international patent applications for the above invention with selected patent offices, initiating a national and regional phase to obtain patent protection in dozens of countries. Based on statistics on multiple sclerosis in specific regions, as well as on the potential of specific markets, Mabion has filed patent applications with selected patent offices covering countries such as: USA, Canada, UK, EU and EFTA countries, Australia, New Zealand, Israel, Turkey, Russia and several others. The commencement of the national and regional patent application phase in each country is the next step to obtaining legal protection for this innovative therapy.

Irrespectively of the above, 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 multiple sclerosis, called "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.

In 2019, the Company has produced both an outline (synopsis) of the clinical trial protocol 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. In August 2019, the final version of these documents was approved after consultation. This event has started the process of scientific consultations with the EMA in order to confirm the compliance of the project assumptions with the requirements of the Agency. 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

The MabionEGFR project concerns the development of a medicine to treat patients with metastatic colorectal cancer expressing the epithelial growth factor receptor (EGFR), wild-type RAS genes, and patients with squamous cell carcinoma in the head and neck region.

For this 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. In 2020, the Company proceeded as part of the project with activities related to:

» determining the quality target product profile (QTPP) of the reference product for protein quality attributes based on the results of the analysis of the current batch pool of the reference product;

» developing a reference material bank;

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

» preliminary optimisation of cell culture and antibody purification conditions.

At the same time, in June 2020 the Company successfully completed the first stage of a project co-financed by the National Centre for Research and Development (NCBR), entitled "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" At this stage, the milestone associated with obtaining a stable cell line producing a cetuximab biosimilar antibody was anticipated. The company has obtained the cell line and verified its stability. Detailed tests were also carried out on the quality of the obtained protein based on available analytical methods. The results confirmed the achievement of the objective of the project phase.

NVX-CoV2373

On 3 March 2021, Mabion entered into a framework agreement with Novavax, Inc. based in the United States, pursuant to which the Company, with Novavax's participation, will undertake activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate antigen under the working name of NVX-CoV2373 and conduct technical trial runs of the process on a commercial scale at the Company's facility. The framework agreement will be in force until 31 December 2023.

With the conclusion of the framework agreement, the parties agreed on the scope and budget of the work contracted to the Company to carry out the technology transfer and technical batch production of the NVX-CoV2373 protein antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order includes technology transfer from Novavax to the Company. In addition, it includes: qualification of analytical methods after the transfer, together with implementation of the transferred methods and documentation related to the manufacturing process into the Company's quality system, production of one technical batch and one test batch confirming the repeatability in batch production of the product in the facility.

By the date of publication of this report, the Company has carried out the following work on this project:

» a detailed analysis of the documentation provided by Novavax Inc. has been conducted;

» the scope and course of activities necessary for the implementation of technology transfer in the field of manufacturing processes as well as transfer of analytical methods have been developed;

» equipment, materials and reagents required to conduct the above activities at laboratory scale have been procured, and procurement of commercial scale measures is underway;

» laboratory space has been adapted to ensure conditions preventing cross-contamination of cell lines and biological products; adaptation of the manufacturing area premises is underway;

» the scope of the Pharmaceutical Quality System documentation necessary to be prepared or updated has been developed;

» drawing up of internal documentation necessary for proper recording of the transfer of technology and analytical methods has been started;

» a preliminary analysis of the manufacturing process of the active substance NVX-CoV2373 antigen has been carried out to identify possible risks associated with the process using the Company's technological line, and actions have been proposed to minimise these risks;

» a project implementation schedule has been set up based on current information related to task implementation and the supply of materials and reagents;

» the cell banks supplied by Novavax Inc. have been defrosted and laboratory-scale tests have commenced.

Business development: IL-1R7 mAb

On 14 October 2020, the Company signed a letter of intent with IcanoMAB GmbH, based in Germany, regarding a possible collaboration with IcanoMAB in the scope of CMC development work and pharmaceutical GMP (Good Manufacturing Practice) compliant production of the human IL-1R7 mAb antibody being developed by IcanoMAB as a potential drug for patients with COVID-19 infection.

The letter of intent provided the basis for further negotiations between the parties with a view to concluding a final agreement, including the financial terms of cooperation between the parties, whereby entry into force of the agreement and collaboration will occur if and when IcanoMAB secures funding for the development programme in respect of the above antibodies.

As at the date of publication of these statements, despite the expiry of the letter of intent and the failure to secure funding for the programme to date, the parties are continuing discussions regarding the possibility of cooperation in the field of protein products owned by IcanoMAB.

Business development: products based on MabionCD20 antibody

On 21 October 2020, the Company signed a memorandum of understanding with Taxon Therapeutics Ltd. based in Israel regarding the parties' intention to work out the terms of a potential long-term collaboration for the research, development, and then worldwide commercialisation of medicinal products based on a monoclonal antibody recognising the CD20 receptor on human B lymphocytes ("Products") in specific clinical indications in the area of rare diseases.

Taxon Therapeutics is an Israeli biotechnology company focused on the orphan drug segment and rare conditions for which there are currently no registered medicines. Taxon Therapeutics is interested in developing the Products, registering and commercialising them on an exclusive basis worldwide, in one or more indications where reference medicines containing rituximab as their active substance (i.e. antibodies that recognise the CD20 receptor) are not currently registered in any market. To this end, Taxon Therapeutics is prepared to cooperate with the Company and conduct the pre-clinical and clinical trials required to register the Products for the above indications, which will be specified by the parties at a later date.

The memorandum was intentional and non-binding in nature. At the date of publication of these statements, although the term of the memorandum had expired, further discussions and negotiations are taking place on the terms and conditions of cooperation between the Parties. Whether the cooperation is established depends on the positive conclusion of negotiations, including the elaboration of terms and conditions of cooperation satisfactory to the parties, in particular the scope of activities of individual parties and financial conditions, and on the conclusion of a final cooperation agreement.

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 from EU countries.

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 5000L L production line, and

» purchasing and installing production equipment for a second 5000 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 20,000 thousand (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, 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 2020, the Company made investment expenditures of PLN 2,800 thousand.

Extension of the existing facility

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 "Technological and Scientific Centre for Advanced Medical Biotechnology of Mabion S.A." with the necessary infrastructure in Konstantynów Łódzki.

In 2019 and 2020, work was underway to prepare detailed designs for all construction and installation sectors. By December 2019, about 75% of all contracting projects were prepared. Following the contractor's consideration of comments by Mabion, the detailed design was completed and accepted by Mabion in February 2021. 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 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 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.).

On 11 June 2018, the Company signed a co-financing agreement with the Minister of Investment and Development for the project "Expansion of the Research and Development Centre of Mabion S.A. – research on the new generation of medicines" (Measure 2.1 Support for investment in R&D infrastructure of enterprises of the Operational Programme Smart Development 2014–2020 co-financed by the European Regional Development Fund). The objective of the Project is to develop the Company's research and development facilities by preparing the necessary infrastructure: the building of the Research and Development Centre, and the purchase of research equipment to conduct research on innovative medicines. The planned Research and Development Centre will be used to develop and prepare for commercialisation the latest generation of biotechnology drugs: monoclonal antibodies. The total cost of the Project was set at PLN 172,880 thousand, with the co-financing amounting to PLN 63,250 thousand. Currently, the Company is in the process of implementing the project in question, however, due to issues related to the financing of its own contribution, the project work is delayed with respect to the originally assumed schedule (in line with the agreement the project should be completed by 31 December 2021). The Company is in ongoing contact with the Ministry of Development in this regard.

Table 12. Planned expansion of the existing Mabion's plant – visualization.

4.3 Factors important for the development

Standards relating to studies

The research and development work of the Company is conducted within the pharmaceutical 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 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 July 2020, the Research and Development Centre in Łódź successfully underwent another GPL inspection, extending thereby its certificate to include the possibility of performing analyses related to pharmacodynamic characterisation.

The activities related to planning, conducting, documenting and communicating the results of human clinical trials are performed in accordance with the principles of good clinical practice (GCP), i.e. the international ethical and scientific standards developed by the ICH (International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

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 Dirk Kreder, having several years of experience in the development and commercialisation of more than 20 medicines. A graduate of the University of Stuttgart and the University of Kiel, he holds a PhD degree in biotechnology and immunology, as well as a Master of Business Administration degree awarded by the Euro*MBA consortium;

» Eng. D. Sławomir Jaros, EMBA (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);

» 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);

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.

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 and/or the schedules of projects carried out by the Company. 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 (SARS-CoV-2) 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;

» delays in the acceptance and commissioning of the ordered equipment due to limited possibilities for external representatives to calibrate the equipment;

» problems with securing all the resources required for research as a result of the reduction in production and the depletion of stocks of external companies cooperating with the Company;

» the possibility of plant closure in order to limit the possibility of virus spread;

» the possibility of restrictions imposed by national government administrations hindering the launch of a clinical trial or affecting the modalities of its organisation and duration.

» potential impact on the conduct of the clinical trial, e.g. through prolonged recruitment time of patients with rheumatoid arthritis, potentially greater drop-out of patients from the clinical trial due to contracting COVID-19 or difficulties in contacting clinical sites, possible longer time to obtain clinical trial approvals from the competent authorities, possible logistical problems due to difficult access to specific materials, medicines, limitations in international transport, possible limited access to certain clinical sites and possibilities to organise monitoring visits or site meetings.

All the above mentioned phenomena may have a direct impact on the financial situation of the Company. 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, together with later updates, 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 SARS-CoV-2 coronavirus 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 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%.[13] 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.

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 drug entered the US market in January 2021.

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. This is supported by the fact that in November 2018, Sandoz abandoned its attempt to apply for marketing authorisation in the US for its biosimilar drug MabThera/Rituxan, after the regulator requested additional data[14].

Partnering risk

In 2016, the Company signed a long-term cooperation agreement with Mylan. The agreement had ensured that Mylan would have had exclusive rights to sell the drug under the working name of MabionCD20 in all EU and Balkan countries. In addition, under the agreement, Mylan provided support to the Company in the process of registration of MabionCD20 by the EMA. At the same time, changes to the existing agreement with the current distribution partner are also possible.

[13] Global Oncology Trends 2019, IQVIA Institute

[14] http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681

On 29 April 2021, the Company signed an annex to the cooperation agreement with Mylan, under which the parties decided that Mylan will remain Company's non-exclusive distribution partner for MabionCD20 in selected countries in regions such as, in particular Australia, New Zealand, Mexico, Central America, South Africa, South East Asia, deciding at the same time that Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries, as well as Mylan's priority right to enter into a commercialization agreement for MabionCD20 in the United States (USA), shall expire.

Owing to the Annex, the Company has obtained the necessary flexibility in the commercialization of MabionCD20 in its key markets in Europe and in the United States (USA). The Company will look for a new distribution partner or partners. There is a risk that this process may fail or its completion may be delayed. This may affect the Company's financial position, related to the need to independently finance the processes related to the registration of the medicine and subsequent work, and the implementation of sales plans. In the process of searching for distribution partners, the Company uses professional entities specialising in such tasks.

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 ruled out that the actual costs of manufacturing and marketing of developed drugs (including MabionCD20) will be significantly higher than currently assumed. A significant increase in the costs of production and introduction of the developed drugs to the market may adversely affect 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 – MabionCD20

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[15]. 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 the work schedule – NVX-CoV2373

In March 2021, Mabion entered into a framework agreement with Novavax, Inc. based in the United States, pursuant to which the Company, with Novavax's participation, will undertake activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate protein antigen under the working name of NVX-CoV2373 and conduct technical trial runs of the process on a commercial scale at the Company's facility. The parties agreed on the scope and budget of the work contracted to the Company as part of the first order to carry out the technology transfer and technical batch production of the NVX-CoV2373 protein antigen. However, the risk that the planned timetable may change due to a number of factors of a technological and logistical nature at the level of supply of materials and substances necessary for the planned work, as well

[15] Global Data

as those related to the currently re-emerging COVID-19 pandemic, cannot be excluded. Due to a number of factors, there is a significant risk of delays in the implementation of the work and the need to postpone the originally adopted work schedule.

Moreover, Novavax is entitled to terminate the framework agreement in whole or in part without stating reasons. Novavax is also entitled to terminate the agreement following a breach of contractual provisions by Mabion, which may involve an obligation on the part of Mabion to indemnify Novavax against any claims made by Novavax, and to refund any overpayment on the part of Novavax if the latter occurs. The Company commenced technology transfer activities immediately after signing the agreement with Novavax. They include, among other things, analysis of the provided documentation as well as ongoing arrangements with the partner, procurement of the necessary consumables, substances, and equipment, as well as adapting laboratory space and planning staff training. It is possible that as a result of the ongoing analysis of the documentation and discussions with the partner, the original assumptions relating to the scale-up process or associated processes will change, which may also affect the work schedule. Due to the COVID-19 pandemic, there is a risk that the supply of goods required to carry out the work may be delayed and that the availability of personnel carrying out the work on the Company's side may be reduced.

To minimise the above risks, the Company's Management Board carries out ongoing monitoring of project work, participates in daily working group meetings and arrangements with the partner so as to counteract possible delays as far in advance as possible. The Company has specialised teams dedicated to the procurement of materials and equipment required for the project, as well as an extensive network of suppliers. On top of this, the Company has procedures in place to reduce the risk of the potential spread of the SARS-Cov-2 virus. A preliminary analysis of project risks (e.g. at the level of the quality system, technology, regulatory matters, technical installation) was also carried out and actions were proposed to minimise possible risks. The team, dedicated to ongoing monitoring and risk analysis, will provide ongoing active support to minimise possible risks to the project.

Possible continuation of cooperation regarding the commercial manufacturing of the active substance for Novavax will require additional agreements on technical, financial, quality and timing issues. Should the cooperation continue, it will be necessary to increase the Company's production capacity, which is why the Company is still carrying out preparatory work related to the implementation of the production capacity expansion project (Mabion 2).

Risk related to low quality or loss of biological material

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

Mabion S.A. entered into cooperation with verified suppliers, it controls the quality of the supplies and stores the biological material in dedicated 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.

Risks related to the production process and 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 (up-scaling). It is very important to ensure continuity, stability and purity of the entire production process. The Company's quality control laboratories are equipped with state-of-the-art equipment that ensures maximum accuracy and repeatability of the obtained results. A panel of validated analytical methods ensures maximum accuracy, precision, specificity and reproducibility of the results. Designed in accordance with the regulator's guidance requirements, it enables reliable product inspection. A key parameter of analytical methods is their variability, which is influenced by a number of factors determined during validation. Continuous control of method variability over time is critical for research where results are collected over years (e.g. product stability, biosimilarity and bioequivalence studies). The absence of a reliable analysis of method trends may adversely affect the final assessment of both production processes and the bioequivalence of tested 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 production of products. Even if the Company is able to successfully produce commercial quantities at our plant, it cannot guarantee that it will not face challenges in terms of guaranteeing a stable supply to global markets in the future.

Any unfavourable events having a negative impact on the Company's production activities could significantly increase costs and reduce the supply of the Company's products. Even small deviations from the normal production process could lead to reduced productivity, product defects and other supply disruptions. If microbial, viral or other contamination is detected in the Company's products or production plant, the plant may have to be closed for a longer period of time to investigate and handle the contamination. Any adverse event affecting the Company's product manufacturing operations may lead to shipping delays, lack of stock, batch failures, recalls or other interruptions in the supply of products. The Company may also be forced to make inventory write-downs and incur other fees and costs due to products not meeting the specification, costly repair work or looking for more expensive production alternatives.

An extremely important factor in the Company's operations is maintaining appropriate conditions

on the premises where the Company's products are being developed. Currently, Mabion holds all required approvals for the equipment and laboratory and manufacturing premises in both plants.

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. Conducting clinical trials involves risks that can be grouped as follows:

- risks associated with inadequate design of the trial protocol, leading to inability to obtain sufficient data required by regulatory agencies, of defined statistical significance;
- the risk of insufficient efficacy or safety of the investigational medicinal product;
- risks associated with conducting the entire clinical trial in a manner inconsistent with GCP requirements;
- risks related to the adverse impact of a pandemic, e.g. coronavirus, on a clinical trial.

The risks mentioned above apply to all studies to be conducted by the Company.

Being aware of the possible risk, the Company undertakes a number of activities leading to its minimisation. As part of these activities, all clinical trials planned by the Company, once an internal strategy has been established, are consulted with experienced, external, independent specialists and regulatory agencies in order to obtain a validated trial protocol designed to ensure the desired results with adequate statistical power.

In addition, the product is evaluated with a broad panel of biological and physicochemical analyses before it is used in a clinical trial. These analyses are a more sensitive model for the characterisation of a medicinal product than a biological model in the form of a patient, and therefore the studies significantly reduce the risk of inadequate efficacy or safety of a Company's product used in a clinical trial.

In order to ensure that the clinical trial complies with the requirements of regulatory agencies, including GCP requirements, the Company has aligned its internal quality system with relevant guidelines. These procedures define both how to proceed in preparing for a trial and how to conduct a clinical trial. They also specify the requirements to be met by the CRO carrying out the trial and how the work will be verified.

When planning a clinical trial, the Company also takes into account the increased probability of events that may occur as a result of situations that are difficult to foresee, including the coronavirus pandemic, such as, for example, a decrease in the recruitment of patients for the clinical trial, a reduction in the availability of the reference drug and other resources necessary to implement the project, prolongation of the administrative processes necessary to carry out the trial, the potential closure of the borders of certain countries and, consequently, hindered transport of clinical samples. The Company's quality system entails a thorough risk analysis prior to the commencement of a clinical trial, defining the impact, ways to reduce the probability of occurrence and ways to mitigate the effects of adverse events. Based on the information about potential risks such as those mentioned above, the Company develops additional procedures and actions to ensure seamless execution of the project, e.g. selects appropriate countries and sites to guarantee the desired level of recruitment, qualifies a wider range of suppliers of a drug and other resources for the clinical trial, verifies the current administrative and legal status in the countries intended as a place of the trial, or cooperates only with experienced partners guaranteeing the highest quality of work.

The risk analysis performed by the Company prior to the commencement of the project and the implementation of appropriate measures to minimise the probability of risk materialisation significantly increase the chance of successful completion of the clinical trial.

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 500L scale, the Company has identified 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). The ongoing monitoring and preventive actions undertaken by the Company were aimed at minimising the risk factors. 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 5000L. In 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 and obtain marketing authorisation at the EMA directly for the drug produced as part of the large-scale, commercial production process. In the opinion of the Company's Management Board, the change of the strategy was the most optimal path in terms of both cost and time of registration of the product coming from the large-scale process and the possibility of commercialization of MabionCD20 in the European Union. The scope and format of the new application concerning the large, target scale of production is being consulted with the representatives of the EMA and national agencies (e.g. German Paul Ehrlich Institut) under the Scientific Advice procedures to align it with the Agency's expectations, which the Company believes should streamline the registration process. In July 2020, the Company received a written response from the EMA as part of the Scientific Advice procedure to the Company's specific assumptions regarding the new product registration process for MabionCD20, in particular to the scope of data to be included in the new registration application, as well as the actions proposed to generate such data. With the help of external regulatory experts, the Company analysed the documents received and adopted a preliminary framework for the scope and schedule of work required to submit a new marketing authorization application (MAA) for the product. However, due to the specific responsibilities of the regulatory authorities, the content of the document is subject to interpretation, which poses some risk of discrepancies in interpretation.

As part of further Scientific Advice discussions, the Company continued to consult with the EMA on the design of the clinical trial in the indication of RA and, following the response and its interpretation, started to implement the recommendations in the trial protocol. Nevertheless, 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 multi-stage, which the final position of the regulator being developed throghout the whole process. 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.

Upon signing an Annex with Mylan in April 2021, under which it was decided to terminate Mylan's exclusive right to sell MabionCD20 in the EU and the Balkan countries, the Company will start seeking a strategic partner through Rothschild & Co. Moreover, through the intermediation of Plexus Ventures LLC, the Company actively looking for an experienced and strong commercial partner to effectively sell Mabion S.A. medicines on the EU market and markets outside the European Union. 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.

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 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 internal and external training, support in undertaking doctoral studies, as well as including in the promotion procedure. The rules governing these benefits are formalised, open and objective (e.g. promotion procedures, implementation of bonus programmes for employees with a certain seniority – "Mabion's Ambassador"). In 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 advisers 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 – 29.12.2020.

The initial deadline for the project was set for 31 December 2019. In December 2019, the NCBR, at the Company's request, agreed to extend the project timeframe by 9 months, i.e. until 30 September 2020. In view of the SARS-CoV-2 pandemic, in accordance with the Act of 3 April 2020 on special arrangements to support the implementation of operational programmes in connection with the COVID-19 outbreak in 2020 (Polish Journal of Laws of 2020, item 694), the deadlines for the completion of projects under the Operational Programme Smart Development were extended by 90 days. The extension of the project implementation did not require the submission of an application or NCBR's approval, but only a relevant notification. As a result of the Company's submission of the required notification, the project deadline has been extended to 29 December 2020. On 28 September 2020, the implementation of the first stage of the project was completed, and was positively evaluated by NCBR. In accordance with the assumed deadline (29 December 2020), the Company has completed all the tasks provided for in the aforementioned project and has submitted the relevant documentation to the NCBR, and is currently awaiting the final settlement of the project.

» *"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.

As at the date of publication of this report, the project is being implemented according to the schedule agreed with the NCBR. The Company has completed Phase I of the project and has received NCBR's approval for the 2019 project report.

» *"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. In September 2019, the Company received information from the NCBR on the obligation to repay the amount of PLN 149 thousand and interest, as reimbursement of funding under the INNOMED project. The Company paid the above liabilities in full in 2019.

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 24 thousand and interest (calculated as for tax arrears from the date of transfer of funds in 2014) remained to be repaid. The Company has settled this receivable and has no liabilities arising from the project in question. On 24 February 2021, the Company received a letter from the NCBR confirming that the final report on the project was assessed negatively and that the project was deemed in its entirety not to have been completed.

» *"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 European Regional Development Fund (ERDF) co-financing: 63,247,441.60
  - Project implementation period: 20.01.2018 – 31.12.2021.

The objective of the Project is to develop the Company's research and development facilities by preparing the necessary infrastructure: the building of the Research and Development Centre, and the purchase of research equipment to conduct research on innovative medicines. Currently, the Company is in the process of implementing the project in question, however, due to issues related to the financing of its own contribution, the project work is delayed with respect to the originally assumed schedule. The implementation of the project in its full, originally assumed scope will require extending its implementation period, for which the Company will probably apply. The Company is in ongoing contact with the Ministry of Development in this regard. All the above indicated co-financing agreements stipulate in detail the dates and scope of tasks which may be subsidized.

There is a risk that if the Company fails to complete the planned work within the deadlines set by the intermediary body, uses all or part of the subsidy contrary to its intended purpose or without complying with the applicable procedures, collects all or part of the subsidy in an undue or excessive manner, it will be obliged to reimburse part or the full amount of the subsidy 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

The Company does not generate current revenue from sales of marketable products and its existing operations are financed by funds raised from share issues, shareholder borrowings, available credit facilities, public funding and proceeds from distribution partners. The Management Board obtains funds to finance the Company's ongoing operations from borrowings and loans.

In January 2021, Mabion adopted a new long-term strategy for financing its operations. The strategy includes the overall capital needs of the Company that should be satisfied to carry out all activities necessary to complete the registration of MabionCD20 with the EMA and to commence sales of MabionCD20, which will allow the Company to generate operating cash flows. The adopted financial strategy consists of parallel processes: commencement of activities aimed at acquiring a strategic investor and two issues of the Company's shares.

At the same time, as a result of the successful completion of the first issue (U shares) and the conclusion of the framework agreement with Novavax, Inc. for the COVID-19 vaccine programme in March 2021, the Company cancelled the Extraordinary General Meeting which was to pass a resolution on the second of the above-mentioned issues of the Company's shares. The decisions to update the Company's financial strategy, including whether or not to carry out a further share issue, will be taken after detailed analyses.

The Company's management monitors current forecasts for the Company's liquid assets and liabilities based on projected cash flows. The risk related to limited access to funding due to the global liquidity situation or the Company's financial position and the assessment of the potential for registration of the key drug MabionCD20 cannot be excluded. One should indicate here the risk related to the impossibility of changing the terms of the existing financing agreements, In particular, the current situation resulting from the pandemic and its impact on capital markets should be borne in mind, as this may cause significant restrictions on sources of funding, including equity funding from share issues.

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 2020, 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 2020, 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 2020, 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., I.Z.2., 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 biotech conferences 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 is working towards the implementation of the Anti-Corruption Code, governing, inter alia, the 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: In accordance with the Company's Remuneration Policy for Members of the Management and Supervisory Boards of Mabion S.A., Members of the Company's Management Board must obtain the approval of the Supervisory Board to act as Members of the Supervisory Board in third-party companies. On the other hand, the Company's internal regulations and agreements with Members of the Management Board do not impose such restrictions in the case of serving as a member of the Management Board in third-party companies.

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 responsible for internal audit in the Company's structure. 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 responsible for internal audit in the Company's structure. 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 carries out further work related to the implementation of the Anti-Corruption Code covering issues concerning conflicts of interest.

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.

On 15 June 2020, the Ordinary General Meeting of Mabion S.A. adopted Resolution No. 27/2020 on the adoption of the Remuneration Policy for Members of the Management Board and Supervisory Board of Mabion S.A. Accordingly, the Company adopted for application recommendation VI.R.1. ("Remuneration of members of the company's bodies and key managers should result from the adopted remuneration policy.") and 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.").

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 1,616,132.60 and is divided into 16,161,326 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 bearer shares,
- 10,000 S series ordinary bearer shares.
- 2,430,554 U series ordinary bearer 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 17,731,326 votes.

Release of 9,500 S series ordinary bearer shares

On 29 January 2020, 9,500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were released, i.e. recorded in the securities accounts of the eligible persons. Accordingly, the Company's share capital was increased to PLN 1,373,027.20. The S series ordinary bearer shares were issued on 18 November 2019 by the Company as part of a conditional share capital increase, in connection with the exercise by eligible persons of their rights under B series subscription warrants granted to such persons as part of the Incentive Scheme for 2018. The issue price of the S shares was equal to their nominal price. The shares were taken up for cash contributions made in full before the shares were released. 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 Company informed about the event in Current Report no. 8/2020 of 29 January 2020.

Admission to trading of 514,773 P series shares and 9,500 S series shares

On 17 January 2020, the National Depository for Securities (KDPW S.A.) (KDPW) effected 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. On 24 January 2020, the Board of the Warsaw Stock Exchange (Giełda Papierów Wartościowych w Warszawie S.A.) adopted a resolution on the admission of the abovementioned shares to trading on the WSE Main Market and their introduction to trading on the basic market as of 29 January 2020 subject to the registration of the shares and their coding as PLMBION00016 by the KDPW on 29 January 2020. 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 aforementioned condition was fulfilled and the shares were introduced to trading on 29 January 2020. 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.

Issue and admission to trading of 500 S series ordinary bearer shares

On 23 June 2020, the Company issued 500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2019. 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 on 23 June 2020. 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 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 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 released on 18 February 2021 (event after the balance-sheet date). A total of 500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were released. Accordingly, the Company's share capital was increased to PLN 1,373,077.20. The shares were taken up for cash contributions made in full before the shares were released. The Company informed about the event in Current Reports no. 27/2020 of 30 June 2020 and no. 10/2021 of 18 February 2021.

On 23 December 2020, the KDPW issued a statement on conditional registration in the securities depository, under ISIN code PLMBION00016, of 500 S series ordinary bearer shares of the Company, with a nominal value of PLN 0.10 each. The condition for the registration of the above mentioned shares was their introduction to trading on the regulated market. On 16 February 2021, (an event after the balance-sheet date), the Board of the WSE adopted a resolution on the admission of the aforementioned shares to trading on the basic market and their introduction to trading on the WSE Main Market as of 18 February 2021, subject to the registration of these shares by the KDPW on 18 February 2021 and coding them as PLMBION00016. On 16 February 2021 (an event after the balance-sheet date), the KDPW published an announcement on the registration of the above shares under the above code in the securities depository as of 18 February 2021. Thus, the aforementioned condition was fulfilled and the shares were introduced to trading on 18 February 2020. The Company informed about the above events in Current Reports no. 48/2020 of 23 December 2020, no. 8/2021 of 16 February 2021 and no. 9/2021 of 17 February 2021.

Process for compulsory dematerialisation of the Company' s registered shares

In September 2020, the Company commenced, pursuant to Article 16 of the Act of 30 August 2019 amending the Act – Commercial Companies Code and certain other acts (Polish Journal of Laws of 2019, item 1798, as amended by Polish Journal of Laws of 2020, item 875), the procedure for dematerialisation of A, B, C, E, F and G shares of the Company, calling on five shareholders holding the above-mentioned shares in documentary form to deposit their share documents with the Company. The calls were published by the Company at an interval of not more than one month and not less than two weeks each. Upon submission of the share documents by the shareholders, the shares were dematerialised and registered with the KDPW on 1 March 2021. The Company informed about the above events in Current Reports no. 36/2020 of 29 September 2020, no. 38/2020 of 16 October 2020, no. 43/2020 of 4 November 2020, no. 44/2020 of 25 November 2020, and no. 47/2020 of 14 December 2020.

Issue and admission to trading of 2,430,554 U series shares of the Company

On 23 February 2021 (an event after the balance-sheet date), the Extraordinary General Meeting of the Company adopted resolution on increasing the Company's share capital by not less than PLN 0.10 and not more than PLN 243,055.40 up to not less than PLN 1,373,077.30 and not more than PLN 1,616,132.60 through the issue of not less than 1 but not more than 2,430,554 ordinary bearer shares with a par value of PLN 0.10 each. Then, as a result of the accelerated book-building process carried out as part of the offering of new issue shares by way of private subscription within the meaning of Article 431 § 2.1 of the Commercial Companies Code, on 15 March 2021 agreements were concluded for the taking up of all 2,430,554 U series ordinary bearer shares of the Company at the issue price of PLN 55 per share. The share capital increase through the issue of U series was been registered with the National Court Register on 2 April 2021. Following the registration, the share capital of the Company amounts to PLN 1,616,132.60 and will be divided into 16,161,326 shares with a nominal value of PLN 0.10 each, and the total number of votes resulting from all issued shares of the Company amounts to 17,731,326 votes. On 14 April 2021, the WSE's Board adopted a resolution on the admission and introduction to trading on the WSE Main Market of the U series shares of the Company, pursuant to which it stated that 2,430,554 U series ordinary bearer shares of the Company are admitted to trading on the main market, and decided to introduce as of 19 April 2021 to trading on the main market the aforementioned shares of the Company, provided that the KDPW, on 19 April 2021, has registered these shares and designated them with the code PLMBION00016. On 15 April 2021, the KDPW published a notice on the registration, as of 19 April 2021, in the depository of securities under ISIN PLMBION00016 code, of 2,430,554 U series ordinary bearer shares of the Company, and therefore the condition for the listing of the shares on the WSE main market on 19 April 2021 has been met. For further information on the issue of U shares, please refer to section 2.8.2. Significant events and factors after the end of the financial year [of this report].

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. 30 April 2021, the following shareholders held at least 5% of votes at the General Meeting of the Company.

No.	Shareholder	Number of shares	Number of votes	Participation in the share capital	Share in the total number of votes
1.	Twiti Investments Limited	2,674,617	3,268,917	16.55%	18.44%
2.	Maciej Wieczorek through*:	1,717,485	2,210,335	10.63%	12.47%
	Glatton Sp. z o.o.	1,097,135	1,097,135	6.79%	6.19%
	Celon Pharma S.A.	620,350	1,113,200	3.84%	6.28%
3.	Polfarmex S.A.	1,474,346	1,957,196	9.12%	11.04%
4.	Generali Otwarty Fundusz Emerytalny	1,714,263	1,714,263	10.61%	9.67%
5.	Funds managed by Nationale-Nederlanden PTE S.A.**	1,467,649	1,467,649	9.08%	8.28%
6.	Funds managed by Investors TFI S.A.***	1,502,649	1,502,649	9.30%	8.47%
7.	Other	5,610,317	5,610,317	34.71%	31.64%
	Total	**16,161,326**	**17,731,326**	**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 75.01% of the total number of votes in Celon Pharma S.A.*

** *Based on the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 18 June 2019, and concluded agreements on taking up the U shares of the Company.*

*** *Based on the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 15 June 2020, and concluded agreements on taking up the U shares of the Company.*

In the table above, the Company presents the shareholding structure of the Company after the registration of the increase of the Company's share capital by the U series shares, assuming no changes other than those resulting from the issue of the Company's U series shares.

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. 30 April 2021, members of the Company's Management Board and Supervisory Board hold the following shares in the Company:

Table 13: Shares held by managing and supervising persons.

Number of shares held by managing and supervising persons as at the date of submitting the annual report for 2020 (i.e. as at 30 April 2021)	
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.
Adam Pietruszkiewicz	holds directly 3,200 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.02% 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 1,717,485 shares in the Company with a nominal value of PLN 0.10 each, constituting 10.63% of the Company's share capital and entitling to 12.47% of votes at the General Meeting.
Krzysztof Kaczmarczyk	holds directly 1,500 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.01% of the Company's share capital and entitling to 0.01% of votes at the General Meeting.

As at the date of publication of this report, i.e. 30 April 2021, 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

Mabion S.A. has an Incentive Scheme for 2018–2021 adopted by Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018. 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 determined, by way of resolutions, the lists of persons entitled to take up subscription warrants of A and B series for 2018 and 2019 together with the maximum number of warrants that may be taken up by each of these persons, provided that the criteria specified in the Incentive Scheme are met. According to the resolutions, the entitled persons will have the right to take up, for

2018 , a maximum of 28,500 A series warrants and 9,500 B series warrants in total, and for 2019, a maximum of 28,500 A series warrants and 500 B series warrants in total.

At the same time, after verifying whether the criteria specified in the Incentive Scheme for 2018 are met, in February 2019 the Supervisory Board stated that in 2018, with respect to A series subscription warrants, the market objective 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 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. On 18 November 2019, the Company issued the aforementioned B series warrants, as a result of which all eligible persons acquired the warrants to which they were entitled and subsequently also on 18 November 2019, filed statements to take up the Company's S series shares to which they were entitled in exercise of their rights carried by the 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 of the eligible persons, which took place on 29 January 2020.

As regards the implementation of the Incentive Scheme for 2019, in January 2020 the Supervisory Board stated that in 2019, with respect to A series subscription warrants, the market objective 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 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. On 23 June 2020, the Company issued the aforementioned B series warrants, as a result of which all eligible persons acquired the warrants to which they were entitled and subsequently also on 23 June 2020, filed statements to take up the Company's S series shares to which they were entitled in exercise of their rights carried by the 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 of the eligible persons, which took place on 18 February 2021.

In February 2020, the Supervisory Board, acting on the basis of the authorisation granted by the Ordinary General Meeting determined, by way of resolutions, the lists of persons entitled to take up subscription warrants of A and B series for 2020 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 eligible persons will have the right to take up, for 2020, a maximum of 28,500 A series warrants and 500 B series warrants in total.

As regards the implementation of the Incentive Scheme for 2020, in February 2021 the Supervisory Board stated that in 2020, with respect to A series subscription warrants, the market objective 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 subscription warrants was met. Therefore the Supervisory Board vested in eligible persons the right to subscribe for a total of up to 500 B series subscription warrants for 2020. By the date of publication of this report, the B series subscription warrants vested under the Incentive Scheme for 2020 have not been issued.

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. The subscription warrants are taken up free of charge. Each subscription warrant of A and B series shall entitle to take up 1 share (R series and S series, respectively). The share issue price for holders of A series warrants will be PLN 91 per each R series share, whereas for holders of B series warrants it will be PLN 0.10 per each S series share. The Incentive Scheme also allows for settlement in the form of an offer made by the Company to persons who have taken up the warrants, to purchase them against payment for the purpose of redemption. For details, see paragraph 8.1 of this report.

6.5 Purchase of own shares

In 2020, 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.

Table 14. Registered shares.

Series	Number of shares	Shareholder	Number of series shares held by the shareholder as at 30 April 2021
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.

In connection with the conditional placement agreement for the U shares entered into by the Company with mBank S.A. on 4 March 2021, (Offering Manager), the following shareholders of the Issuer – Twiti Investments Limited, Polfarmex S.A. and Glatton sp. z o.o. – have undertaken not to sell or offer the shares acquired by them as part of the issue of U series shares during the period of 120 days from the date of the first listing of the rights to the U series shares without the consent of the Offering Manager. However, this obligation does not apply to transfers within a given shareholder group, transfers required by law or pursuant to competent authorities' decisions as well as to possible sale of the Company's shares to a strategic investor as part of the contemplated process of attracting such an investor.

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

The Management Board of Mabion S.A. consists of three to seven members. 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.

As of 1 January 2020, 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. Previously, Mr. Dirk Kreder served as Member of the Company's Supervisory Board. The Company informed about the event in Current Report no. 14/2020 of 16 March 2020.

On 31 August 2020, Mr. Jarosław Walczak tendered his resignation as Member of the Company's Management Board effective as of the date of the resignation. The aforementioned resignation was part of the reorganisation of responsibilities within the Company's Management Board commenced in March 2020 and involving the transfer of responsibilities for regulatory area oversight (pharmaceutical regulation, clinical trial regulation, drug registration supervision) directly to the CEO, Mr. Dirk Kreder. The Company informed about the event in Current Report no. 33/2020 of 31 August 2020.

On 16 September 2020, the Company's Supervisory Board adopted a resolution to delegate a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to act as a Member of the Management Board. The period of delegation specified in the Supervisory Board's resolution was from 17 September 2020 to 17 December 2020. The Company informed about the event in Current Report no. 35/2020 of 16 September 2020.

As at 31 December 2020, the composition of the Company's Management Board was as follows:

» Mr. Dirk Kreder – President of the Management Board

» Mr. Sławomir Jaros – Member of the Management Board

» Mr. Grzegorz Grabowicz – Member of the Management Board

On 25 January 2021, the Company's Supervisory Board adopted another resolution to delegate a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to act as a Member of the Management Board of the Company. The period of delegation specified in the Supervisory Board's resolution was from 25 January 2021 to 25 April 2021. The Company informed about the event in Current Report no. 2/2021 of 25 January 2021.

On 3 March 2021, Mr. Adam Pietruszkiewicz tendered his resignation from the Company's Supervisory Board. At the same time, on 3 March 2021 the Supervisory Board of Mabion S.A. adopted a resolution to appoint Mr Adam Pietruszkiewicz as Member of the Management Board of the Company as of 3 March 2021. The Company informed about the event in Current

Report no. 18/2021 of 3 March 2021.

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. Grzegorz Grabowicz – Member of the Management Board

» Mr. Adam Pietruszkiewicz – Member of the Management Board

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 2020 to the Management Board Members for serving on the Company's Management Board.

Table 15. Remuneration of the Management Board Members.

Member of the Management Board	Gross remuneration due for 2020	Gross remuneration paid in 2020
Adam Pietruszkiewicz*	PLN 60,301.07	PLN 49,333.33
Jarosław Walczak*	PLN 32,000.00	PLN 36,000.00
Sławomir Jaros**	PLN 510,000.00	PLN 523,680.00
Grzegorz Grabowicz**	PLN 480,000.00	PLN 484,800.00
Dirk Kreder***	EUR 150,594.03	EUR 100,444.03

* *Total remuneration shown in the table due/paid for appointment to the Management Board;*

** *Total remuneration shown in the table due/paid under the employment contract (basic salary plus other components);*

*** *Total remuneration shown in the table due/paid for sitting on the Management Board (appointment and contract);*

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 2020.

In 2020, no awards or benefits, in cash, in kind or in any other form, were paid to Members of the Management Board outside the Incentive Scheme referred to below.

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, February 2020, and January 2021, the persons entitled to take up subscription warrants for different years in the period 2018–2020 include persons sitting on the Management Board of the Company within 2020:

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

» Mr. Jarosław Walczak (Member of the Management Board as of 31.08.2020) – 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 (Member of the Management Board) – 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, 2019 and 2020 were not granted due to failure to meet the market target in these periods. 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.

The B series subscription warrants for 2018 and 2019 have been granted and the rights thereunder have been exercised, resulting in an eligible person taking up the Company's S series shares to which they were entitled. 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. Then, on 23 June 2020, Mr. Sławomir Jaros took up, free of charge, 213 B series warrants allocated to him and submitted a declaration on taking up 213 S series shares of the Company in the exercise of his rights carried by those warrants. The S shares were released similarly to the above by crediting the shares to the securities account, which took place on 18 February 2021 (an event after the balance-sheet date).

B series subscription warrants for 2020 were granted under a resolution of the Supervisory Board of January 2021, but have not been issued as at 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

The Supervisory Board of Mabion S.A. consists of five to nine members. Members of the Supervisory Board are elected for a joint term of office, which lasts 3 years. The second 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 2023. Members of the Supervisory Board are appointed and dismissed by the General Meeting.

As of 1 January 2020, 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 continues to serve as 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. Moreover, on the same day Mr. Józef Banach tendered his resignation from the position of Deputy Chairman of the Supervisory Board. Mr. Józef Banach continues to act as Member of the Supervisory Board. At the same time, the Company's Supervisory Board adopted a resolution to elect Mr. Maciej Wieczorek as Deputy Chairman of the Supervisory Board. The Company informed about the above events in Current Reports no. 14/2020 and 18/2020 of 16 March 2020.

On 15 June 2020, the Ordinary General Meeting of the Company adopted resolutions on the appointment of following persons as Members of the Supervisory Board for the second joint term of office: Mr. Józef Banach, Mr. David John James, Mr. Krzysztof Kaczmarczyk, Mr. Robert Koński, Mr. Jacek Nowak, Mr. Tadeusz Pietrucha, Mr. Adam Pietruszkiewicz and Mr. Maciej Wieczorek. The resolutions came into force on 16 June 2020. The Company informed about the event in Current Reports no. 23/2020 of 15 June 2020 and no. 24/2020 of 16 June 2020.

On 16 September 2020, the Company's Supervisory Board adopted a resolution to delegate a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to act as Member of the Management Board. The period of delegation specified in the Supervisory Board's resolution was from 17 September 2020 to 17 December 2020. The Company informed about the event in Current Report no. 35/2020 of 16 September 2020.

As at 31 December 2020, the composition of the Company's Supervisory Board was 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 Koński – Independent Member of the Supervisory Board;
- Adam Pietruszkiewicz – Member of the Supervisory Board.

On 25 January 2021, the Company's Supervisory Board adopted another resolution to delegate a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to act as Member of the Management Board of the Company. The period of delegation specified in the Supervisory Board's resolution was from 25 January 2021 to 25 April 2021. The Company informed about the event in Current Report no. 2/2021 of 25 January 2021.

On 9 February 2021, Mr. Tadeusz Pietrucha tendered his resignation as Member of the Company's Supervisory Board with effect as of 23 February 2021. The Company informed about the event in Current Report no. 7/2021 of 9 February 2021.

On 23 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the dismissal of Mr. Jacek Nowak from the Supervisory Board. Furthermore, on the same day, the Extraordinary General Meeting of the Company adopted resolutions on appointment of Mr. Wojciech Wośko and Mr. Sławomir Kościak to the Supervisory Board of the Company for the second joint term of office. The resolutions of the Extraordinary General Meeting of the Company came into force on the date of their adoption. The Company informed about the above events in Current Reports no. 12/2021 and 13/2021 of 23 February 2021.

On 3 March 2021, Mr. Adam Pietruszkiewicz tendered his resignation from the Company's Supervisory Board. At the same time, on 3 March 2021 the Supervisory Board of Mabion S.A. adopted a resolution to appoint Mr Adam Pietruszkiewicz as Member of the Management Board of the Company as of 3 March 2021. The Company informed about the event in Current Report no. 18/2021 of 3 March 2021.

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;
- David John James – Independent Member of the Supervisory Board;
- Robert Koński – Independent Member of the Supervisory Board;
- Wojciech Wośko – Member of the Supervisory Board;
- Sławomir Kościak – Independent Member of the Supervisory Board;

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 at least three persons 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 at least 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 2020 was as follows:

Table 16: Remuneration of the Supervisory Board Members.

Supervisory Board Member	Remuneration due for 2020, gross*	Remuneration paid for 2020, gross**
Józef Banach	PLN 55,075.00	PLN 56,000.00
David James	PLN 101,000.00	PLN 102,000.00
Krzysztof Kaczmarczyk	PLN 104,000.00	PLN 105,000.00
Robert Koński	PLN 56,075.00	PLN 57,000.00
Dirk Kreder	PLN 11,935.48	PLN 15,935.48
Jacek Nowak	PLN 50,060.00	PLN 51,000.00
Tadeusz Pietrucha	PLN 8,000.00	PLN 9,000.00
Adam Pietruszkiewicz	PLN 14,073.11	PLN 12,266.66
Maciej Wieczorek	PLN 55,060.00	PLN 56,000.00

* *The amount stated above is inclusive of the remuneration due in respect of the year 2020 for performing the function of Member of the Supervisory Board.*

** *The amount stated above is inclusive of the remuneration paid in the year 2020, paid as part of "remuneration transfer".*

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 2020.

In 2020, 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 2020, 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 2020, 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 2020, 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 and remuneration for participating in the Supervisory Board's meeting.

7.2.4 Appointed Committees

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

Audit Committee

As of 1 January 2020, the composition of the Company's 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.

As of 31 December 2020, the composition of the Company's 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. Józef Banach – Member of the Audit Committee.

On 23 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the dismissal of Mr. Jacek Nowak from the Supervisory Board.

As at the date of publication of this report, the composition of the Audit Committee was as follows:

» Mr. David John James – Chairman 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 2020, the Audit Committee held 2 meetings.

The criteria of independence within the meaning of the Act in the composition of the Audit Committee in 2020 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 » Dirk Kreder (until 16 March 2020) » Jacek Nowak (until 23 February 2021) » Józef Banach	» Krzysztof Kaczmarczyk » Dirk Kreder (until 16 March 2020) » Jacek Nowak (until 23 February 2021) » 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 32 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. In 2016–2018, Advisor to the Management Board of KGHM Polska Miedź S.A. Currently, professionally independent member of supervisory boards of companies listed on the Warsaw Stock Exchange. His almost 15 years of supervisory experience were gained by sitting on more than 30 supervisory boards, of companies listed on the Warsaw Stock Exchange and non-listed companies, including: Action, Alta, Arteria, Braster, BEST, BSC Drukarnia, Celon Pharma, Duon, Emitel, TP Edukacja i Wypoczynek, Warsaw Stock Exchange, Graal, Integer, InPost, KGHM Polska Miedź, KGHM International, KGHM TFI, Develia (former LC Corp), Magellan, PolimexMostostal, Polish Energy Partners, Robyg, SARE, TIM, Vigo System, Wirtualna Polska, Work Service, 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.

» **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.

» **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 (until 23 February 2021)**

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.

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 2020 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 2020. The audit firm was selected by the Supervisory Board by resolution no. 2/V/2020 dated 7 May 2020 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 2020, 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 2020 to 30 June 2020, as well as services related to:

1. the Company's Directors' Report drawn up pursuant to Art. 6a(1) of the Act on Public Offering, Conditions Governing the Introduction of Financial Instruments to Organised Trading, and Public Companies, of 29 July 2005, in relation to the intention to set off financial liabilities arising from the obligation to pay the issue price for new issue U shares by subscribers,

2. statement of remuneration.

The services listed in items 1–2 above have been given a prior positive recommendation by the Audit Committee of the Company's Supervisory Board regarding the auditor's independence assessment. The Company's Supervisory Board has agreed to the provision of the above services.

For more information on the audit firm, please refer to point 8.4.

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 Commercial Companies Code.

As of 1 January 2020, the composition of the Company's Appointment and Remuneration Committee was 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.

On 30 June 2020, Mr. Adam Pietruszkiewicz was appointed to the Appointment and Remuneration Committee, while Mr. Robert Koński was appointed as Chairman of the Appointment and Remuneration Committee

As of 31 December 2020, the composition of the Company's Appointment and Remuneration Committee was as follows:

» Mr. Robert Koński – Chairman of the Appointment and Remuneration Committee;

» Mr. Maciej Wieczorek – 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.

» Mr. Adam Pietruszkiewicz – Member of the Appointment and Remuneration Committee.

On 3 March 2021, Mr. Adam Pietruszkiewicz tendered his resignation as Member of the Supervisory Board, as a result of which the composition of the Appointment and Remuneration Committee for the period from 4 March 2021 to the date of publication of this report was as follows:

» Mr. Robert Koński – Chairman of the Appointment and Remuneration Committee;

» Mr. Maciej Wieczorek – 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 or perpetual usufruct 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 Commercial Companies Code (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 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).

10) 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).

11) 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).

12) 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).

13) The right to inspect the book of minutes and request that copies of resolutions certified by the Management Board be issued (Article 421 § 3 of the CCC).

14) 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.

15) 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.

16) 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 Commercial Companies Code. Amendments to the Articles of Association require a resolution of the General Meeting and entry into the National Court Register. The General Meeting may authorise the Supervisory Board to set the consolidated text of the Company's amended Articles of Association or to make other editorial changes as specified in the resolution of the Meeting.

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

On 15 June 2020, the Ordinary General Meeting of the Company adopted a resolution on the adoption of the Remuneration Policy for the Members of the Management Board and Supervisory Board of Mabion S.A. ("Remuneration Policy"). The Remuneration Policy contains the framework and general principles for the remuneration of the Management Board and the Supervisory Board Members, to be followed by the Supervisory Board and the General Meeting when determining the remuneration of individual members of the company's bodies in accordance with statutory requirements. The objective of these principles is to lay the foundations for the implementation of the Company's strategy and its stable development, to ensure effective and smooth management of the Company, to increase the long-term value for investors, to ensure the Management Board's loyalty to investors, to build motivation of members of the Management Board to take actions conducive to long-term development of the Company and innovation, without taking excessive risk, to create a framework to manage potential conflicts of interest and to take into account the interests of employees and respect for the environment. Detailed rules on remuneration are part of direct negotiations between the parties concerned

Pursuant to the adopted Remuneration Policy, the members of the Management Board exercise their functions and receive remuneration on the basis of one or more legal relationships between them and the Company (appointment for a joint term of office, fixed-term or indefinite-term employment contracts, managerial contract, mandate agreement or another civil law contract). The Remuneration Policy provides for the following components of the total remuneration of Members of the Management Board:

» basic salary, paid monthly, at three levels (1A: President, 1B: Member of the Management Board for Operations and Scientific Affairs, Member of the Management Board for Finance, 1C: Member of the Management Board for Pharmaceutical Regulation) differentiated depending on the external and internal criteria set out in the Remuneration Policy (comparison to adequate remuneration markets for the members of the Management Board, scope of responsibility of individual members of the Management Board, scale of problems solved, specialist skills);

» variable remuneration in the form of:

» annual bonus payable after an annual performance evaluation of the Management Board Member including, inter alia, assessment of the Management Board Member's achievements, assessment of relations with employees, and assessment of the avoidance of discrimination for any reason,

» a task bonus paid out upon achievement of assumed objectives, i.e. completion of tasks resulting from current operations and the Company's strategy, concerning achievement of milestones and final objectives in the area of research and product development, broadly understood compliance, including product registration, manufacture of individual products, implementation of products in individual markets (domestic and foreign), obtaining financing for individual products and markets, upscaling the production, cost and budget control, building distribution and business partnerships,

» bonus based on a financial instrument - in the form of the Incentive Scheme enabling subscription for the Company's shares;

» additional non-monetary and monetary benefits (telephone, company computer, car, medical insurance for the Management Board Member and their family, third party liability policy, professional literature, training, coverage of expenses related to business trips capped by a limit, paid notice period of up to six months, paid non-competition period of up to 12 months after termination of contract).

The variable components of remuneration and additional benefits are non-compulsory, which means that members of the Management Board do not have to receive all components of remuneration.

The Company's Management Board is motivated to work for the long-term development of the Company, hence the Remuneration Policy focuses on the achievement of non-financial performance targets on a multi-year basis and puts less weight on short-term financial targets.

Members of the Supervisory Board are remunerated on the basis of their appointment. Remuneration of the Supervisory Board consists of two components:

» fixed remuneration for Supervisory Board Members who attended a Supervisory Board meeting,

» monthly remuneration for Supervisory Board Members who are members of the Standing Committees of the Supervisory Board.

Members of the Supervisory Board may be reimbursed for expenses incurred in attending Supervisory Board meetings and when working in Committees. Members of the Supervisory Board do not participate in the Incentive Scheme and do not receive additional benefits. In determining the remuneration of the Members of the Supervisory Board, the General Meeting of the Company is guided by the market practices of comparable listed companies. Other than serving on the Supervisory Board, the Supervisory Board Members do not provide any material services to the Company.

The terms and conditions, and amounts of remuneration of individual Members of the Company's Management Board and non-financial elements of remuneration for which they are eligible in 2020 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 shares, the Incentive Scheme also allows for settlement in the form of an offer made by the Company to eligible persons who have taken up the subscription warrants, to purchase them against payment for the purpose of redemption. Detailed conditions for the implementation of the Incentive Scheme are set out in the Incentive Scheme Rules and Regulations adopted by Resolution No. 3/XII/2018 of the Company's Supervisory Board.

The subscription warrants are issued free of charge. The subscription warrants are taken up by eligible persons in the number indicated in the resolution of the Supervisory Board. Each A and B series subscription warrant entitles to subscribe, respectively for 1 R or 1 S series share. 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. The rights attached to the subscription warrants may be exercised until 31 July 2022. R series shares and S series shares may be taken up only for cash contributions made in full before the shares are released. S series and R series ordinary bearer shares are subject to dematerialisation and to application for their admission to trading on the regulated market, and therefore they are released by recording them in the securities accounts of the eligible persons. Detailed information is contained in Notes 4 t and 17 c of the Financial Statements of the Company.

In accordance with a Resolution 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 another Resolution of the Supervisory Board of 12 January 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 B series subscription warrants granted for 2018 were taken up on 18 November 2019 by all (six) eligible persons. At the same time, all eligible persons made statements on 18 November 2019 on taking up the S series shares to which they are entitled, in exercise of their rights carried by the B series subscription warrants. The S series ordinary bearer shares were issued as part of the conditional share capital increase and therefore no allotment 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 eligible 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 a Resolution 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 another Resolution of the Supervisory Board of 30 January 2020, 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 2019 within the meaning of § 5.3.ii of Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company. The B series subscription warrants granted for 2019 were taken up on 23 November 2020 by all (six) eligible persons. At the same time, all eligible persons made statements on 23 June 2020 on taking up the S series shares to which they are entitled, in exercise of their rights carried by the B series subscription warrants. The S series ordinary bearer shares were issued as part of the conditional share capital increase and therefore no allotment of shares took place. Due to the fact that the S series shares were dematerialized, the S series shares were released by recording them in the securities accounts of the eligible persons. The number of shares subscribed for was 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 50. The S series ordinary bearer shares were taken up for cash contributions made in full by the eligible persons before the shares were released.

In accordance with a resolution of the Supervisory Board of 27 February 2020, a list of persons entitled to participate in the Incentive Scheme for 2020 in respect of taking up A and B series warrants was adopted. In accordance with a resolution of the Supervisory Board of 25 January 2021, the Company did not issue A series warrants entitling it to acquire R series shares due to failure to achieve the Market Target in 2020, 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 another Resolution of the Supervisory Board of 25 January 2021, 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 2020 within the meaning of § 5.3.ii of Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company. By the date of publication of this report, the B series subscription warrants vested under the Incentive Scheme for 2020 have not been issued.

The Company positively assesses the functioning of the Remuneration Policy from the point of view of its objectives. In the Company's opinion, application of the Remuneration Policy contributes to a long-term increase in shareholder value and stability of the Company's operations.

The Remuneration Policy is available on the Company's website at: www.mabion.eu.

8.2 Liabilities under pensions and similar obligations

In 2020, 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 2020, 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 for 2020 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. 2/V/2018 dated 7 May 2020 on the basis of the authorisation provided for in the Company's Articles of Association. The agreement with PwC was entered into on 20 July 2020 for a period of 2 years and includes the audit of interim financial statements and the audit of annual financial statements for 2020 and 2021. The total remuneration for the performance of the aforementioned services covered by the agreement was set at PLN 465,000 net.

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

- audit of the annual financial statements for 2019 and review of the interim condensed financial statements for the period from 1 January 2019 to 30 June 2019;
- 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 (on the territory of Europe or the United States), i.e. support for the Company in the preparation for the conversion of the financial statements for 2016 and 2015 prepared in accordance with PAS into IFRS-compliant statements, audit of the Company's financial statements for 2016 and 2015 prepared in accordance with the IFRS, preparation of comfort letters in connection with the planned listing of the Company's shares on the aforementioned stock exchange, support and other services related to the preparation of issue documents necessary for the implementation of the share issue on the aforementioned stock exchange;
- audit of the annual financial statements for 2015 and 2016 and review of the interim condensed financial statements for the periods 1 January 2015 to 30 June 2015 and 1 January 2016 to 30 June 2016.

In 2020, PwC provided authorised non-audit assurance services to the Company as set out in paragraph 7.2.4 of this report.

Table 17. Remuneration due to PwC for services provided in 2020 and 2019.

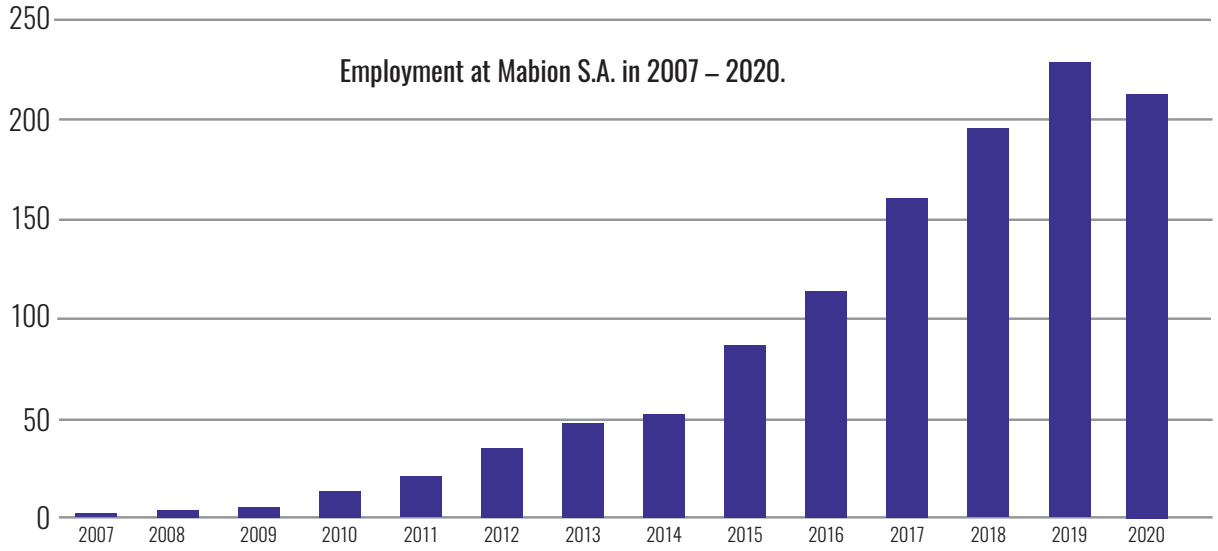
	2020	2019
Audit of the annual financial statements	160,000	185,000
Other assurance services, including the review of financial statements	60,000	60,000
Tax consultacy services	0	0
Other services	0	0
Review of the statement of receivable conversion	30 000	0
Review of the statement of remuneration	22 500	0
Reimbursement of expenses	8,800 *	9,800

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

8.5 Employment

As at 31 December 2020, the Company employed 213 people, while the average employment in 2020 was 222.25 full-time equivalents.

Tabela 18: Employment at Mabion S.A. in 2007 – 2020.



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 2020, the Company conducted active research on the achievement of the key objectives of the main project of the Company – development of the rituximab molecule (a medicine biosimilar to MabThera and Rituxan). In 2020, 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. They included:

» 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

Issues related to environmental protection, but also to ensuring safe working conditions and improving energy efficiency are a very important aspect of the Company's operations, which, acting on the basis of current regulations, guidelines and legislation in these areas, pursues the Company's strategic objectives guided by the principle of sustainable development.

An important aspect of the Company's operations is to conduct the processes at the plant in a manner that minimises negative impact on the environment.

Considering the above, the Company has made every effort to implement an Integrated Management System in accordance with ISO 14001:2015, 45001:2018 and 50001:2018 standards, which contributes to the improvement of its operations in the management of the EP, OHS, and energy areas. The Company has implemented all planned measures to ensure that the plant's operations and processes comply with all guidelines arising from ISO standards and legislation relating to the areas of EP, OHS, and energy.

In November 2020, the Company completed a two-stage certification process, which was conducted by independent auditors from an accredited certification body. The scope of certification covered the main and ancillary processes that comprise research and development activities enabling the development and subsequent implementation of new biotech medicines, including biosimilar medicines, and activities related to the manufacture of biosimilars.

The audit team reported that the organisation has established and maintains its management system in accordance with

the requirements of the standards and demonstrates the ability to meet in a systematic manner the agreed requirements for products and services in accordance with the organisation's scope of certification, objectives and policy.

The certificates obtained confirm the successful implementation and certification of IMS.

The basic assumption of the Integrated Management System Policy in the area of environmental protection, occupational health and safety and energy efficiency is to raise the awareness of all employees with regard to the systems in force, which translates into effective implementation of the Policy, as well as to build a sense of responsibility for its implementation with regard to:

- continuous improvement in the areas of environmental protection, occupational health and safety, and energy efficiency;
- elimination of hazards and mitigation of risks;
- prevention of injuries and health problems;
- environmental protection and pollution prevention;
- improving energy performance;
- compliance with legal and other requirements in the area of environmental protection, occupational health and safety and energy use and consumption, binding upon the Company;
- consultation and participation of employees in building an effective system;
- the availability of information and resources necessary to achieve the objectives and targets;
- taking into account environmental, occupational health and safety, and energy efficiency issues in investment processes and procurement plans.

Simultaneously, the Company implements a project related to environmental education of employees, as part of which, in 2020, the following actions were organised:

» art competition for children of the Company's employees: "Bee Day";

» collection of batteries as part of "Battery Day";

» additional signs reminding to save light, paper towels, printer paper, and on correct waste segregation.

As part of the project, the Company continues its cooperation with the "RECAL" foundation and participates in the "Every Can Counts" campaign. Together with the "Our Earth" Foundation, the Company's employees took part in a nationwide campaign to clean up the world.

Due to the existing epidemiological situation and the resulting restrictions, the Company was obliged to suspend its environmental education project for the benefit of the local community.

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".

These actions are intended to make every effort to improve energy efficiency, increase the level of waste segregation and reduce the consumption of natural resources, while implementing optimal production processes.

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 Państwowe Gospodarstwo Wodne Wody Polskie, the Regional Water Management Board in Poznań of 08 March 2019 (reference: PO.RUZ.421.456.5.2018.ML) on granting the water-legal permit covering the special use of waters consisting in injection of industrial sewage containing substances particularly harmful to the aquatic environment (total phosphorus) into the sewage system of another entity – for the Company's location in Konstantynów Łódzki.

3. Notification of the fuel combustion installation to the District Office in Pabianice – confirmation of the notification receipt of 3 April 2018 (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 April 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 2020 in Mabion S.A. as part of the waste management:

1. With EGOLIT Sp. z o. o. of 21.08.2015 along with Annex 5 to the Agreement, entered into on 31.12.2020. 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 June 2019, 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. With REMONDIS Sp. z o. o. of 20.07.2020 for the collection of municipal waste and selective waste. Remondis is providing services from 01.09.2020.

4. With PreZero Service Centrum Sp. z o. o., no. 48/03/2020/LODZ/SG on the provision of solid, municipal waste collection services. PreZero provided services until 31.08.2020.

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 installation and non-installation waste generation. In October 2020, 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 with annex no. UM/2021/1374 of 22 September 2020 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.

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

» Annual information on the types and quantities of category 2 drug precursors used at the Mabion's facility.

» Annual report on products, packaging, and waste management.

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 and makes entries in the Database on Products, Packaging, and Waste Management.

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

8.8 Social responsibility policy

1. POLITYKA RÓWNYCH SZANS

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 all ages from the age of majority. 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. Every person working for the Company is subject to the following rules:

» knows his or her duties;

» may engage in an open and constructive dialogue about his or her work 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, behaviour, physical and mental characteristics than their own;

» easy access to job offers – advertisements are published in several ways (industry portals, Mabion website, recruitment portals, social media, presence at universities and cooperation with research clubs) 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.

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.

In 2020, a programme called "Mabion Ambassador" was developed and implemented. It is addressed to all employees of the Company and its aim is to motivate, support the development of soft and hard competencies, and to recognise the best employees.

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.

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 agrees with his/her supervisor on the type and pace of promotion. The high score of the employee's appraisals and the degree of experience obtained in his/her work (laboratory, process, or administrative) predispose him/her to participate in the promotion procedure organised by the heads of departments.

The promotion procedure envisages professional development in terms of substantive or functional positions. The guidelines for the promotion procedure are established in a clear and transparent manner that takes into account all positions in the Company. The promotion procedure concludes with the employee writing a test, completing an assignment or preparing a multimedia presentation based on the material presented to the employee prior to the procedure.

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 Communication and investor relations

In 2020, as in previous years, the Company carried out active communication activities, reaching out to a wide audience of stakeholders. Due to the SARS-Cov-2 virus pandemic, the Company did not participate in stationary events and instead focused its activities online.

Communication activities, including in the area of investor relations, included:

- participation in national and international fairs and conferences;
- meetings (mainly online) with institutional and individual investors, analysts from brokerage houses, and the media;
- educational activities among investors and the media;
- Preparation and distribution of information and press materials for, among others, the media, institutional and individual investors, and analysts at brokerage houses;
- expert statements and comments of the Company's officials in Polish and international media (news media, media from capital market related sectors and specialised industry media dedicated to biotechnology), 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 (e.g. "Młodzi w Łodzi" initiative);
- CSR activities (pandemic health care support, charity actions, education and environmental activities).
- on 26–29 October 2020, the Company participated in the 6th edition of BIO-Europe 2020® – one of the most important international partnering events in the life science industry worldwide. During the event, the Company's representatives held numerous meetings with representatives of large pharmaceutical and biotechnological companies – regarding the MabionCD20 project, the Company's other biological drug projects and the possibility of partnering in new projects (e.g. CDMO activities);
- Company's involvement in the PolishBiotech initiative promoting Polish biotechnology internationally;
- Company's involvement in the initiative aimed at establishing the Union of Biotechnology Companies to develop the innovative biotechnology industry in Poland, through, among other things, consultation in shaping laws, building awareness and knowledge of representatives of public authorities on the role and importance of the biotechnology industry, and mutual support in the process of registration, production of biotechnology products in the European Union.

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 investors, and to ensure the Company's transparency through full compliance with disclosure obligations and corporate governance principles.

The Company communicates with investors via its website which contains a separate section for investors and another separate one – for the media, with the materials available in Polish and English. The website includes:

Information about the Company and its bodies (bodies, shareholders, current share price, strategy, corporate documents, general meetings, corporate governance, financial information);

» Current and interim reports;

» Current share quotation of the Company;

» Investor relations contact details;

» Materials for investors, presentations and recordings of speeches by Company's representatives;

» Press releases and image bank (in the media section).

The Company regularly informs about the most important events through current reports published via the ESPI system, as well as through press releases in key daily newspapers, on financial and business portals. The Company's Management Board representatives gave interviews to key biotechnological and financial media and answered the enquiries of the media, shareholders, and stakeholders on an ongoing basis.

The main topics communicated by the Company in 2020 were:

» Procedures for the registration of MabionCD20 with the EMA, including the timetable and the required scope of data;

» Dialogue with the US regulator – FDA;

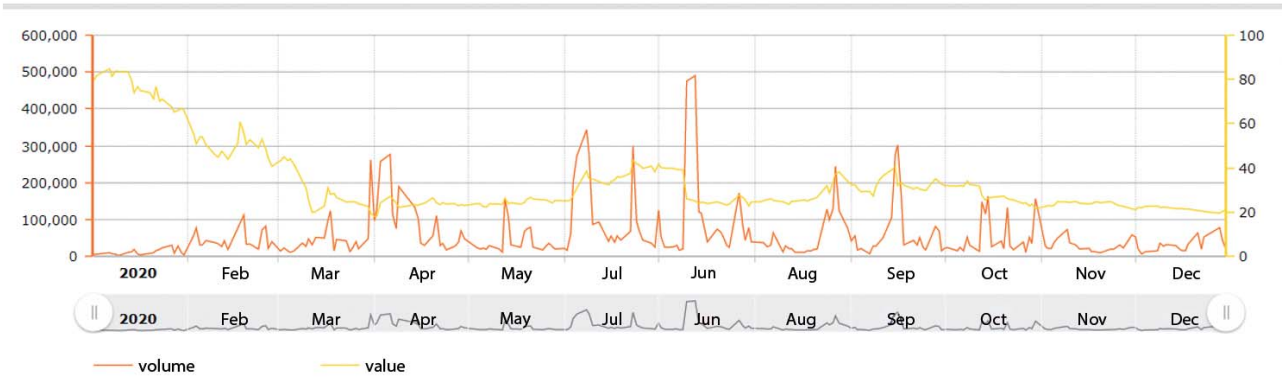
» Preparations for a bridging clinical trial;

» The Company' s financing strategy, including plans to raise capital and issue shares and partnership projects;

Contact for investors: relacjeinwestorskie@mabion.eu.

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

Table 22. Mabion S.A. stock quotes on the Warsaw Stock Exchange (02.01.2020 – 30.12.2020) – a chart.



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

Table 23. Mabion S.A. stock quotes on the Warsaw Stock Exchange (02.01.2020 – 30.12.2020) – a summary.

Start date:	02.01.2020
End date:	30.12.2020
Reference price:	PLN 77.00 (30.12.2019)
End price:	PLN 20.75 (30.12.2020)
Change:	–73.05%
Change:	PLN –56.25
Minimum:	PLN 17.00 (02.04.2020)
Maximum:	PLN 87.10 (07.01.2020)
Average:	PLN 33.31
Trading volume:	14,439,723 pcs.
Average volume:	57,300 pcs.
Turnover:	PLN 446.943 million
Average turnover:	PLN 1.774 million

Management Board

Dirk Kreder
President of the Management Board

Sławomir Jaros
Member of the Management Board

Grzegorz Grabowicz
Member of the Management Board

Adam Pietruszkiewicz
Member of the Management Board

Konstantynów Łódzki, 30 April 2021