Mabion S.A.
Directors' Report for the 1st half of 2020

Konstantynów Łódzki, 22 September 2020

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1. Selected financial data

	in PLN thousand		in EUR thousand	
	from 01.01.2020 to 30.06.2020	from 01.01.2019 to 30.06.2019	from 01.01.2020 to 30.06.2020	from 01.01.2019 to 30.06.2019
Net income from sales of products, commodities and materials	0	0	0	0
Operating profit (loss)	-29 031	-32 252	-6 537	-7 521
Gross profit (loss)	-30 829	-31 696	-6 941	-7 392
Net profit (loss)	-30 829	-31 696	-6 941	-7 392
Weighted average number of shares (in pcs)	13 730 272	13 720 772	13 730 272	13 720 772
Profit (loss) per one ordinary share (in PLN/ EUR)	-2.25	-2.31	-0.51	-0.54
Diluted profit (loss) per one ordinary share (in PLN/ EUR)	-2.25	-2.31	-0.51	-0.54
Net cash flows from operating activities	-15 201	-19 324	-3 423	-4 507
Net cash flows from investing activities	-3 079	-7 041	-693	-1 642
Net cash flows from financing activities	-1 516	-1 243	-341	-290
Total net cash flows	-19 796	-27 608	-4 457	-6 438
	30.06.2020	31.12.2019	30.06.2020	31.12.2019
Total assets	87 038	113 545	19 489	26 663
Liabilities and provisions for liabilities	139 471	135 125	31 230	31 731
Long-term liabilities	49 343	48 743	11 049	11 446
Short term liabilities	90 128	86 382	20 181	20 285
Equity	-52 433	-21 580	-11 740	-5 068
Share capital	1 373	1 372	307	322
Number of shares (in pcs)	13 730 272	13 730 272	13 730 272	13 730 272
Book value per one share (in PLN/EUR) *	6.34	8.28	1.42	1.94
Diluted book value per one share (in PLN/EUR)	6.34	8.28	1.42	1.94
Dividend declared or paid per one share (in PLN/EUR)	0	0	0	0

* *Net assets/ Weighted average number of shares*

Individual items of the balance sheet presented in EUR were translated at the average EUR exchange rate announced by the National Bank of Poland on 30 June 2020 (4.4660 PLN/EUR) and on 31 December 2019 - 4.2585 PLN/EUR. Individual items of the income statement and cash flow statement have been converted into EUR announced by the National Bank of Poland for the euro at the exchange rate being the arithmetic average of the average exchange rates, effective on the last day of each month in the period of 6 months ended 30 June 2020 and 6 months ended 30 June 2019 (respectively: 4.4413 PLN/EUR and 4.2880 PLN/EUR).

2. Information about Mabion S.A.

2.1. Introduction

Mabion S.A. ("Mabion" or "Company") was established on 30 May 2007 as a limited liability company with its registered office in Kutno. The legal form of the Company changed on 29 October 2009 as a result of transformation of the limited liability company into a joint stock corporation. Currently, Mabion S.A. is entered on the Register of Entrepreneurs of the National Court Register kept by the District Court for Łódź Śródmieście in Łódź, 20th Commercial Department of the National Court Register, with KRS number 0000340462. The Company was assigned tax identification number NIP 7752561383 and statistical identification number REGON 100343056.

The Company's registered office is at 60 gen. Mariana Langiewicza St. in Konstantynów Łódzki.

Mabion S.A. is a biotechnology company focusing on research, development, and manufacturing activities aimed at developing and commercially introducing biotech drugs based on the monoclonal antibody technology amongst others, to the market. The main objective of the Company's activity is development, manufacture and marketing of drugs biosimilar to the marketed original biotechnological drugs (so-called reference products) in the area of oncology, autoimmunity, neurology and metabolic diseases. Also, the Company has potential and resources to conduct research, development, and manufacturing tasks in the field of vaccine and innovative therapies in response to the current SARS-CoV-2 pandemic.

The Company's shares are listed on the regulated market of the Warsaw Stock Exchange.

2.2. Composition of the Management Board and the Supervisory Board

As at the date of publication of this report, the Company's Management Board was composed of the following persons:

- 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 Supervisory Board delegated to temporarily act as Member of the Management Board.

Changes in the composition of the Company's Management Board in the first half of 2020 and after the balance-sheet date:

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

On 31 August 2020, Mr. Jarosław Walczak tendered his resignation from the position of Member of the Management Board of the Company as of the date of his resignation. The above resignation forms part of the reorganization of responsibilities of the Company's Management Board started in March this year and consisting in delegating oversight of the regulatory affairs activities (pharmaceutical regulations, clinical trials regulations, supervision of drug registration) within the Management Board directly to the President of the Management Board, Mr. Dirk Kreder. The Company informed about the event in Current Report no. 33/2020 of 31 August 2020.

On 16 September 2020, the Supervisory Board of the Company adopted a resolution on delegating a member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to perform the duties of Member of the Management Board. The period of delegation specified in the resolution of the Supervisory Board lasts 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 the date of submission of this report, the Company's Supervisory Board was composed of the following persons:

- 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 delegated to temporarily act as Member of the Management Board.

Changes in the composition of the Supervisory Board of the Company during the first half of 2020:

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

On 15 June 2020, the Ordinary General Meeting of the Company adopted resolutions on the appointment of the 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.

As mentioned above, on 16 September 2020 the Supervisory Board of the Company adopted a resolution on delegating a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to perform the duties of Member of the Management Board. The period of delegation specified in the resolution of the Supervisory Board lasts from 17 September 2020 to 17 December 2020. The Company informed about the event in its Current Report no. 35/2020 of 16 September 2020.

2.3. Consolidated entities

Mabion S.A. does not own any shares or interests in other entities. There are also no other situations that could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1(4) of the Commercial Companies Code. In the first half of 2020, Mabion did not form a capital group and did not draw up consolidated financial statements.

3. Operations of Mabion S.A.

3.1. Scope of activities

The primary objective of Mabion is the development, manufacture and marketing of drugs biosimilar to the existing original biotechnology drugs (so-called reference drugs), in the field of oncology, autoimmunity, neurology and metabolic diseases. Every year, the Company analyses the development plan for medicinal products and modifies it as necessary, 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 drug production technology, the competence and experience of the team, and competition in the field of biosimilar medicines.

In 2019, after reviewing and updating the strategy for the development of medicinal products, the catalogue of projects which the Company, now or in the future, alone or with partners, is interested in implementing was changed. The Company have qualified scientific and research projects to three groups of projects, i.e. active projects, new projects whose commencement was planned for 2019, and partnership projects.

In March 2020, the Company's Management Board started work related to the annual update of the strategy plan for medicinal product development. It was finally decided to maintain the product development strategy as it was in 2019.

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 the first half of 2020:

- Reference drugs Prolia[1] and Xgeva[2] (based on denosumab) – work on the construction of the vector encoding the biosimilar antibody and on the creation of a reference material bank was continued;

- Reference drug Xolair[3] (based on omalizumab) – work on the creation of a reference material bank continued.

Partnership projects

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

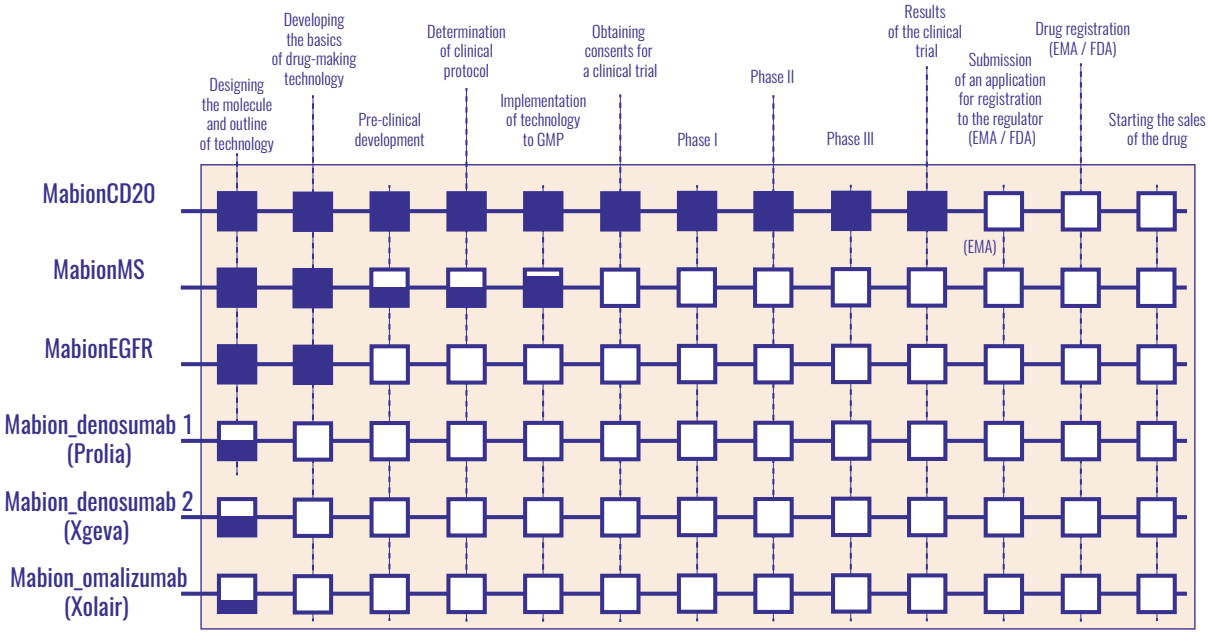
On 14 September 2020, Mabion entered into a Memorandum of Understanding ("MoU") with Vaxine Pty Ltd. to negotiate a joint project consisting of process development, production and commercialization of Covax-19™ which is a proposed vaccine for Covid-19 disease caused by the Sars-Cov-2 virus, with particular emphasis on the Polish and European Union markets. The MoU provides that the parties aim to negotiate and conclude agreements concerning the manufacturing of the product by Mabion, the process development tasks to be performed and the commercialization of the product by Mabion in the agreed markets, and prior to concluding agreements - to conduct mutual due diligence and cooperate to organise future government or EU funding or reimbursement.

[1] Reference drug Prolia - indications: osteoporosis, sales value in 2019 approximately USD 2.7 billion (based on Amgen, Letter to Shareholders 2019, increase by 17% compared to 2018). The patent for the drug Prolia expires in Europe in 2022. (except for France, Italy, Spain and the United Kingdom where it expires in 2025), and in the USA in 2025. Currently, several entities are working on a biosimilar version of the drug.

[2] Reference drug Xgeva - indications: prevention of bone complications (pathological fractures, necessity of bone irradiation, spinal cord compression or necessity of bone surgery) in adults with metastases of solid tumors to bone. Sales in 2019 are approximately USD 1.9 billion (based on Amgen, Letter to Shareholders 2019, increase by 8% compared to 2018). Patent for Xgeva expires in Europe in 2022 (except for France, Italy, Spain and the United Kingdom where it expires in 2025) and in the United States, where it expires in 2025. Currently, several operators are working on a biosimilar version of the drug.

[3] Reference drug Xolair - indications: asthma, sales value in 2019 about USD 3,1 billion (based on data from the annual reports of Roche and Novartis). Patent protection ended in 2017. Currently, several entities are working on a biosimilar version of the drug - among others, Celltrion and BiosanaPharma.

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



MabionCD20

The Company's priority and most advanced project is currently the biosimilar MabionCD20, a reference drug to MabThera/Rituxan (Roche). In 2018, the Company elaborated the results of the clinical trial which confirmed the effectiveness of the therapy. The Company then proceeded to the registration and marketing authorisation of MabionCD20 with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

With regard to the registration procedure with the European Medicines Agency, at the beginning of 2020, the procedure of evaluation of registration applications (MAA) submitted by the Company in June 2018 (basic application) and in May 2019 (duplicate application, whose aim was to obtain an additional trade name for which the list of indications for the product would be limited and would not include rheumatoid arthritis) was continued. In January 2020, the Company responded to the EMA's list of questions received in December 2019 and in February 2020, the Company received from the EMA a list of issues to be presented to the Committee for Medicinal Products for Human Use (CHMP), which was held on 24-27 February 2020. On 26 February 2020, the Company's Management Board participated in the CHMP meeting with a team of experts to present the issues identified by the EMA in the invitation (oral explanation).

Then, on 16 March 2020, on the basis of opinions of external consultants and recommendations of the Supervisory Board, the Management Board of the Company decided to modify the current regulatory strategy for MabionCD20 pursued for the EMA. Prior to the change, a two-step strategy was implemented, consisting in obtaining a marketing authorization for the product manufactured in a small scale in the first place, and then on the basis of another application - a marketing authorization for the product manufactured in the target, i.e. large commercial scale. The change in the regulatory strategy was related to the withdrawal of the registration applications relating to the product originating from the small production scale. The withdrawal of applications took place on 16 March 2020, which was subsequently confirmed by the European Medicines Agency on 30 March 2020.

A new registration application, as part of which the Agency will assess the target (commercial) scale of MabionCD20 production, will be submitted after the process validation has been completed and after biosimilarity data relating to the reference drug and bioequivalence data for the small scale manufacturing process, in which the drug was subject to clinical trials, have been obtained. In addition to generating the analytical data package, the Company's intention is to conduct a smaller-scale clinical bridging trial (Phase I/II) for the registration dossier, which, in the Company's opinion, is required to demonstrate comparability

and, at the same time, will limit the regulatory risk, thus reducing the costs 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, scale: estimated <80 patients per arm), which is intended to confirm the biosimilarity between MabionCD20 and MabThera (European reference product) and Rituxan (US reference product).

The existing analytical data originating from the large production scale analytical data already indicate a reproducible quality and high degree of analytical similarity both to reference medicines and to the product historically used in clinical trials, which, in the Company's opinion, significantly translates into the probability of waiving additional, larger clinical trials for the purposes of registration with the EMA. In the opinion of the Company's Management Board, the change in the regulatory strategy was the optimal path in terms of both cost and time in terms of product registration and the possibility of commercialisation of MabionCD20 in the European Union.

The scope and format of the new registration application (MAA) were consulted with representatives of the EMA as part of the Scientific Advice procedure in the first half of 2020. The aim was to adapt it to the Agency's expectations and streamline the application registration procedure based on data for the large-scale product. In April 2020, the Company submitted the Briefing Package to the EMA, and in July 2020, the Company received, under the Scientific Advice procedure, a written response to the Company's specific objectives for the new registration process, particularly the scope of data to be included in the new application, as well as the actions required to generate such data which were proposed by the Company.

After internal analyses, consultations with external experts and arrangements with the Company's Supervisory Board, the initial framework for the scope and schedule of work necessary to submit the new registration application was adopted. In June 2020, the validation of the MabionCD20 large-scale manufacturing process based on three validation batches was completed. Preliminary analytical tests prove that the batches produced meet the requirements for all quality attributes analysed at the drug substance (DS) level. In addition, the Company has started product stability tests, and will soon start biosimilarity and bioequivalence tests. In order to extend the scope of analytical data presented in the registration application, the Company is considering the production of additional batches to base the application on data from at least four to five large-scale product batches. In the Company's opinion, presenting a broad package of analytical data would significantly reduce the regulatory risk.

The Company does not preclude the possibility of modifying the above assumptions should circumstances require it. The Company's objective is to respond quickly and decisively to all the needs arising from the registration process in order to reduce the regulatory risk while keeping the costs of the process at a level that can be financed by the Company and to conduct the product registration procedure as soon as possible. The above assumptions may also change in the future as they are based on a number of factors that may affect the time frame, including factors beyond the Company's control (such as the speed of recruitment in clinical trials). Last but not least, the assumptions made and actions performed do not guarantee product registration with the EMA.

With respect to the activities conducted for the marketing authorisation of the drug under the working name of MabionCD20 in the United States, according to the summary of the BPD (Biosimilar Biological Product Development) Type 2 meeting with the U.S. Food and Drug Administration (FDA) held in June 2018, the FDA has allowed the Company's data to be used as application support. At the same time, it proposed an overall strategy to link the EU registered product (MabThera) to the US approved product (Rituxan). Based on the data available at that time, the Agency did not indicate the need for a completely separate process of developing MabionCD20 for the US market. The Agency considered that in relation to trials already performed in Europe based on the reference drug MabThera, which the Company will want to use in the FDA application process, there is a need for a clinical bridging trial. The bridging trial should be three-arm and include the US reference product Rituxan, European MabThera, and MabionCD20 produced as part of the large-scale, commercial manufacturing process. It will also be necessary to carry out a three-arm analytical trial. In this manner, the Company will be able to use data obtained from the bridging trial in the application process, in a package with other data obtained separately for the US market to the extent necessary to submit a registration dossier. Details of the strategy for building a "clinical data bridge" are continuously discussed with the Agency.

On 22 January 2020, the Company held a Type 3 BPD meeting with the FDA. The purpose of the meeting was to obtain confirmation of the regulatory strategy. During the meeting, there was a productive discussion on the data needed to submit an application for registration in the USA for all indications of the reference medicine. In February 2020, the Company received a summary of the meeting from the FDA and thoroughly analysed the document and the conclusions and guidelines contained therein and assessed their impact on the actions planned by the Company so far to register and release the drug to trade in the USA. In accordance with the Company's interpretation, the FDA confirmed the possibility of submitting an application for MabionCD20 and the validity of the presented approach.

Then, as part of continuing discussions on the application program, Mabion S.A. prepared and sent to the FDA both a set of further questions specifying the clinical parameters under investigation as well as detailed comparative analyses of MabionCD20 with the reference drug Rituxan. The Company also applied for the possibility of holding another (Type 2) meeting with the regulator, which took place remotely on 11 August 2020. In accordance with the FDA guidelines, Type 2 meetings address specific issues for which the FDA presents a directional recommendation, while at Type 3 meetings, a comprehensive, in-depth analysis of the complex data package is conducted. The Type 2 meeting in August 2020 was intended to clarify the details of the clinical development of MabionCD20 for the US market.

On 28 August 2020, the Company informed about receiving a summary of this meeting with the FDA. In accordance with the summary contents, the Company received confirmation from the Agency of a number of proposed clinical programme parameters, including the ability to use significant parts of already generated data for the release of MabionCD20 in the EU, as well as data from the planned bridging trial in RA patients for the commercially produced drug. This confirms previous consultations in which the Agency indicated that it was not necessary to conduct a completely separate development programme for MabionCD20 to obtain approval of the drug in the US. However, the Company reserves that data obtained from the bridging clinical trial for the purpose of the registration application at the EMA will only support the application process before the FDA, which means that the data does not meet all of the Agency's expectations regarding the overall scope of data. The detailed data scope is still subject to discussions with the Agency.

In addition, the Company has also begun to verify with the Agency whether it is possible to apply an innovative regulatory strategy that allows for an earlier initial application for registration than originally envisaged and proposed by the Agency. The Company accepted the Agency's suggestion to clarify the details of this approach at another separate meeting. The current arrangements are non-binding for the Agency.

The US registration and marketing authorisation process for MabionCD20 is a complex one, 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.

In order to start the bridging clinical trial necessary to first admit MabionCD20 to the market in the EU, the Company, based on the trial protocol, must obtain the consent of competent authorities and of bioethics committees. At the same time, the Company has to provide financing for the study, which is a prerequisite for its commencement and thus determines the date of the study. Funds for the implementation of the above may come from a distribution partner, European Union funds, or other sources. In addition to the European market, where the Company cooperates with Mylan, partners for further markets are actively sought. For the US market, a potential partner for the Company is Mylan. However, based on the current contractual arrangements, Mabion is free to engage in discussions with potential partners other than Mylan, under the condition that Mylan has a one-off right to match the best offer for the US market within a certain timeframe.

Summarizing the research and development work on MabionCD20, the following actions were successfully carried out in the first half of 2020 and by the date of publication of this report:

» a preliminary study was performed to characterize the active substance (drug substance - (MabionCD20DS) on a scale of 2x2500L for 4 batches (technical batch and 3 validation batches), confirming its equivalence with the active substance obtained on a scale of 2x250L (MabionCD20DS 2500L vs. MabionCD20DS 250L), and the similarity of MabionCD20DS to the reference drug (MabionCD20DS vs. MabThera) was confirmed;

- the production of MabionCD20DP (finished product - MabionCD20 drug product) was completed in four batches (sterile technical filling of immediate packaging in two formats: 10 ml and 50 ml with the technical batch and three validation batches);
- a continuous process of stability testing for MabionCD20 on a scale of 250L was conducted;
- a stability study on the active substance (drug substance - MabionCD20DS) and the finished product (drug product - MabionCD20DP) obtained from 3 validation batches on a scale of 2x2500L was started;
- plans were developed to study the bioequivalence and biosimilarity of 2x2500L MabionCD20DP compared to the 2x250L product as well as the European (MabThera) and American (Rituxan) reference drug;
- the scope of work on determining the process space for the MabionCD20 manufacturing process has been extended;
- additional analytical methods have been developed and qualified to enable a wider in-house characterisation of the MabionCD20 particle;
- validation of the process of aseptic filling of the product on the automatic filling line was carried out in three successfully completed Media Fill tests for mixed filling (10 ml and 50 ml formats);
- physicochemical, biological and microbiological analyses of the technical batch and three validation batches were conducted according to the developed MabionCD20 manufacturing process control strategy;
- optimisation of analytical methods has been carried out. The methods, after their prior validation using material taken from patients during the clinical trial, will allow characterisation of pharmacokinetics, pharmacodynamics and immunogenicity in subsequent clinical trials related to MabionCD20;
- new operational GCP procedures have been developed to launch and conduct a clinical trial, supervise CROs and monitor safety during ongoing trials;
- in April 2020, the Company documentation with inquiries ("Briefing Package") as part of the EMA Scientific Advice, to which it received a reply in July 2020; the replies confirmed the scope of trials necessary to register MabionCD20 manufactured on a scale of 2x2500L with the EMA;
- the Company has applied for an advisory meeting (under the national "Scientific Advice" procedure) with the German Paul-Ehrlich-Institut (PEI) to clarify the details of the trials necessary to register MabionCD20 manufactured on a 2x2500L scale with the EMA;
- the trial protocol has been updated in accordance with the EMA comments in the Scientific Advice dossier;
- in January 2020, the Company took part in a meeting with the FDA. Then, in May 2020, the Company sent the FDA a set of further questions specifying clinical parameters, as well as detailed comparative analyses. The Company has proposed additional variants of the bridging clinical trial in connection with the restrictions caused by the SARS-COV-2 coronavirus pandemic; on 11 August 2020, a Type II meeting with the FDA was held.

MabionMS

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

In 2018, the Company filed another patent application with the Patent Office of the Republic of Poland (with the possibility of extension under the PCT procedure) for the area of application of MabionCD20 in the treatment of patients with MS, entitled "Low aggregate anti CD20 ligand formulation". This is the second patent application in the area of use of MabionCD20 for the treatment of multiple sclerosis, constituting an innovative indication for the molecule. The said application concerns the use of MabionCD20 as a monotherapy.

In July 2020, the Company filed international patent applications for the invention entitled "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand" (combined therapy) to selected patent offices, which initiated a national and regional phase to obtain patent protection in several dozen countries. Based on statistics on multiple sclerosis in individual regions, as well as the potential of individual markets, Mabion submitted patent applications to selected patent offices covering countries such as the US, Canada, the UK, the EU and EFTA countries, Australia, New Zealand, Israel, Turkey, Russia, and several others. The start of the national and regional patent application phase in each country is the next step to obtain legal protection for this innovative therapy.

Currently, the Company is looking for partners for further work related to the development of the above-mentioned therapy.

In 2019, the Company prepared both a clinical trial synopsis and a Briefing Package. The content and regulatory assumptions of the project were consulted with external experts in the area of clinical trials in multiple sclerosis therapy. After consultation and approval of the final version of these documents, the Company submitted them to the EMA in August 2019 and received a response from the regulator confirming part of the assumptions. The event started the process of scientific consultations with the EMA in order to confirm the compliance of the project assumptions with the Agency's requirements. The consultation with regulators is a multi-stage process, which may consist of research and development reports and a round of Scientific Advice enquiries. The timing of reaching a consensus in the course of the consultation may be difficult to predict.

MabionEGFR

The MabionEGFR project concerns the development of a drug for the treatment of patients with metastatic colorectal cancer showing expression of epithelial growth factor receptor (EGFR), with wild type RAS genes, and in patients with squamous cell carcinoma in the head and neck.

Within the scope of the project, the Company is in the process of developing technological bases and analytical tools. Part of the expenditure related to the development of the drug is co-financed from EU funds. With regard to the above project, in the first half of 2020, the Company continued its activities related to:

- determining the scope of the quality target product profile (QTPP) for qualitative attributes of protein on the basis of the results of the analysis of the current pool of the reference product batches;
- developing a reference material bank;
- developing biological and physico-chemical analytical methods to characterise the protein obtained;
- initial optimisation of the antibody purification conditions.

At the same time, the Company successfully completed the first stage of the project co-financed by the National Centre for Research and Development (NCBiR), entitled "Development of a biotechnological drug through the development of an innovative monoclonal antibody of the IgG1 subclass with a reduced content of unfavourable glycosides against the reference drug - directed against EGFR". The stage involved reaching a milestone in achieving a stable cell line producing a cetuximab biosimilar antibody. The company obtained the cell line and verified its stability. Detailed tests of the quality of the obtained protein were also carried out based on the available analytical methods. The results confirmed the achievement of the assumed goal of the project stage.

Business development: Covax-19™

On 14 September 2020 (an event after the balance-sheet date), Mabion announced that it entered into a Memorandum of Understanding with Vaxine Pty Ltd., an Australian biotech company, to work out arrangements for the process development, production and commercialization of Covax-19™ which is a possible vaccine for COVID -19 caused by the Sars-Cov-2 virus, with particular focus on the Polish and European Union markets.

Vaxine is developing Covax-19™, a potential COVID-19 vaccine based on a proven, scalable platform using recombinant insect cell-based protein. In combination with Vaxine's patented Advax™ adjuvant, Covax-19™induces an immune response of T cells against the jointly produced antigen. In various animal trials, Covax-19™ has proven to provide robust protection against COVID-19 infection.

In July this year, Vaxine started Phase I of its clinical trials on Covax-19™ to test the vaccine in 40 healthy volunteers. Based on the safety data from the initial study, regulatory authorities approved further clinical development of the vaccine.

The memorandum of understanding states that the parties are to negotiate and conclude, if they deem it appropriate, agreements concerning the manufacturing of Covax-19™ by Mabion, the process work to be carried out, and the commercialization of Covax-19™ by Mabion in agreed markets, and, prior to entering into agreements, to conduct mutual due diligence and cooperate in arranging future government or EU funding or reimbursement.

After the possible finalization of the cooperation agreement, Mabion would become a partner of Vaxine, leading the future clinical development, production and commercialization of the vaccine on the Polish and European markets.

As part of the intended cooperation, the companies plan to quickly launch further clinical trials in Europe, which will be possible thanks to the decisions of the European Medicines Agency (EMA) to speed up regulatory procedures in order to release safe and effective vaccines and drugs with the COVID-19 treatment indication as soon as possible.

The memorandum of understanding between Mabion and Vaxine is aimed at negotiating and concluding further agreements setting out the terms and conditions of cooperation, including those relating to clinical development, production and marketing of the vaccine. However, the memorandum is intentional and non-binding, and its conclusion does not prejudge the conclusion of an agreement or future cooperation of the parties. Either party may terminate the memorandum if the parties do not conclude the relevant agreements by 30 October 2020, or if, in the opinion of the party concerned, the outcome of the due diligence is negative.

Retrofitting an existing plant

The investment, which is the subject of permit No. 301 for conducting business activity within the Łódź Special Economic Zone, consists in increasing the production capacity of the current plant and includes retrofitting of the existing production line 2x2500L, and purchase and installation of production equipment for the second production line 2x2500L, which will be located in the existing building. Under permit No. 301, the Company undertook to incur investment expenditures within the Zone amounting to at least PLN 20 million (within the meaning of § 6 of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit to conduct business activity in the areas of special economic zones).

On 7 February 2020, the Minister of Development gave consent, at the request of the Company, to amend permit No. 301 by extending the deadline for incurring investment expenditure from 31 December 2019 to 30 June 2021. The application for the above change resulted from the change of the schedule for the commencement of the Company's investment. The investment is planned to be completed by 31 December 2021.

On 23 June 2020, the Company received a control record concerning the implementation by the Company of the condition of permit No. 301 in the scope of maintaining employment in the Zone at the level of at least 100 employees in the period from 2 March 2017 to 1 March 2020. On the basis of the control activities, it was concluded that the aforementioned condition has been fulfilled.

Under permit no. 301, as of 30 June 2020, the Company incurred investment expenditure of PLN 2.8 million.

Extension of the plant

In 2017, the Company commenced preparatory activities related to the expansion of the existing plant (MABION II), which will result in a significant increase in the Company's production and research and development capacities. A concept for the expansion of the Scientific-Industrial Complex for Medical Biotechnology was developed, and in 2018, the Management Board of the Company selected an international consortium of architectural and technological companies, to which it entrusted the development of a technological and construction design. In 2018, the Company received a decision of the Starost of Pabianice to approve the construction design and grant a building permit for the above mentioned investment, entitled "Scientific and Industrial Centre for Advanced Medical Biotechnology for Mabion S.A." together with the necessary infrastructure in Konstantynów Łódzki.

In 2019, work was underway to prepare detailed designs for all construction and installation industries. At the end of June 2020, all detailed designs have been prepared, and the process of checking and receiving them is now underway. In November 2019, an application for a replacement building permit was also submitted, allowing for increasing the volume 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. On 12 February 2020, the Company received the decision of the Starost of Pabianice to change the above mentioned building permit.

Obtaining a building permit and completing the design works enable the commencement of work on the expansion of the existing plant; however, the moment of its commencement depends both on the situation of the Company, including possible leveraging of financing), as well as formal opportunities to enter non-European markets with MabionCD20 as well as other possible products including a vaccine (signed distribution agreements, formal regulatory approvals, etc.).

3.2. Description of significant achievements and failures of Mabion S.A. in H1 2020 and by the date of publication of the report

Registration procedure for MabionCD20 with the European Medicines Agency (EMA)

On 13 January 2020, as a result of telephone consultations with the EMA, the Company planned to submit in January 2020 an answer to the list of questions received from the EMA in December 2019. This was to enable the Company to continue to process its registration application at the meeting of the Committee for Medicinal Products for Human Use (CHMP) 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 to the list of questions 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 does not include rheumatoid arthritis (duplicate application). The submission of the answers allowed the EMA to continue its evaluation of the applications., whereas due to the fact that the regulator has a number of tools at its disposal to ensure its discretion and the possibility of adjusting the solution individually to the needs of a given registration procedure, the Company has stressed

that it had no influence on the assessment of the EMA and that there were a number of possible subsequent events - issuing 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 envisaged 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, which was scheduled for 24–27 February 2020. On 26 February 2020, the Management Board of the Company participated in the meeting of CHMP together with the team, presenting the issues indicated by EMA in the invitation (oral explanation).

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 with the Food and Drug Administration (FDA) was held 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 United States of America. During the meeting, there was a productive discussion on the data needed to apply for registration in the USA for all indications of the reference drug. The company was invited to contact the FDA on a regular basis in order to smoothly implement activities aimed at filing the registration application in the USA. The Type 3 BPD meeting was a stage of implementation of activities aimed at obtaining registration of MabionCD20 in the USA, however, holding it does not guarantee a positive effect of these activities.

On 14 February 2020, the Company received from the FDA a summary of the Type 3 Biosimilar Biological Product Development (BPD) meeting with the FDA held on 22 January 2020 and attended by representatives of the Company and the FDA. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the United States of America. The Company has proceeded to analyse the document received and the applications and guidelines contained therein, as well as to assess their impact on the actions planned by the Company to date to register and admit the drug to trading in the USA. The Company has reserved that the process of registration and approval of the drug for marketing in the United States was multi-stage and it cannot be ruled out that additional requirements related to product approval by the FDA might appear in the future.

The Company informed about the above events in Current Reports no. 4/2020 of 22 January 2020 and no. 12/2020 of 14 February 2020.

On 28 August 2020 (an event after the balance-sheet date), the Management Board informed that the Company received a summary of the Type 2 BPD meeting with the FDA on the registration and marketing authorisation of MabionCD20 in the USA. The purpose of the meeting was to clarify the details of clinical development of MabionCD20 for the US market. The Company received confirmation from the Agency of a number of proposed clinical programme parameters, including the ability to use the significant data packages generated for the approval of MabionCD20 in the EU. This confirms previous consultations in which the Agency indicated that it was not necessary to conduct a completely separate development programme for MabionCD20 to market the drug in the US. In addition, the Company has begun to verify with the Agency whether it is possible to apply an innovative regulatory strategy that allows for an earlier initial application for registration than originally envisaged and proposed by the Agency. The Company accepted the Agency's suggestion to clarify the details of this approach at another separate meeting. The arrangements are non-binding for the Agency. The Company informed about this event in current report no. 32 on 28 August 2020.

Permit to conduct business activity within an economic zone

On 7 February 2020, the Company received the decision of the Minister of Development on the change of permit no. 301 obtained in January 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 expenses in the amount of at least

PLN 20 million 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 activity in the areas of special economic zones was extended from 31 December 2019 to 30 June 2021. The application for the above change resulted from the change in the schedule of the Company's investment commencement. At the same time, the deadline for completion of the investment planned for 31 December 2021 did not change.

On 23 June 2020, the Company received a control record concerning the implementation by the Company of the condition of permit no. 301 to conduct business activity in the Łódź Special Economic Zone (the Zone) in terms of maintaining employment in the Zone at a total of at least 100 employees in the period from 2 March 2017 to 1 March 2020. On the basis of the control activities, it was concluded that the aforementioned condition has been fulfilled. The remaining conditions of the above mentioned permit are: to incur the above-mentioned investment expenditure in the Zone and to complete the investment by 31 December 2021.

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

Change of the building permit for the Science and Technology Centre

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

Change of the regulatory strategy for MabionCD20 in the EMA and withdrawal of registration applications

On 16 March 2020, the Company's Management Board decided to modify the regulatory strategy for MabionCD20 pursued in the procedures carried out with the EMA. The main change is to obtain a marketing authorisation in the EMA directly for the medicine manufactured on a large commercial scale as opposed to the two-year strategy pursued so far (obtaining a small scale marketing authorisation and then on the basis of a variation, obtaining large scale authorisation). The Company's Management Board made its decision on the basis of the opinion of external consultants received on 16 March 2020 and the recommendation of the Company's Supervisory Board. The change of strategy is related to the withdrawal of registration applications submitted on 1 June 2018 and 6 May 2019.

On 30 March 2020, the EMA website published information confirming the withdrawal of the Company's registration applications submitted in June 2018 and May 2019. The confirmation of the withdrawal of the registration application by the Company has ended the previous registration procedure initially based on a two-year strategy (obtaining approval for a small scale and then submitting a variation for a large scale manufacturing process). Although the Company responded to the vast majority of queries for additional information, in light of the Company's objective of registering a product based on a high quality, commercially attractive large-scale production process, the Company, given its interactions with the EMA to date, decided that the data will be revised in future application, and therefore the applications for the small-scale manufacturing process were withdrawn.

In line with the Company's intention the new application, in which the target scale will be evaluated by the Agency, was to be be submitted after obtaining validation and biosimilarity data of the product coming from the large production scale. However, the scope and format of the new applications will first be consulted with EMA representatives as part of the Scientific Advice procedure in order to adapt them to the Agency's expectations, which will streamline the registration procedure. For procedural and formal reasons, the Company could not proceed with the applications submitted earlier with additional data on the large scale. In the opinion of the Company's Management Board, the change of strategy was the most optimal path in terms of both cost and time of product registration and the possibility of commercialising MabionCD20 in the European Union.

The decision did not affect the original schedule of work on the large-scale manufacturing validation and bridging clinical trial as well as work on registering MabionCD20 in the US market. At the time of the decision to change the strategy, work was underway to launch the 3rd large-scale production validation batch.

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.

On 30 March 2020, the EMA published a "Questions and Answers" document ("Q&A"), containing a short summary of the process, but details of the completed registration procedure (European public assessment report, EPAR), in line with the EMA regulations, were published by the regulator on 25 June 2020. The EPAR will be based on the latest CHMP-approved version of the assessment report (version from Day 195 of the registration procedure), which identified more unresolved issues than those pending at the time of withdrawal of the application, and therefore the report will not reflect the most current status of the completed 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.

Arrangements for financing the Company' s operations

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

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 coronavirus pandemic announced by the WHO (World Health Organization) worldwide, the Management Board of Mabion S.A. provided information on the possible impact of this situation on the Company's operations. The Management Board identified that the Company's operations may be temporarily affected by reduced availability of employees and, consequently, delays in research and development processes, due to the need to introduce home office for certain positions. The Management Board indicated that it has some control over the pace and continuity of manufacturing processes, but it cannot be ruled out that the introduction of home office for certain positions and the potential for 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 are focused on maintaining progress and completing work on the MabionCD20 validation, enabling the transition to the next 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 planned schedules, and there were no delays in the delivery of components, materials, machinery or equipment. However, it could not be excluded that such delays may occur in the future. The Management Board of the Company also recognized the risks associated with the liquidity disruption in the markets resulting from the spread of the SARS-CoV-2 virus and the consequent possible restriction of the Company's access to funding. In addition, the Company has noted potential shifts in administrative processes, including both in the area of decisions of the authorities regulating the

release of medicinal products to the market and in the area of decisions of public bodies granting and settling subsidies and grants or VAT refunds. At the moment of submitting the current report, as well as until the date of publication of this interim report, the Management Board did not receive any information from the indicated authorities concerning any shifts in the processes underway. The Management Board further observed that the persisting pandemic, including, among others, passenger traffic limitation, might contribute to 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 ongoing talks. Due to the high dynamics of the events, the Company's Management Board monitors the situation on an ongoing basis, and the Company complies with all applicable administrative decisions. The Company informed about the impact of the SARS-CoV-2 virus spread on the operations of Mabion S.A. in Current Report no. 17/2020 of 16 March 2020. Information on the current impact of SARS-CoV-2 on the Company's operations is presented in point 4 of this report.

Intention to carry out the issue of U and V series shares of the Company

On 18 May 2020, the Company's Management Board decided to issue up to 1,907,281 U-series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each, in order to increase the share capital of the Company. On 18 May 2020, the above decision was also positively assessed by the Company's Supervisory Board. In connection with the above, the Company proposed an item in the agenda of the Ordinary General Meeting of the Company providing for the adoption of a relevant resolution.

On 15 June 2020, the Ordinary General Meeting of the Company (OGM) adopted a resolution on increasing the Company's share capital by an amount not lower than PLN 0.10 and not higher than PLN 190,728.10 to the amount not lower than PLN 1,373,027.30 and not higher than PLN 1,563,755.30 by issuing not less than 1 but not more than 1,907,281 ordinary bearer shares with a nominal value of 0.10 PLN each.

The purpose of the planned issue is to obtain additional financing for the Company's working capital, and in particular to accelerate the development of MabionCD20 and to achieve the milestones aimed at submitting a marketing authorisation application for MabionCD20 to the EMA as soon as possible. In addition, the Company will continue the required development work to obtain registration in the US. The capital obtained will allow Mabion S.A., a fully integrated company certified in the field of Good Manufacturing Practice (GMP), to further develop based on the Company's previous experience, a solid quality process, experienced and qualified personnel, as well as technological capabilities.

The shares shall be issued in the form of a private placement within the meaning of Art. 431 §2(1) of the Commercial Companies Code, carried out by way of a public offering exempt from the obligation to publish a prospectus within the meaning of the relevant provisions of the law, or another information or offering document for the purposes of such an offering. In particular the selection of investors to whom offers to acquire shares will be made shall take into account the book-building process or another process aimed at acquiring entities holding shares. In the interest of the Company, all existing shareholders of the Company have been deprived of their pre-emptive rights to all new issue shares in full. The Management Board of the Company has been authorized to determine the issue price of shares, however, the issue price of one share may not be lower than 90% of the average market price of the Company's shares, being the arithmetic mean of the average daily prices of the Company's shares weighted by the volume of trade (excluding holding transactions) from the period of 30 days preceding the date of commencement of the book-building process or another process aimed at acquiring entities taking up shares, during which the Company's shares were traded on the regulated market. Share subscription agreements may be concluded no later than 6 months from the date of adoption of the resolution, that is no later than 15 December 2020. U series shares will be dematerialized and will be subject to application for admission and introduction to trading on the regulated market operated by the Warsaw Stock Exchange.

As a consequence of the above, on 15 June 2020, the OGM also adopted a resolution on a conditional increase of the share capital by not more than PLN 5,595.40 through the issuance of not more than 55,954 V series ordinary bearer shares and the issuance of not more than 55. 954 D series registered subscription warrants, entirely addressed to the European Investment Bank (EIB), to perform the agreements concluded with the EIB in 2019 (financing agreement and warrant agreement), obliging the Company to issue and offer to the EIB a specific number of subscription warrants in case the Company's share capital is

increased. In accordance with the provisions of the warrant agreement and the resolution of the OGM, the issue price of one V series share will be PLN 0.10 and the subscription warrants will be issued free of charge. The right of the holders of subscription warrants to subscribe for V series shares may be exercised until 29 November 2029 on the terms and conditions specified in the resolution of the OGM.

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. Until the date of publication of this report, amendments to the Company's Articles of Association related to the above resolutions of the OGM were not registered in the National Court Register.

"Scientific Advice" consultation with EMA

On 1 July 2020 (an event after the balance-sheet date), the Company received a written response from the EMA under the Scientific Advice procedure (i.e. scientific consultations with EMA representatives) concerning the Briefing Package submitted by the Company in April 2020. The document contains the Agency's response to the individual assumptions of the Company concerning the new registration process of MabionCD20. In particular, in refers the scope of data to be included in the new registration applications, as well as actions required to generate such data proposed by the Company. In the opinion of the Company, the consultation with the EMA allows for a significant reduction of uncertainty and regulatory risks, as well as for optimisation of the time and effort required for the submission of a marketing authorisation application (MAA) and its regulatory review. However, the Company points out that due to the specific responsibilities of regulatory authorities the content of the document is subject to interpretation, which creates some risk of discrepancies in interpretation. The Company informed about the event in Current Report no. 28/2020 of 1 July 2020.

Preliminary assumptions for the second registration application for MabionCD20 to the EMA

On 9 July 2020 (an event after the balance-sheet date), the Management Board of the Company, after internal analyses, consultations with external experts and arrangements with the Supervisory Board of the Company, adopted preliminary framework assumptions concerning the scope and schedule of work necessary to submit a new marketing authorisation application (MAA) for the product. As at the date of publication of the current report, the validation of the large-scale manufacturing process of MabionCD20 based on three validation batches was completed. Initial analytical tests prove that the batches produced meet the requirements for all quality attributes analysed at the DS level. In addition, the Company has started product stability tests, and will soon start biosimilarity and bioequivalence tests. In order to broaden the scope of 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 large scale product batches. In the Company's opinion, presenting a broad package of analytical data would significantly reduce the residual regulatory risk.

In addition to generating the analytical data package, the Company intends to conduct a smaller-scale bridging clinical trial (Phase I/II trial) for the purposes of the registration dossier, which, in the Company's opinion, is required to demonstrate comparability and at the same time will make it possible to reduce the aforementioned risk, thus reducing the costs and duration of the preparation stage for the registration process. The Company has developed a draft protocol for the bridging clinical trial (3-arm clinical trial, scope of study: safety and pharmacokinetics, indication: rheumatoid arthritis, scale: estimated >80 patients per arm), which will aim to confirm the biosimilarity between MabionCD20 and MabThera and Rituxan. Based on the above assumptions, the Company estimated that the work to obtain the data necessary to submit a new marketing authorisation application, including a bridging study, will be completed before or in early 2022. The planned activities according to the Company's best estimates involve a net outlay of approximately PLN 75-85 million over the assumed period of time, of which approximately 70% will be R&D costs (estimates include the bridging study). The remaining expenditure is made up of production and maintenance costs (additional validation batches), costs of the regulatory process (including fees to the EMA) and expenditure on quality assurance and control. Estimates do not include costs of day-to-day operations and capital expenditure related to capacity expansion. The Company does not exclude the possibility of modifying the above mentioned assumptions if such a need arises. 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 maintaining the cost of the process at a level that can be financed by the Company and to conduct the product registration procedure as soon as possible. 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 time frame, including factors beyond the Company's control (such as the speed of recruitment in clinical trials). Moreover, the assumptions made and actions performed do not guarantee product registration. The Company informed about the event in Current Report no. 29/2020 of 9 July 2020.

Loan agreements with the shareholders of the Company

On 15 July 2020 (an event after the balance-sheet date) the Company concluded with Glatton Sp. z o.o. - a related party and a shareholder holding directly and indirectly a total of 11.85% of the Company's share capital - a loan agreement in the amount of PLN 15 million, in order to refinance the revolving credit facility granted to the Company in 2018 by Santander Bank Polska S.A. The Company informed about the granting of the revolving loan in Current Report no. 55/2018 of 17 July 2018, however, under the credit agreement the Company used only the amount of PLN 15 million. The loan agreement with Glatton Sp. z o.o. entered into force on 16 July 2020. The Company's Supervisory Board gave its consent to conclude the loan agreement. The loan forms an additional financing not included in the financing declared on 16 March 2020 by the Company's main shareholders. According to the loan agreement, the Company is obliged to repay the loan by 31 December 2020. However, the parties allow for the possibility of extending the aforementioned deadline. The interest rate on the loan was agreed on market conditions as a variable interest rate based on WIBOR 3M increased by a margin. The loan is secured by: a mortgage on a real estate located in Konstantynów Łódzki up to the amount of PLN 45 million with priority right over other potential mortgage creditors and a statement on submission to enforcement in the form of a notarial deed. Subject to the mortgage referred to above, the nominal value of the collateral for the benefit of the lender will be jointly equal or higher than 150% of the loan amount.

On 12 August 2020 (an event after the balance sheet date), the Management Board of the Company, having obtained relevant consents of the Supervisory Board, concluded, with Twiti Investments Ltd. and Glatton Sp. z o.o. (Lenders), loan agreements up to the total amount of PLN 15 million. Entering into the agreements implements the Company's shareholders' declaration of 16 March 2020 on the recapitalization of Mabion S.A. The loans may be paid out by the Lenders to the Company in tranches, in amounts and on dates set by the parties in separate schedules of payments, with the Lenders paying out tranches each time upon written request of the Company. The interest rate on the loans, the same for each of the agreements, has been agreed upon on market terms as a variable interest rate based on WIBOR 3M plus margin. The loans shall be repaid by way of conversion into U-series shares to be issued under the terms and conditions established by the resolution of the Ordinary General Meeting of the Company dated 15 June 2020 (share subscription agreements in accordance with the resolution of the OGM should be concluded not later than 15 December 2020) or repaid in cash not later than 31 March 2021).

The Company informed about the above events in Current Reports no. 30/2020 of 15 July 2020 and no. 31/2020 of 12 August 2020.

Conclusion of a memorandum of understanding regarding potential cooperation on development, production and commercialization of a Covid-19 vaccine candidate

On 14 September 2020 (an event after the balance-sheet date), the Company concluded a Memorandum of Understanding ("MoU") with Vaxine Pty Ltd. based in Australia ("Vaxine") to make arrangements with respect to the process development, production and commercialization of the Covax-19™ product which is a possible vaccine for Covid-19 disease caused by the Sars-Cov-2 virus ("Product"), with particular emphasis 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. Covax-19™ is a product developed by Vaxine based on a scalable vaccine platform using recombinant insect cell-based protein combined with the patented Advax™ adjuvant to enhance both the antibody and immune response of T-cells against the commonly administered antigen. Covax-19™ is currently in Phase I of clinical trials and also has the appropriate approvals to start Phase II of clinical trials in Australia after the results of Phase I have been obtained.

The MoU provides that the parties are to negotiate and conclude, if they deem it appropriate, agreements regarding Mabion's manufacture of the Product, the process work to be performed, and Mabion's commercialization of the Product in agreed markets, and, prior to concluding agreements, to carry out mutual due diligence and cooperate in arranging future government or EU funding or reimbursement.

The Company has reserved that the MoU is intentional and non-binding, and its conclusion does not prejudge the conclusion of an agreement or cooperation of the parties in the future. Either party may terminate the MoU if the parties do not conclude the relevant agreements by 30 October 2020 or if, in the opinion of the party concerned, the outcome of the due diligence is negative. At the same time, the Company has assured that the potential establishment of the above cooperation will not have a negative impact on the implementation of the Company's current projects, and in particular, it has assured that the development and commercialization of MabionCD20 will remain its priority. The Company informed about this event in its Current Report no. 34/2020 of 14 September 2020.

3.3. Transactions with related parties

In the first half of 2020, the Company did not conclude transactions with related parties on terms other than market terms.

In the first half of 2020, the surety granted to the Company in 2018 by Glatton Sp. z o.o. (an entity related to the Company) was in force in the amount up to 45 million PLN. The surety related to the revolving credit agreement of 17 July 2018 concluded by the Company 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 on market conditions an agreement with Glatton Sp. z o.o., the above-mentioned affiliate, regulating the principles of payment by virtue of the surety granted, referred to above. Then, on 15 July 2020 (an event after the balance-sheet date) the Company concluded a loan agreement with Glatton Sp. z o.o. in the amount of PLN 15 million to refinance the revolving loan granted to the Company in 2018 by Santander Bank Polska S.A. The funds received were used to repay, on 17 July 2020, the entire debt under the loan contracted with Santander Bank Polska S.A. Thus, the surety of Glatton Sp. z o.o. referred to above ceased to apply.

On 12 August 2020 (an event after the balance-sheet date), the Company concluded loan agreements with Glatton Sp. z o.o. and Twiti Investments Ltd. to implement the support documents received on 16 March 2020 from major shareholders. According to the agreements, the financing will be paid out in tranches of up to PLN 15 million until the end of 2020.

3.4. Information on granted guarantees and sureties for a loan or credit facility

In the first half of 2020, the Company did not grant any credit or loan sureties or guarantees jointly to one entity or its subsidiary, where the total value of the existing sureties or guarantees would be significant for the Company.

3.5. Description of basic threats and risks for Mabion S.A.

Risk related to the macroeconomic, legal and political situation

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

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

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

Risk of force majeure

If unforeseen events occur, such as wars or terrorist attacks or epidemics, adverse changes in economic conditions and the financial market may occur, which may adversely affect the Company's financial condition. In addition, such random events as

fires, floods and other extraordinary natural disasters may cause failures or destruction of material property belonging to Mabion S.A., as well as disruptions to the Company's operations, which may adversely affect the Company's financial results.

Risk related to operations carried out on an international scale

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

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

Risk related to the coronavris (COVID-19) pandemic

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

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

- delays in the acceptance and commissioning of the ordered equipment resulting from the limitation of the possibility of performing calibration of the equipment by representatives of external companies;
- problems with guaranteeing all the resources necessary to conduct research as a result of production limitations and depletion of inventories of external companies cooperating with the Company;
- the possibility of plant closure in order to limit the possibility of virus spread;
- a possibility that restrictions will be introduced by the governmental administrations of individual countries that will hinder the launch of a clinical trial or affect its organization and duration.

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

With regard to the epidemic risk, the Management Board has taken steps to significantly reduce the risk both through the education of employees and the implementation of solutions to protect workers' health (e.g. a resolution was adopted on the introduction of countermeasures by the Management Board, together with later updates, in connection with the entry into force of the Act of 2 March 2020 on special solutions related to the prevention, counteracting and combating of COVID-19, other infectious diseases and crisis situations caused by them (Polish Journal of Laws, item 374 of 2020). The Management Board is monitoring the situation on an ongoing basis and in the event of significant new circumstances related to the coronavirus COVID-19 pandemic and affecting the Issuer's operations, the Company will introduce appropriate solutions, adapting to administrative decisions

Risk related to changes in legal regulations and their interpretation

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

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

Risk related to the tax policy

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

Risk related to administrative decisions

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

Exchange rate risk

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

Market risk

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

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

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

Oncological diseases on which the ongoing R&D efforts are focused are the most intensively studied group of diseases in biomedical sciences. Clinical development activities for oncological drugs are undertaken by more than 700 companies and are at a record high level, and the estimated expenditure will have a CAGR (until 2023) of 11-14%[4]. 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 in April 2020 Pfizer has received the European Commission's consent for its antibody. In the US, Celltrion and Pfizer have received a positive regulatory approval. In December 2019, Amgen submitted an application to the FDA for registration of a biosimilar rituximab.

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

4 Global Oncology Trends 2019, IQVIA Institute

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 confirmed by the fact that in November 2018, Sandoz resigned from applying for admission to trading in the US of its drug biosimilar to MabThera/Rituxan , after the regulator applied for additional data[5].

Partnering risk

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

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

However, it cannot be excluded that Mylan's position may change in the future. Mabion has no influence on the scope of cooperation of third parties and it cannot be completely excluded that the development strategy for medicinal products adopted by the new entity (Viatris) will be competitive in relation to the Company's offer. On 30 June 2020, Mylan's shareholders opted for the merger, which will take place in the fourth quarter of 2020 due to the COVID-19 pandemic.[6]

In addition, as a result of the change in Mabion's regulatory strategy in March 2020 and the withdrawal from the EMA of registration applications for MabionCD20, the introduction of the drug to the European market will be delayed in comparison to the original arrangements with Mylan. The existing agreement with the distribution partner provides for the possibility of termination after 2020 in the absence of drug registration by that time. In the event of termination of the agreement, Mylan will be entitled to demand from the Company the reimbursement of a significant part of the payments made in the past as shown in note 17 to the financial statements.

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

Risk related to the research and development process

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

[5] http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681
[6] https://www.bizjournals.com/pittsburgh/news/2020/06/30/mylan-shareholders-approve-upjohn-merger.html

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 generally adopted by the biotechnological industry, the development and production of a biosimilar which meets global standards lasts about 10 years and costs between USD 100 and 300 million[7]. Guidelines relating to biosimilars are only now being formed and each case is analysed by market regulators individually, therefore, the scope of requirements relating to the technology, documentation, analytics and clinical development is not strictly specified. Therefore, the exact scope of research and development work cannot be determined, and the development costs of the medicines cannot be precisely anticipated.

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

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

- amendments to the regulations concerning the production of medicines and the need to use more expensive technological solutions or creating entirely new ones;
- increase in the costs of purchase of raw materials and materials used to manufacture medicines, following from the market conditions or new guidelines;
- amendments to regulations concerning the scope of analyses needed to characterise the product, e.g. the need to perform additional costly analyses or develop new analytical methods or tools;
- increasing requirements concerning registration documentation, e.g. the need to perform additional trials or studies.

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

Risk related to the work schedule

The achievement of the Company's strategic goal, which is the registration and market launch of biosimilars as soon as possible after the expiry of patent protection of the original medicines, is connected with the need to develop a detailed work schedule for several years. The possibility of pursuing this schedule depends on many various factors, both internal and external. Potential

[7] The impact of biosimilar competition in Europe, October 2019

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[8]. The Company's goal was to market MabionCD20 as soon as possible after patent expiration, which would allow the Company to achieve a temporarily favorable competitive position.

In order to prevent registration risks, the Company, since the start of work on the development of MabionCD20, has cooperated with EMA regarding compliance with guidelines and procedures related to the registration process in the European Union. It has held scientific advice sessions to eliminate doubts and to refine the activities related to the preparation of registration documentation. However, the EMA has a number of tools at its disposal to ensure the regulator's discretion and the possibility of adjusting the solution individually to the needs of a specific registration procedure. The Company has no influence on the EMA's assessment of applications and responses. There are a number of possible events in the registration process - positive or negative decisions, obtaining a list of additional questions (once or more), filling in a round of oral answers (once or more), withdrawal of the application by the Company and its resubmission after supplementing, or other events not envisaged by the Company. The schedule of work on the part of the Company also depends to a large extent on the recommendations of the regulator, which the Company may receive during the aforementioned scientific advice sessions. For the US market, the Company is actively pursuing a consultative process with the FDA, the purpose of which is to determine and perform activities consistent with the FDA's expectations and necessary for the registration of MabionCD20 in the United States. However, there is a risk that after analysis of data presented by the Company in the consultation process, FDA will indicate the need for additional work to be carried out by the Company, which may affect the schedule of drug registration in the USA.

Risk related to low quality or loss of biological material

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

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

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

Risk related to the production process and the quality control process

One of the key elements in the production of biotechnological medicines is the production process, which must be carried out in compliance with the previously planned parameters. The process of producing such medicines consists of several stages and even the smallest change in any of them may negatively affect the properties of the drug (e.g. in terms of efficacy or safety).

8 Global Data

An extremely important element of the medicine manufacturing process is the transition from a small laboratory scale to the scale of industrial production (so-called up-scaling). It is very important to ensure continuity, including quality control of the product at intermediate and final stages, and stability and purity of the entire production process. The Quality Control Laboratories have been equipped in line with the highest pharmaceutical standards. A panel of validated analytical methods ensures maximum accuracy, precision, specificity and repeatability of the results. The panel is designed in accordance with the requirements of the regulator's guidelines and enables reliable product control. A key parameter of analytical methods is their variability, which is influenced by a number of factors determined during the validation. Constant control of the method variability over time is critical in the case of tests in which the results are collected over years (e.g. product stability, biosimilarity and bioequivalence studies). Lack of reliable trend analysis of methods may adversely affect the final assessment of both the production processes and bioequivalence of the test and reference products. The materials used in the production zone have appropriate certificates for use in the pharmaceutical industry. The installed production line is based on sterile materials. The managing staff of the Company's departments are high-ranking specialists with a major education background, trained and properly prepared to carry out their scope of duties, both by internal and external experts.

The Company's production also depends on key suppliers. In the case of disposable technology, the Company depends on specialist solutions (disposable bags) and this may have an impact on production. In addition, the quality of the bags may vary and, in some cases, may affect the product, which will make it unsuitable. The Company is also dependent on timely deliveries and the quality of all raw materials essential for the effective manufacturing of products. Even if the Company is able to successfully produce commercial quantities at our plant, it cannot guarantee that it will not face challenges in terms of guaranteeing a stable supply to global markets in the future.

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

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

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

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

Currently, it is difficult to estimate the precise demand for Mabion CD20, but the plans to sell the medicine on the US market and other markets are connected with the need to increase production capacity above the level possible at the present plant in Konstantynów Łódzki. The company is aware of these needs and it took care of the possibility of increasing its production capacity. 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.

There is a risk related to possible delays in the construction schedule and its conformity with the Company's expectations and needs, and thus the risk of failure to achieve production capacity in line with demand. However, the Company will implement this investment based on its own experience gained during the construction and operation of the plant in Konstantynów Łódzki, as well as in cooperation with outstanding external experts.

Risk related to clinical trials

One of the important stages of work related to the preparation for registration and marketing of medicines is clinical trials. Conducting clinical trials involves risks that can be divided into the following groups:

» the risk that the trial protocol is not properly planned, leading to the impossibility of obtaining sufficient data of defined statistical significance for the regulatory agencies;

» risks associated with insufficient efficacy or safety of the tested medicinal product;

» risks associated with conducting the entire clinical trial in a manner inconsistent with GCP requirements;

» risks related to adverse effects of a pandemic, e.g. coronavirus on a clinical trial.

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

The Company, being aware of the potential risk, undertakes a number of activities leading to its minimisation. As part of these activities, all clinical trials planned by the Company, after establishing an internal strategy, are consulted with experienced external independent specialists and regulatory agencies, which allows to obtain a verified trial protocol to ensure the desired results with adequate statistical power.

In addition, the product is analysed using a wide panel of biological and physicochemical analyses before being used in a clinical trial. These analyses are a more sensitive model for the characterisation of the medicinal product than the biological model being a patient and therefore the studies performed significantly reduce the risk of insufficient efficacy or safety of the Company's product used in the clinical trial.

In order to ensure compliance of the clinical trial with the requirements of regulatory agencies, including GCP requirements, the Company has adapted its internal quality system to relevant guidelines. These procedures define both the conduct during the preparation for the trial and the conduct of the clinical trial itself. They also define the requirements for the CRO company conducting the study and how to verify the work performed.

When planning a clinical trial, the Company also takes into account the increased probability of occurrence - as a result of unpredictable situations, such as a coronavirus pandemic - events such as e.g. reduced recruitment of patients to the clinical trial, reduced availability of the reference medicine and other resources necessary for the project, prolongation of administrative processes necessary to conduct the trial, potential closure of borders of certain countries and, consequently, impeded transport of clinical trials. The quality system in force in the Company involves conducting an in-depth risk analysis prior to the commencement of a clinical trial, defining the impact, ways of reducing the probability of occurrence and ways of mitigating the effects of adverse events. Based on information about potential risks such as those mentioned above, the Company develops additional procedures and activities ensuring a smooth implementation of the project, e.g. it selects appropriate countries and centres to guarantee the desired level of recruitment, qualifies a wider number of suppliers of drugs and other resources for the clinical trial, verifies the current administrative and legal status in the countries envisaged for the conduct of the trial or cooperates only with experienced partners who guarantee 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 minimize the probability of risk occurrence 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 the FDA, respectively.

In developing its regulatory strategy for MabionCD20 on a 2x250L 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). Ongoing monitoring and preventive actions undertaken by the Company were aimed at minimising the risk factors indicated.

The original regulatory strategy assumed obtaining a marketing authorisation for a medicine manufactured in a small scale - step 1, and then, on the basis of a variation, a marketing authorisation for a large, commercial scale - step 2. At the same time, the Company carried out works related to the validation of a batch manufactured in the scale 2x2500L. 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 from the EMA directly for the product manufactured on a large commercial scale. In the opinion of the Company's Management Board, the change of strategy was the most optimal path in terms of both cost and time as regards registering of the product coming from the large-scale process and the possibility of commercialising MabionCD20 in the European Union. The scope and format of the new application for the large target production scale is consulted with representatives of the EMA as part of the Scientific Advice procedure, in order to adapt it to the Agency's expectations, which will streamline the registration procedure for the target large scale production process. In July 2020, the Company received a written response from the EMA under the Scientific Advice to the individual assumptions of the Company concerning the new registration process of MabionCD20. In particular, the scope of data to be included in the new registration application, as well as actions required to generate such data proposed by the Company. With the help of external regulatory experts, the Company has analysed the documents received and adopted a preliminary framework for the scope and schedule of work necessary to submit a new marketing authorisation application (MAA) for the product. However, due to the specific obligations of regulatory authorities, the content of the document is subject to interpretation, which creates some risk of discrepancies in interpretation.

Despite the fact that the registration process takes place in accordance with the adopted regulations and according to specific guidelines, the regulators (both the EMA and the FDA) have a number of tools at their disposal which provide them with considerable decision-making freedom and the possibility of individual adaptation of solutions to the needs that occur, in the regulator's assessment, in a given registration procedure. The process of registration and authorisation of a medicine is a multi-stage process aimed at working out the final position of the regulator. Even if the regulator provides guidance and guidelines on the shape and scope of the data currently required, it cannot be ruled out that additional requirements for product approval may arise in the future.

Risk related to launching and maintaining medicines on the market

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

There is a risk that launching Company's medicines on particular global markets will not be compliant with the current assumptions or that as a result of negligence or error in sales, logistics or distribution the medicines will prove to be unsellable on a given market which could have a negative impact on the sales revenue earned by the Company and on its financial results.

Mabion has acquired a distribution partner for the EU and the Balkans and is currently, through the intermediation of Plexus Ventures LLC, actively looking for an experienced and strong partner to effectively sell Mabion S.A. medicines on markets outside the European Union. The process is complex and long-lasting – it consists in contacting companies, signing confidentiality agreements and presenting data at various levels of detail depending on the stage of development of the process. At the same time, the companies are updating their offers.

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

Risk of losing of key employees

Mabion's business is based on the knowledge and experience of its highly skilled managers and scientific and research personnel. However, there is a risk that key employees may leave the Company in the future, which could adversely affect the quality of its products. The Company may also be unable to attract or retain qualified personnel due to strong competition for such personnel among biotechnology, pharmaceutical and other companies. If the Company is unable to attract, retain and motivate the necessary staff to achieve its business objectives, it may face constraints that will make it significantly more difficult to achieve its growth objectives, as well as limit its ability to raise capital and pursue the Company's business strategy. The Company's future performance will also depend, in part, on its ability to successfully integrate newly hired executive officers into its management team and the Company's ability to develop an effective working relationship among senior management. If it is not possible to integrate these people and establish good employee relations between them and other members of management, this may have a negative impact on the Company's performance.

In order to counteract the above risk, the Company's Management Board pursues an active HR policy aimed at retaining the most valuable specialists in the company and supporting their development. The success of the Company depends, among other things, on the continuous ability to attract, maintain and motivate highly qualified management and scientific staff. The Company implements activities aimed at supporting the professional development of its employees, e.g. through their participation in the "Mabion Academy" project which covers internal and external training, support in undertaking doctoral studies, as well as including in the promotion procedure. The rules for obtaining the above-mentioned benefits are formalised, open and objective (e.g. promotion procedures, implementation of bonus schemes for many-year employees, implementation of loyalty programmes and bonus schemes. 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 advisors and experts in the field in question.

Risk related to industrial and intellectual property disputes

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

Risk related to the funding obtained

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

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

The initial deadline for the project was set for 31 December 2019. In June 2019, the Company applied to the NCBR to extend the project implementation by 9 months, i.e. until 30 September 2020. In connection with 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 2020, item 694), the deadlines for completion of projects under the Intelligent Development Operational Programme were extended by 90 days. The extension of the project implementation did not require the submission of an application or consent of the NCBR, but only the submission of a relevant notice. In connection with the submission of the required notice by the Company, the project implementation deadline has now been extended to 29 December 2020.

» *"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 of the date of publication of this report, the project is implemented in accordance with the schedule agreed with the NCBR. The Company has completed Stage I of the project and obtained approval from the NCBR for the report on project implementation for 2019.

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

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

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

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

Liquidity risk

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

With regard to the change in Mabion's regulatory strategy adopted on 16 March 2020 and the withdrawal of applications for registration of MabionCD20 from the EMA, the registration of MabionCD20 to the European market will be delayed as compared to the original arrangements with Mylan. The existing agreement with the distribution partner provides for the possibility of termination after 2020 in the absence of drug registration by that time. In case of lack of registration of MabionCD20 by December 31, 2020, Mylan may terminate the contract, consequently, may require the Company to reimburse most of the advances obtained in Note 17 to the financial statements. The Company continues an ongoing close cooperation with Mylan representatives and exercises due care to ensure that its course is satisfactory to both the entities.

In addition, failure to apply for new EU aid may also expose Mabion to liquidity problems and the need to obtain an alternative source of funding. Also delays in the process of raising capital by the Company through the issuance of shares or its failure to do so may have a material impact on the Company's financial condition.

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

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. Analysis of the financial and asset situation of Mabion S.A.

4.1. Rules for drawing up the condensed semi-annual financial statements

The interim condensed financial statements of Mabion S.A. for the six-month period ended 30 June 2020 have been prepared in accordance with International Accounting Standard 34 "Interim Financial Reporting", approved by the European Union ("IAS34"). The statements are also compliant with IAS 34 issued by the IASB due to the fact that there are no differences between IFRS adopted in the European Union and IFRS issued by the IASB to the extent they concern the Company. The financial statements cover the comparative period from 1 January to 30 June 2019. The financial statements were prepared on the historical cost basis, except for derivative financial instruments, available-for-sale financial assets which have been measured at fair value. The interim condensed financial statements, except for the cash flow statement, have been prepared on the accrual basis.

To prepare the condensed interim financial statement, accounting principles were applied in the unchanged scope in relation to the principles applied in the preparation of the annual financial statement for 2019. The condensed interim financial statements do not contain all the information required for full financial statements compliant with the IFRS adopted in the European Union ("IFRS") and should be read in conjunction with the Company's audited financial statements for the financial year ended 31 December 2019.

In the first half of 2020, there were no changes in the rules of determining the value of assets and liabilities and measuring the financial result.

The interim condensed financial statements have been prepared in accordance with the going concern principle, which provides that the Company will continue its operations in the foreseeable future. Therefore, no adjustments were made to the financial statements, which might be necessary if there was a risk of the Company not continuing its operations. Since its establishment, the Company has focused on conducting research and development activities in order to develop and commercially launch its products. As a result, the Company has incurred operating losses and generated negative cash flows from operating activities. As at 31 December 2019, the Company generated a cumulative loss which resulted in negative equity. On 15 June 2020, the Ordinary General Meeting of the Company adopted Resolution No. 18/VI/2020 concerning confirmation of the continued existence of the Company in connection with the circumstances provided for in Article 397 of the Commercial Companies Code. It is expected that such situation may reoccur in the foreseeable future.

The extension of the registration process poses a risk that cooperation with Mylan will not be continued, the Company will not attract other partners and will not obtain the required funding. These factors indicate that there is considerable uncertainty that may raise doubts as to the company's ability to continue operations in the foreseeable future. The change in the terms of current debt financing agreements and further acquisition of financing available on the market, financing available under EU projects and projects supporting R&D, and exclusive agreements with future distribution partners or support from shareholders (both strategic shareholders and stock market participants) should provide the Company with the financing necessary to complete the registration process and commercialise MabionCD20. The Company actively monitors its environment for the prospects for obtaining new funding opportunities, which will enable it 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. However, the risk related to limited access to funding sources cannot be excluded due to the global liquidity situation and the situation caused by the COVID-19 pandemic and its impact on capital markets.

The interim condensed financial statements of the Company for the period from 1 January 2020 to 30 June 2020 were not audited, but were reviewed by the audit firm PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k.

4.2. Asset situation of Mabion S.A. after the first half of 2020

Sales, costs and financial result

The table below presents an analysis of the results achieved by the Company in the first half of 2020 (in PLN thousand):

	01.01-30.06.2020	01.01-30.06.2019	Change (%)
Net income on sales and equal to them	0	0	0
Costs of products, goods and materials sold	0	0	0
Gross profit (loss) on sales	0	0	0
General and administrative expenses	-9 882	-16.91%	-16.91%
Research and development costs	-20 050	-4.95%	-4.95%
Other operating income and expenses, net	901	22.59%	22.59%
Profit (loss) on operating activities	-29 031	-9.99%	-9.99%
Gross profit (loss)	-30 829	-31 696	-2.74%
Income tax	0	0	n/a
Net profit (loss)	-30 829	-31 696	-2.74%

In the first half of 2020, the Company did not generate any sales revenue. In the 6-month period ended 30 June 2020, the Company incurred a tax loss of PLN 9,286 thousand. The Company did not recognize a deferred tax asset on this loss due to failure to meet the conditions of IAS 12 as to the probability of achieving tax revenues allowing the loss to be utilized before the end of the period. The amount of tax losses from previous years was presented in the financial statements for the financial year ended 31 December 2019.

Company assets and financing thereof

Assets	30.06.2020		31.12.2019		Change (%)
	Value (PLN tousand)	Structure	Value (PLN tousand)	Structure	
Fixed assets	**70 778**	**81%**	**73 246**	**64%**	**-3%**
Intangible assets	1 299	1%	1 448	1%	-10%
Property, plant and equipment	69 284	80%	71 688	63%	-3%
Long-term receivables	195	0%	110	0%	77%
Long-term investments	0	0%	0	0%	0%
Long-term prepayments and accruals	0	0%	0	0%	0%
Current assets	**16 260**	**19%**	**40 299**	**36%**	**-60%**
Inventories	6 061	7%	8 806	7%	-31%
Trade and other receivables	1 546	2%	2 841	3%	-46%
Prepayments	479	1%	682	1%	-30%
Cash and cash equivalents	8 174	9%	27 970	25%	-60%
Total assets	**87 038**	**100%**	**113 545**	**100%**	**-23%**

The value of assets of Mabion S.A. as at 30 June 2020 amounts to PLN 487,038 thousand; this is 77% of the value of the assets as at 31 December 2019.

Liabilities and equity	30.06.2020		31.12.2019		Change (%)
	Value (PLN tousand)	Structure	Value (PLN tousand)	Structure	
Equity capital	**-52 433**	**-60%**	**-21 580**	**-19%**	**143%**
Liabilities and provisions for liabilities	**139 471**	**160%**	**135 125**	**119%**	**3%**
Bank loans and borrowings	16 047	18%	16 390	15%	-2%
Long-term liabilities	2 815	3%	3 435	3%	-18%
Short-term liabilities	71 785	83%	67 404	59%	6%
Prepayments and accruals	48 824	56%	47 896	42%	2%
Liabilities and equity in total	**87 038**	**100%**	**113 545**	**100%**	**-23%**

Cash flow statement

The Company's cash flow statement is presented in the table below (in PLN thousand):

	01.01.2020 -30.06.2020	01.01.2019 -30.06.2019	Change (%)
Net cash flows from operating activities	-15 613	-19 324	-22%
Net cash flows from investment activities	-2 667	-7 041	-55%
Net cash flows from financial activities	-1 516	-1 243	-22%
Total net cash flow	**-19 796**	**-27 608**	**-28%**

In the first half of 2020, the Company generated a negative balance of cash flows from operating activities. The most significant impact on the value of generated cash flows from operating activities was the costs of research and development incurred by the Company.

Selected assessment metrics for the company's financial standing

In 2019 and 2020, the Company did not conduct any sales of goods or services as part of its core activity. At the same time, the Company incurred costs of operating activities in connection with the costs of development work, investments in machines and equipment used for development work and for the production of medicines in the future, as well as costs of general management related to, among others, obtaining financing for ongoing operations.

Therefore, both in 2019 and 2020, the Company recognized a loss on operating activities and a net loss, and therefore it is not possible to determine financial ratios for the Company related to profitability.

4.3. Description of factors and events that have a material impact on the condensed financial statements

In the first half of 2020, there were no factors or events other than those indicated in other points of the report, including events of extraordinary nature, which could have a significant impact on the condensed financial statements of the Company.

4.4. Factors that will affect the achieved results in the perspective of at least the following three months

The main factors that will affect the Company's results in the next quarters are as follows:

- the scope and schedule of work needed to submit a new marketing authorisation application (MAA) for MabionCD20 following the Scientific Advice consultation with the EMA;
- the implementation of the product stability and similarity and comparability tests for the product from large scale validation batches and the achievement of the expected results;
- costs of conducted research and development work concerning MabionCD20 and other drugs in the Company's pipeline;
- a possibility of concluding a vaccine development agreement with Vaxine Pty Ltd. and obtaining European funds aimed at fighting the COVID-19 pandemic;
- personnel costs and costs of general management of the Company;
- financing of the planned capacity increase taking into account the intensification of activities as part of the project aimed at building a new production plant;
- foreign exchange differences resulting from changes in foreign exchange rates;
- market risk - competitive environment and price developments for reference and biosimilar medicines;
- amendments to the conditions for the release of the tranches by the European Investment Bank currently negotiated;
- a possibility of termination of the agreement by the distribution partner - Mylan - and, as a consequence, the possible need to return most of the advances received, if it is not possible to change the terms of the current agreement;
- proceeds from the aid granted from the EU funds;
- the issue of U series shares on time and in the volumes consistent with the Company's assumptions.

The amount of proceeds/reimbursement of costs incurred may be affected by possible delays in talks or unforeseen deviations from the schedules of agreements already signed.

In connection with the global coronavirus SARS-CoV-2 pandemic, additional risks and factors have been identified that may have a direct impact on the financial situation of the Company. Particularly important risks and factors may include the financial risk associated with liquidity disruption in the markets, resulting from the spread of the virus and the resulting possible restriction of the Company's access to financing. As a result of the persisting pandemic, there may also be a risk of delays or suspensions of work for an indefinite period of time, associated with the actual or potential restrictions and restrictions, as indicated below:

- limited staff availability (quarantine, childcare in the event of educational establishments closing, risk of disease);
- limiting the mobility of the Company's employees - suspension of participation of the Company's representatives in meetings and conferences, both foreign and domestic;
- suspension of meetings with external companies, including consultants;
- delays in supplies resulting in the inability to conduct certain processes in the Company;
- the possibility of plant closure in order to limit the possibility of the virus spreading.

All the aforementioned phenomena may have a direct impact on the Company's financial situation. Detailed information on the impact of the consequences of the spread of SARS-CoV-2 virus on the activities of the Company is described in points 3.2. and 6.2. of this report.

4.5. The Management Board's position regarding the possibility of meeting the previously published forecasts for the year

In 2012, the Company decided to revoke the financial forecasts published for 2010-2020 in connection with applying for the introduction of I series shares to trading in an alternative trading system and for the abandonment of financial forecasts.

5. Shares and shareholders

5.1. Share capital structure

As at 30 June 2020 and as at the submission date of this report, the share capital of the Company amounts to PLN 1,372,077.20 and is divided into 13,720,772 shares with a nominal value of PLN 0.10 each, including:

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

Registered shares of series A, B, C, E, F and G are preference shares, which means that each of them entitles to two votes at the General Meeting. The total number of votes resulting from all the issued shares is 15,300,272.

On 29 January 2020, 9,500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were issued i.e. recorded on the securities accounts of the eligible persons. Therefore, the share capital of the Company was increased. The S series ordinary bearer shares were issued by the Company as part of a conditional increase in the share capital in connection with the exercise by the entitled persons of the rights carried by B series subscription warrants granted to them under the Incentive Scheme for 2018. The issue price of S series shares was equal to the nominal price. The shares were taken up in exchange for a cash contribution made in full before the release of the shares. The Company informed about the event in Current Report no. 8/2020 of 29 January 2020. On 18 June 2020, the amount of the Company's new share capital and the number of shares including 9,500 S series shares was disclosed in the National Court Register.

On 17 January 2020, the Krajowy Depozyt Papierów Wartościowych (the National Depository for Securities, KDPW) made a conditional registration in the securities depository, under ISIN code PLMBION00016, of 514,773 P series ordinary bearer shares of the Company and 9,500 S series ordinary bearer shares of the Company. The condition for registration of the shares of each of the above-mentioned series was their introduction to trading on the regulated market where other shares of the

Company marked with the above mentioned ISIN code are present. On 24 January 2020, the Management Board of the Warsaw Stock Exchange (WSE) adopted a resolution on the admission and introduction of the Company's P and S series shares to exchange trading on the WSE Primary Market. Pursuant to the resolution, the above-mentioned shares of the Company were admitted to exchange trading on the primary market and introduced to trading on 29 January 2020 provided that the KDPW registered the shares on 29 January 2020 and marked them with code PLMBION00016. On 27 January 2020, the KDPW published an announcement on the registration of the above shares under the above code in the securities depository as of 29 January 2020. Therefore, the above condition was met and the shares were introduced to exchange trading on 29 January 2020. The Company informed about the above events in its Current Reports No. 3/2020 of 17 January 2020, No. 5/2020 of 24 January 2020 and No. 6/2020 of 27 January 2020.

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 warrants were taken up free of charge by eligible persons, i.e. those appointed by the Supervisory Board. Each B series subscription warrant entitled to subscribe for 1 S series ordinary bearer share of the Company at an issue price equal to the nominal value of shares of PLN 0.10. The deadline for exercising the rights attached to B series subscription warrants was to expire on 31 July 2022, with all authorised persons submitting declarations of subscription for their S series shares on 23 June 2020. The S series ordinary bearer shares were issued as part of a conditional share capital increase; therefore no allocation of shares took place. The issue of S series shares took place in the execution of Resolution No. 25/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the issue of A and B series subscription warrants with the exclusion of the pre-emptive right of the existing shareholders to take up R series shares and S series shares, and the conditional increase of the share capital by way of 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. Pursuant to the aforementioned Resolution No. 25/VI/2018 of the Ordinary General Meeting of Shareholders of the Company, the ordinary bearer shares of series S will be dematerialised and will be subject to an application for admission to trading on the regulated market. Therefore, the issue of the S shares will be effected by recording the shares on the securities accounts of the eligible persons. All S series shares referred to above have been taken up and fully paid for by the eligible persons. However, until the date of publication of this report, the S series shares have not been released to the above-mentioned persons, i.e. they have not been recorded on the securities accounts. The Company informed about the event in Current Report no. 27/2020 of 30 June 2020.

5.2. Shareholders holding at least 5% of the total number of votes

To the knowledge of the Management Board, as at the date of submitting the report for the first half of 2020 (22 September 2019), the following shareholders hold at least 5% of the total number of votes at the Company's General Meeting:

No.	Shareholder	Number of shares	Number of votes	% in the share capital	% in the total number of votes
1.	Twiti Investments Limited	2 380 072	2 974 372	17.33%	19.44%
2.	Maciej Wieczorek:*	1 626 576	2 119 426	11.85%	13.85%
	Glatton sp. z o.o.	1 006 226	1 006 226	7.33%	6.58%
	Celon Pharma S.A.	620 350	1 113 200	4.52%	7.28%
3.	Polfarmex S.A.	1 437 983	1 920 833	10.47%	12.55%
4.	Funds managed by Generali PTE S.A.**	1 800 000	1 800 000	13.11%	11.76%
5.	Funds managed by Nationale Nederlanden PTE S.A.***	1 140 600	1 140 600	8.31%	7.45%
6.	Funds managed by Investors TFI S.A.**	1 102 232	1 102 232	8.03%	7.20%
7.	Other	4 242 809	4 242 809	30.90%	27.73%
	TOTAL	**13 730 272**	**15 300 272**	**100%**	**100%**

* *Mr. Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 66.67% of the share capital of Celon Pharma S.A. and 75% of the total number of votes in Celon Pharma S.A.*
** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 15.06.2020*
*** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 18.06.2019*

To the Management Board's knowledge, as of the date of submitting the report for the first quarter of 2020 (25 May 2020), the following shareholders held at least 5% of the total number of votes at the General Meeting of the Company:

No.	Shareholder	Number of shares	Number of votes	% in the share capital	% in the total number of votes
1.	Twiti Investments Limited	2 380 072	2 974 372	17.33%	19.44%
2.	Maciej Wieczorek:*	1 626 576	2 119 426	11.85%	13.85%
	Glatton sp. z o.o.	1 006 226	1 006 226	7.33%	6.58%
	Celon Pharma S.A.	620 350	1 113 200	4.52%	7.28%
3.	Polfarmex S.A.	1 437 983	1 920 833	10.47%	12.55%
4.	Funds managed by Generali PTE S.A.	1 629 847	1 629 847	11.87%	10.65%
5.	Funds managed by Nationale Nederlanden PTE S.A.**	1 140 600	1 140 600	8.31%	7.45%
6.	Funds managed by Investors TFI S.A.***	1 097 769	1 097 769	8.00%	7.17%
7.	Other	4 417 425	4 417 425	32.17%	28.87%
	TOTAL	**13 730 272**	**15 300 272**	**100%**	**100%**

* *Mr. Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 66.67% of the share capital of Celon Pharma S.A. and 75% of the total number of votes in Celon Pharma S.A.*
** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 18.06.2019.*
*** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 29.11.2019.*

5.3. Number of shares held by managing and supervising persons

	Shares held by managing and supervising persons as at the submission date of the report for the first half of 2020 (22 September 2020)
Management Board	
Sławomir Jaros	holds directly 4,043 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.03% of the Company's share capital and giving 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., 66.67% of the share capital) holds 1,626,576 shares of the Company in total with a nominal value of PLN 0.10 each, constituting 11.85% of the share capital of the Company and 13.86% of votes at the General Meeting.

The number of shares held by the above-mentioned managing and supervising persons has not changed since the date of submitting the previous interim report, i.e. the report for the first quarter of 2020 published on 25 May 2020.

Other managing and supervising persons did not hold any shares in the Company in the period from the date of submission of the previous interim report to the date of submission of this report. Members of the Management Board and Supervisory Board of Mabion S.A. do not have any rights to the Company's shares other than those specified below.

In 2018, the Incentive Scheme for the years 2018-2021 was adopted. As part of the implementation of the Incentive Scheme, the persons participating in it - eligible persons - i.e. key persons in the Company - will be able to obtain the right to subscribe for A and B subscription warrants. Subscription warrants are issued free of charge in tangible form as registered securities. Each A and B subscription warrant will entitle to subscribe for 1 share (R shares and S shares, respectively). The issue price of shares in the case of holders of A warrants will be PLN 91 per each R share, while in the case of holders of B warrants it will be PLN 0.10 per each S share. The rights arising from subscription warrants may be exercised until 31 July 2022. The Incentive Scheme allows for settlement in the form of offering by the Company to persons who have acquired the warrants the possibility of purchasing them for consideration in order to redeem them. The decision on the form of exercising the rights is made by the Supervisory Board of the Company after verification that the criteria set out in the Incentive Scheme have been met and on the basis of a recommendation of the Management Board.

As a result of the implementation of the Incentive Scheme for 2019, on 23 June 2020 the Company issued B series subscription warrants which were taken up by eligible persons, including Mr. Sławomir Jaros, Member of the Management Board of the Company, in the amount of 213 warrants. Each series B subscription warrant entitled to take up 1 S series ordinary bearer share of the Company. On 23 June 2020, Mr. Sławomir Jaros submitted a statement on taking up the S series shares he was entitled to, and then paid in full for the shares taken up. However, the S series shares are subject to dematerialization, therefore the shares are issued by recording them on the eligible person's securities account. Until the date of publication of this report, the S series shares have not been released, i.e. they have not been recorded on the securities account of Mr. Sławomir Jaros.

Moreover, in accordance with the resolutions of the Company's Supervisory Board of February 2019 and February 2020, the persons eligible to take up subscription warrants for 2018, 2019 and 2020 (as at the date of publication of this report) include the Company's Management Board members:

» Mr. Sławomir Jaros - for 2018: right to take up a maximum of 5,644 A series warrants; for 2019: right to take up a maximum of 3,960 A series warrants; for 2020: right to take up a maximum of 6099 A series warrants and 213 B series warrants;

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

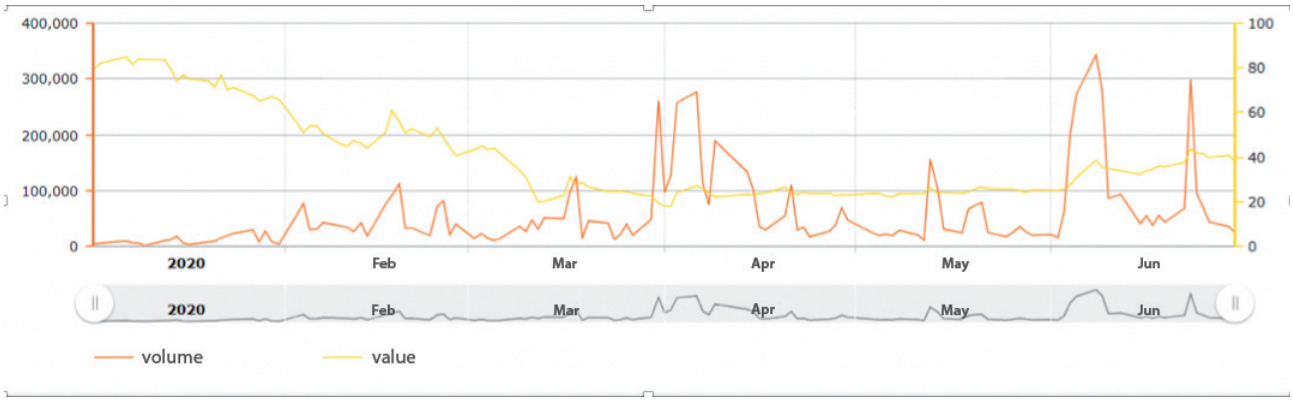
» Mr. Grzegorz Grabowicz - for 2019: right to take up a maximum of 3,300 series A warrants; for 2020: right to take up a maximum of 5101 series A warrants.

The A series subscription warrants for 2018 and 2019 were not granted due to failure to meet the market target in 2018 and 2019. However, in accordance with the Rules and Regulations of the Incentive Scheme, these warrants may be granted to eligible persons during the term of the Incentive Scheme together with the A series warrants for the year in which the market target is met. The A and B series subscription warrants provided for 2020 will be finally granted by the Supervisory Board of the Company to the eligible persons after verification of the fulfilment of the respective conditions for 2020.

5.4. Quotations of shares on the Warsaw Stock Exchange

Data for H1 2020:

Reference price:	PLN 77.0000 zł (2019-12-30)
Start date:	2020-01-02
End date:	2020-06-30
Change:	-50.39%
Change:	- PLN 38.8000
Minimum:	PLN 17.0000 (2020-04-02)
Maximum:	PLN 87.100 (2020-01-07)
Average:	PLN 39.6356
Trading volume	7 184 917 pcs
Average volume	57 943 pcs
Turnover:	237.852 million
Average turnover:	1.918 million



6. Other significant information and events

6.1. Proceedings before a court, arbitration authority or public administration authority

In the first half of 2020, as well as by the date of submission of this report, no material court, administrative or arbitration proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority or public administration authority.

6.2. Other information important for the assessment of the personnel, property, financial and assets situation, financial result and their changes, as well as information that is important for the assessment of the ability of Mabion S.A. to meet its obligations.

The Company's success in the future depends in particular on the provision of funds necessary to finance the Company's operations and its ability to register and commercialise medicines.

The level of the Company's equity as at 31 December 2019, as well as at 30 June 2020, shows a loss exceeding the sum of supplementary capitals and reserves and one third of the share capital On 15 June 2020, the Ordinary General Meeting of the Company adopted a resolution on the Company's continued existence in accordance with Article 397 of the Commercial Companies Code *(„If 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")*. The occurrence of negative equity, which is a prerequisite specified in Article 397 of the Commercial Companies Code, results from the nature of the Company's operations and is typical of research and development companies. The Company's biotech operations are characterized by the constant incurrence of high research costs with no sales revenues until the project is commercialised, as a result of which the Company incurs losses on its operating activities and generates negative cash flows from operating activities. This situation is expected to continue in the foreseeable future. To date, the Company has financed its operating activities with cash received from shareholder loans, capital issues, bank loans, grants and proceeds from distribution partners.

As a strategic partner of the Company, Mylan decided to support the Company financially and provide strategic development support. In turn, the Company undertook to grant Mylan, subject to the approval of MabionCD20, the right to distribute in Europe for contracted countries. In previous periods, the Company has pursued, in cooperation with Mylan, a strategy consisting in registering its product with the European Medicines Agency based on a small batch production. In March 2020, the Company decided to change its registration strategy - it decided to move directly to the registration of the drug produced on a large scale (2x2500L), which results in a postponement of the possibility of registering the drug, which in turn is related to the inability to receive the expected next payment from the partner, conditional on this event in the short term. The existing agreement with Mylan also provides for the possibility of its termination. In the absence of registration by the end of 2020, Mylan will have the opportunity to decide, by 30 April 2021, to terminate the agreement and consequently demand from the Company the reimbursement of most of the advances received. In this case the Company will have to acquire a new distribution partner or partners. The process of registration of MabionCD20 is longer than originally expected and goes beyond the current period provided for in the agreement with Mylan. The Company, after changing its registration strategy, remains in ongoing contact with the partner and took actions to continue the existing agreement and introduce appropriate changes to its relevant terms.

The change in the registration strategy also requires the Company to provide additional funding for current liabilities and costs necessary to implement the updated strategy in the long term. In its strategy, the Company assumes continued cooperation with Mylan and obtaining or maintaining the required financing. However, the extension of the registration process creates the risk that cooperation with Mylan may not be continued and the Company may not acquire other partners or the required financing.

As at 30 June 2020, the Company used part of the available loan of PLN 15 million from Santander Bank Polska S. A. In accordance with the agreement in force, the date of its completion and the loan repayment was July 2020. On 15 July 2020, the Company entered into a loan agreement with Glatton Sp. z o.o. for the amount of PLN 15 million ("Loan"), in order to refinance the revolving

credit facility granted to the Company in 2018 by Santander Bank Polska S.A. The entire loan granted by Santander Bank Polska S.A. was repaid on 17 July 2020 with funds obtained from the loan agreement with Glatton Sp. z o.o. The Company is obliged to repay the latter by 31 December 2020, however, the parties allow for the possibility of extending the aforementioned deadline.

In 2019, the Company concluded a loan agreement with the European Investment Bank ("EIB") for a total of EUR 30 million for a period of 5 years from the date of disbursement of individual tranches. The loan availability period is 36 months from the date of concluding the agreement. According to the agreement, the disbursement of tranche A is subject to submission to the EIB by 30 September 2020 of a copy of a scientific opinion issued by the CHMP (Committee for Medicinal Products for Human Use) containing a recommendation on the marketing authorisation of MabionCD20. The Company has taken steps to adapt the applicable agreement to the Company's current registration strategy, including the conditions for releasing the individual tranches, as well as the schedule.

As at the date of publication of this report, the Company has letters of support from key shareholders (Twiti Investments Limited, Glatton Sp. z o. o., Polfarmex S. A.), in which they express their willingness and ability to continue financial support for the current operations of the Company in the near future. In addition, in accordance with the declarations received in March 2020 from the Company's main shareholders and relating to recapitalisation of the Company, in August this year, Twiti Investments Ltd. and Glatton Sp. z o.o. signed loan agreements up to the total amount of PLN 15 million paid out in tranches (repayment by way of conversion into U series shares or in cash not later than 31 March 2021).

The change in the terms of current debt financing agreements and further acquisition of financing available on the market, including exclusive agreements with future distribution partners or declared support from shareholders (both strategic and stock market participants), should provide the Company with the financing necessary to complete the registration process and commercialise MabionCD20.

The Company actively monitors its environment in terms of the prospects for obtaining new funding opportunities, which will enable it 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. The Company has also undertaken activities aimed at acquiring a distribution partner for the US market and other markets not covered by the existing agreements. However, risks related to limited access to funding cannot be excluded due to the global liquidity situation and the situation caused by the SARS-COV-2 pandemic and its impact on capital markets.

On 15 June 2020, the Ordinary General Meeting of the Company (OGM) adopted a resolution on increasing the share capital of the Company. The purpose of the planned issue is to obtain additional financing for the Company's working capital, and in particular to accelerate the development of MabionCD20 and achieve the assumed milestones aimed at submitting a marketing authorisation application for MabionCD20 to EMA as soon as possible.

The assumed share issue should take place in the form of private subscription within the meaning of Article 431 §2 (1) of the Commercial Companies Code, carried out by way of a public offering exempt from the obligation to publish a prospectus. In the interest of the Company, all existing shareholders of the Company have been completely deprived of the right to acquire all shares of the new issue. The Management Board of the Company was authorized to mark the issue price of shares, however, the issue price of one share cannot be lower than 90% of the average market price of the Company's shares constituting the arithmetic mean of the average daily prices of the Company's shares weighted by the volume of trade (excluding package transactions) from the period of 30 days preceding the date of commencement of the book-building process or another process aimed at obtaining entities taking up the shares, during which the Company's shares were traded on the regulated market. The success of the planned share issue is an important element in the implementation of the financing strategy and ensuring that the plans can be implemented, including coverage of existing and future liabilities.

The SARS-COV-2 pandemic affects the functioning of both Mabion S.A. and external entities cooperating with it. Most companies in the world are limiting their activities due to the epidemic. Many suppliers of the Company are representatives of European companies that have warehouses in many countries in Europe, which results in a risk of untimely deliveries. In addition, limitations occur as a result of the lack of possibility of carrying out e.g. calibration of equipment by a representative of an external company

at the Company's premises, without which the equipment cannot be started up and its acceptance finalised. There were situations when materials and process substances are delivered at the last minute, which causes a delay in the process of transferring materials for testing. Nevertheless, in the reporting period there were no events affecting the framework work schedules in the Company. There is a current risk that due to a possible second wave of epidemic threat companys' inventories may be depleted, and the production limitation will contribute to the reduced supply of products, and thus potential problems with guaranteeing all the resources necessary to conduct research. In order to prevent the above-mentioned risk, the Management Board of the Company monitors the course of cooperation with contractors and the internal situation of the Company on an ongoing basis, trying to proactively adjust the strategy to the existing threats in the areas described above. The Management Board also analyses the situation caused by the pandemic in terms of its possible impact on the implementation of clinical trials. It cannot be ruled out that the restrictions introduced by government administrations in individual countries may hinder the launch of the study or affect both its organisation and duration. In order to minimize this risk, the Management Board monitors potential threats on an ongoing basis to adapt the Company's plans to the epidemic situation.

The Company, due to the specific nature of its operations and the financial results achieved, could not be a beneficiary of the aid measures proposed by governmental bodies from the so-called Anti-Crisis Shield introduced as a result of the present pandemic.

As at the date of submitting this report, there is no other information that is significant for the assessment of the human resources, property, financial situation, financial result and their changes, and information that is significant for the assessment of the ability of Mabion S.A. to meet its obligations.

Management Board of the Company

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 Supervisory Board
delegated to temporarily perform the duties
of Member of the Management Board

Konstantynów Łódzki, 22 September 2020