Mabion S.A.
Directors' Report for the first half of 2021

Konstantynów Łódzki, 16 September 2021

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Contents

1. Selected financial data

	in PLN thousand		in EUR thousand	
	from 01.01.2021 to 30.06.2021	from 01.01.2020 to 30.06.2020	from 01.01.2021 to 30.06.2021	from 01.01.2020 to 30.06.2020
Net income from sales of products, commodities, and materials	1,590	0	350	0
Operating profit (loss)	-18,510	-29,031	-4,071	-6,537
Gross profit (loss)	-19,572	-30,829	-4,304	-6,941
Net profit (loss)	-19,572	-30,829	-4,304	-6,941
Weighted average number of shares (in pcs)	16,161,326	13,730,272	16,161,326	13,730,272
Profit (loss) per ordinary share (in PLN/EUR)	-1.21	-2,25	-0.27	-0,51
Diluted profit (loss) per ordinary share (in PLN/EUR)	-1.21	-2,25	-0.27	-0,51
Net cash flows from operating activities	-29,397	-15,613	-6,379	-3,515
Net cash flows from investing activities	-7,977	-2,667	-1,754	-600
Net cash flows from financing activities	112,280	-1,516	26,607	-341
Total net cash flows	74,906	-19,796	16,473	-4,457
	30.06.2021	**31.12.2020**	**30.06.2021**	**31.12.2020**
Total assets	227,418	78,321	50,305	16,972
Liabilities and provisions for liabilities	195,591	155,709	43,265	33,741
Long-term liabilities	57,376	51,138	12,692	11,081
Short-term liabilities	138,215	104,571	30,573	22,660
Equity	31,827	-77,388	7,040	-16,770
Share capital	1,616	1,373	357	298
Number of shares (in pcs)	16,161,326	13,730,272	16,161,326	13,730,272
Book value per share (in PLN/EUR) *	14,07	5,71	3,11	1.24
Diluted book value per share (in PLN/EUR)	14,07	5,71	3,11	1.24
Dividend declared or paid per share (in PLN/EUR)	0	0	0	0

** Net assets/Weighted average number of shares*

Selected balance-sheet items presented in EUR have been translated according to the average EUR exchange rate announced by the National Bank of Poland on 30 June 2021 (4.5208 PLN/EUR) and on 31 December 2020 (4.6148 PLN/EUR). Selected items of the income statement and cash flow statement have been converted into EUR at the exchange rate announced by the National Bank of Poland and being the arithmetic average of the average exchange rates for the euro effective as at the last day of each ended month in the period of six months ended 30 June 2021 and the period of six months ended 30 June 2020 (respectively: 4.5472 PLN/EUR and 4.4413 PLN/EUR).

2. Information on Mabion S.A.

2.1. Introduction

Mabion S.A. ("Mabion" or "Company") was established on 30 May 2007 as a limited liability company with the registered office in Kutno. The legal form of the Company changed on 29 October 2009 as a result of the transformation of the limited liability company into a joint-stock company. 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 under KRS number 0000340462. The Company was assigned tax identification number NIP 7752561383 and statistical identification number REGON 100343056.

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

The activity of Mabion S.A. focuses on research and development work enabling the implementation of new biotechnological medicines, including biosimilars, obtained owing to the achievements of modern genetic engineering. In addition, the available GMP-certified manufacturing capacity and the experience of the staff in the research and development, clinical, and regulatory areas enable the Company, among other things, to participate in the development of new recombinant protein vaccines related to the prevention of COVID-19 infection. In the area of therapeutic products, the strategic goal of the Company is to develop, manufacture, and sell drugs used in the treatment of neoplastic, autoimmune, metabolic, and neurological diseases, including rare diseases. In the area of prevention of COVID-19 infection, the Company's strategic objective is to collaborate with a strategic partner in the development and production of new protein vaccines for use against the persisting COVID-19 pandemic. Biological medicines developed by the Company are targeted preparations characterised by the ability to recognise a factor, e.g. a receptor whose overexpression is associated with the development of cancer, and to interact only with that factor. Appropriate engineering of the structure of such drugs and thereby a high degree of similarity to the proteins of the patient's body makes the immune system treat the therapeutic antibody as its own protein. This guarantees a lower toxicity of the therapies developed by the Company and is a significant benefit for the patient.

Currently, the Company's most advanced product is a biosimilar medicine, MabionCD20, a reference drug to MabThera/ Rituxan (Roche).

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

2.2. Composition of the Management Board and Supervisory Board

2.3. Management Board of Mabion S.A.

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

- Mr. Krzysztof Kaczmarczyk – President of the Management Board;
- Mr. Sławomir Jaros – Member of the Management Board;
- Mr. Grzegorz Grabowicz – Member of the Management Board;
- Mr. Adam Pietruszkiewicz – Member of the Management Board.

Changes in the composition of the Company's Management Board in H1 2021 and after the balance-sheet date:

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

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

On 13 May 2021, Mr. Krzysztof Kaczmarczyk tendered his resignation from the position of Chairman and Member of the Supervisory Board of the Company. At the same time, on 13 May 2021 the Supervisory Board of the Company adopted a resolution to appoint Mr. Krzysztof Kaczmarczyk as President of the Management Board of the first joint term of office in the Company as of 14 May 2021. The above resolution followed the dismissal of Mr. Dirk Kreder from the position of President of the Company's Management Board by the Company's Supervisory Board on 13 May 2021. The resolution on the dismissal entered into force upon its adoption. The Company informed about the event in Current Report no. 36/2021 of 13 May 2021.

The distribution of key areas/tasks and responsibilities within the Company at the Management Board level is as follows:

- Krzysztof Kaczmarczyk – President of the Management Board, CEO – cooperation with Novavax, Inc. and leading the process of strategic investor acquisition,
- Sławomir Jaros – Member of the Management Board, COO and CSO – scientific and technological area of projects, operating management in the Company, MabionCD20 project, Novavax project in technological scope,
- Adam Pietruszkiewicz – Member of the Management Board – cooperation with Novavax, Inc. (leading the antigen project for the vaccine candidate) and new strategic and development projects,
- Grzegorz Grabowicz – Member of the Management Board, CFO – financing strategy.

2.4. Supervisory Board of Mabion S.A.

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

- Robert Koński – Chairman of the Supervisory Board (Independent Member);
- Maciej Wieczorek – Deputy Chairman of the Supervisory Board;
- Józef Banach – Independent Member of the Supervisory Board;
- David John James – Independent Member of the Supervisory Board;
- Wojciech Wośko – Member of the Supervisory Board;
- Sławomir Kościak – Independent Member of the Supervisory Board;
- Zofia Szewczuk – Independent Member of the Supervisory Board.

Changes in the composition of the Company's Supervisory Board in H1 2021 and after the balance-sheet date:

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

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

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

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

On 13 May 2021, Mr. Krzysztof Kaczmarczyk tendered his resignation from the position of Chairman and Member of the Supervisory Board of the Company. At the same time, on 13 May 2021 the Supervisory Board of the Company adopted a resolution to appoint Mr. Krzysztof Kaczmarczyk as President of the Management Board for the first joint term of office in the Company as of 14 May 2021. Accordingly, on 13 May 2021, the Supervisory Board of the Company adopted a resolution to elect a Member of the Supervisory Board – Mr. Robert Koński as Chairman of the Supervisory Board of the Company. The Company informed about the event in Current Report no. 36/2021 of 13 May 2021.

On 22 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the appointment of Ms. Zofia Szewczuk as Member of the Supervisory Board for the second joint term of office. The resolution of the Company's Ordinary General Meeting came into force on the date of its adoption. The Company informed about the event in Current Reports no. 42/2021 and 43/2021 of 22 June 2021.

2.5. Entities subject to consolidation

Mabion S.A. does not hold any shares in other entities. There are also no other situations which could lead to the conclusion that the Company is a dominant company within the meaning of Article 4 §1(4) of the Commercial Companies Code. In H1 2021, Mabion did not form a capital group and did not draw up consolidated financial statements.

3. Operations of Mabion S.A.

3.1. Object of activity

The Mabion's primary objective is the development, manufacturing and marketing of biosimilars, i.e. biological medicines that are developed to be similar to the original biotech drugs (known as reference medicines) in the fields of oncology, autoimmunity, neurology and metabolic diseases, including rare diseases.

The Company analyses on an annual basis its development plan for medicinal products and modifies it according to the needs, taking into account, among other things, the expiry dates of patents for reference medicines, the current and forecast size of the market for reference medicines, the Company's technology in the area of manufacturing of medicines, the competence and experience of the team, and competition in the field of biosimilars.

In 2019, following a review and update of the medicines development strategy, the catalogue of projects which the Company, currently or in the future, on its own or with partners, is interested in implementing, was changed. The Company classified scientific and research projects to three groups of projects, i.e. active projects, new projects which were to be launched in 2019, and partner projects. Until the date of this report, the development strategy in force was maintained.

Active projects

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

Projects launched in 2019

The projects for which the Company started research and development work in 2019 are three biosimilar drugs in the area of autoimmunity, metabolic diseases, and oncology (denosumab and omalizumab antibodies). At present, a significant part of the team responsible for the development of the aforementioned antibodies has been assigned to support the Company's priority projects (MabionCD20 and cooperation with Novavax), in connection with the need to carry out work related to the development and optimisation of the process, as well as analytical and manufacturing work.

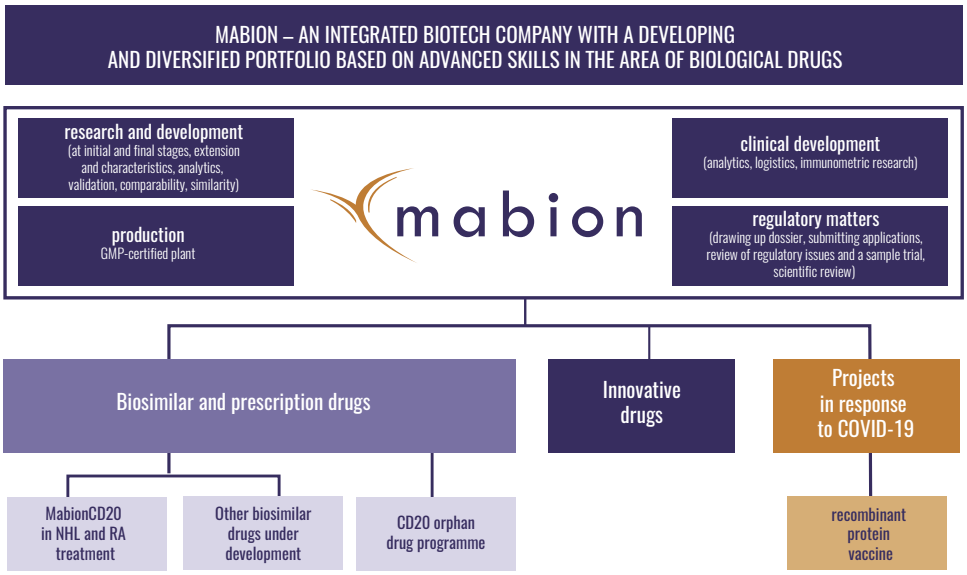
Partnership projects

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

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

- signing a letter of intent with IcanoMAB GmbH regarding potential collaboration to conduct CMC (Chemistry, Manufacturing and Controls) type development and manufacturing of a human IL-1R7 mAb antibody under development by IcanoMAB as a potential drug to treat patients with COVID-19 infection (October 2020),
- signing a Memorandum of Understanding with Taxon Therapeutics Ltd. regarding cooperation in the research, development, and commercialisation of MabionCD20 antibody drug in specific clinical indications in the area of rare diseases (October 2020);
- entering into a framework agreement for contracted services with Novavax, Inc. under which the Company, with Novavax's participation, will undertake activities related to the transfer of the manufacturing process technology and antigen analytics of the vaccine candidate for COVID-19 under the working name of NVX-CoV2373 and will carry out technical trial runs of the process on a commercial scale at the Company's facility (March 2021).

Detailed information on the above projects can be found further on in this report. Mabion S.A. product strategy – a summary.



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

** incl.: Australia, New Zealand, Mexico, Central America, southern Africa, south-east Asia*

MabionCD20

The Company's priority and most advanced project is MabionCD20, a proposed biosimilar to the reference drug MabThera/Rituxan (rituximab) (Roche). In 2018, the Company published the results of a clinical trial using the medicine originating from the 500L manufacturing process that confirmed the efficacy and safety of the therapy. Currently, preparations are under way to initiate a trial at clinical sites using the medicine originating from a target, commercial scale (5000L). The Company is also preparing to submit a marketing authorisation application for MabionCD20 originating from the target manufacturing process with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

On 30 July 2021, following a round of interactions with the European regulatory agencies as part of the Scientific Advice procedure (two consulting sessions with the EMA and two consulting sessions with PEI) and with the FDA, the Company established a strategy for the co-development of MabionCD20 for registration in the European and US markets. The essential elements of the Company's regulatory strategy have not changed and include:

1. A three-arm bridging clinical trial in patients with rheumatoid arthritis ("RA")

2. A three-arm analytical bridging trial

3. Implementing the aforementioned tasks using MabionCD20 originating from the target, i.e. large, commercial production scale (5000L)

4. Including, in the registration procedure for the European market, the results of the already completed Phase III clinical trial with MabionCD20 originating from a small manufacturing scale (500L); the trial was carried out with participation of 709 patients for the RA indication and 143 patients with NHL (non-Hodgkin's lymphoma).

The Company has simultaneously completed the reconciliation process and developed the final scope of data (including the scope of the bridging clinical trial) for the application for registration and marketing authorisation of MabionCD20 under the central procedure for the European market. The three-arm clinical and analytical bridging trials referred to above include: (a) MabionCD20 originating from large-scale production, (b) MabThera, being the European reference, and (c) Rituxan, being the US reference, which all in all forms the basic assumption of the co-development strategy for MabionCD20. At a further stage, the Company will clarify with the FDA the scope of additional trials (which may, as expected by the Company, include a clinical trial in an oncology indication as a required element of the registration application) necessary for MabionCD20 to be approved for the US market. The three-arm bridging clinical trial in patients with RA referred to in item 1 above is expected to include as a target a population of 280 patients, which is in accordance with the Company's assumption that it is not necessary to carry out separate new Phase III clinical trials in order to register MabionCD20 on the European market. The primary endpoint of the trial is to analyse pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. Such patient population will also allow assessment of treatment efficacy, which constitutes the secondary endpoint of the trial.

With respect to item 2, the Company has defined with the EMA and the PEI the target quality profile of MabionCD20 based on data obtained from validation batches of MabionCD20 produced at the target manufacturing scale and has established the scope of analytical trials for MabionCD20 produced on a commercial scale. The analytical trials are aimed at confirming analytical similarity to reference drugs and comparability to MabionCD20 originating from small-scale manufacturing, used in earlier clinical trials. In the Company's opinion, the aforementioned trials and the scope of data (items 1–4) developed as part of the arrangements with the EMA and the PEI are sufficient for the submission of a registration application to the EMA. The above assumptions may be subject to change in the future (due to the fact that they are based on a number of factors that may affect the time-frame, including factors beyond the Company's control such as the speed of clinical trial recruitment). Moreover, the assumptions made and actions undertaken do not guarantee the registration of the product.

In planning the scope and timing of the clinical trial, the foreseeable constraints of the COVID-19 pandemic were taken into account.

With respect to the bridging trial in rheumatoid arthritis, the Company has undertaken a number of activities to develop the internal quality systems required for the initiation of the clinical trial, including a number of procedures to allow for adequate control of the trial, conducting a risk analysis taking into account both the potential risks specific to research in immunological diseases, observations from previous clinical work, as well as the current situation related to the coronavirus pandemic. The documents necessary to launch the clinical trials were also drawn up, including the IMPD (Investigational Medicinal Product Dossier) and the IB (Investigator's Brochure), and the clinical trial protocol. In October 2020, a contract was signed with one of the most experienced CROs on the market, i.e. Parexel, which is to co-lead the clinical trial. In parallel, advanced work has been carried out leading to the development of a logistics plan for the clinical trial. The Company has also qualified and positively identified over 35 clinical sites in Poland, Belgium, Ukraine, and Georgia for the planned trial and is now finalising contracts with these sites. However, Mabion does not exclude conducting a clinical trial in other European countries. The suppliers of reference medicines (i.e. MabThera and Rituxan) for the trial were contracted and quality audits and supplier qualification were carried out. Procurement of reference products has been continued to secure the availability of drugs for the clinical trial and analytical panels.

With respect to the ongoing activities aimed at the registration and marketing authorisation of MabionCD20, the Company emphasises that in order to commence the clinical bridging trial necessary for the authorisation of MabionCD20 in the EU in the first instance, the Company is currently obtaining consents from the relevant authorities and bioethics committees to start the clinical trial. The Company has submitted appropriate applications for this purpose to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and to the competent bioethics committee to commence clinical trials in Poland. In July, the Company was informed of the positive opinion of the bioethics committee regarding the application. A similar procedure was launched in the subsequent key countries for the clinical trial – Ukraine, Georgia, and Belgium, where the relevant applications for trial approval were submitted to the national competent authority (Ukraine), the local bioethics committee and, following a favourable opinion by the committee in August, to the national competent authority (Georgia); also a joint application to both the local ethics committee and the competent authority (Belgium).

To sum up, in the research and development work on MabionCD20, in H1 2021 and until the date of this report, the Company considers the following activities to be successfully carried out:

» physicochemical, biological and microbiological analyses conducted in accordance with the MabionCD20 manufacturing process control strategy;

» verification of the parameters of the antibody subjected to stability tests under routine storage conditions for the validation batches;

» development of analytical methods for qualitative and comparative analyses of MabionCD20.

MabionMS

With regard to the MabionMS (multiple sclerosis, MS) innovative therapy project, the Company has so far submitted the following patent applications in this therapeutic area:

» In 2017 – European patent application (extended under the PCT procedure in 2018) for legal protection for the invention called "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand". The subject of the patent application was an innovative therapy for the treatment of multiple sclerosis patients using the MabionCD20 antibody combined with other substances (MabionMS combination therapy project). In July 2020, the Company filed international patent applications for the above invention with selected patent offices, initiating a national and regional phase to obtain patent protection in dozens of countries. Based on statistics on multiple sclerosis in specific regions, as well as on the potential of specific markets, Mabion has filed patent applications with selected patent offices covering countries such as: USA, Canada, UK, EU and EFTA countries, Australia, New Zealand, Israel, Turkey, Russia, and several others. The commencement of the national and regional patent application phase in each country is the next step on the path to obtaining legal protection for this innovative therapy.

» In 2018, a European patent application (with the possibility of extension under the PCT procedure) in the area of application of MabionCD20 in the treatment of patients with multiple sclerosis, called "Low aggregate anti CD20 ligand formulation". This is the second patent application in the area of use of MabionCD20 for the treatment of multiple sclerosis, constituting an innovative indication for the molecule. This application concerns the use of MabionCD20 as a monotherapy.

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

MabionEGFR

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

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

In H1 2021 and until the publication of this report, the Company proceeded, as part of the project, with activities related to:

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

» preliminary optimisation of cell culture and antibody purification conditions.

NVX-CoV2373

On 3 March 2021, Mabion entered into a framework agreement with Novavax, Inc. based in the United States, pursuant to which the Company, with Novavax's participation, undertook activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate antigen under the working name of NVX-CoV2373 and to the conduct of technical runs of the process on a laboratory and commercial scale at the Company's facility. The framework agreement will be in force until 31 December 2023. With the conclusion of the framework agreement, the parties agreed on the scope and budget of the work contracted to the Company to carry out the technology transfer and a technical run for the NVX-CoV2373 protein antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order includes the transfer of technology from Novavax to the Company. In addition, it comprises: the transfer and verification of analytical methods, together with integration of the transferred methods and documentation related to the manufacturing process into the Company's quality system, completion of one technical run and one confirmatory run demonstrating the repeatability in batch production of the product in the facility.

On 25 March 2021, the Company received the first payment from Novavax, Inc. as part of the execution of the aforementioned order placed under the framework agreement. The funds received represented the first tranche of remuneration for the work commissioned under the agreement and an advance on materials and reagents.

By the date of this report, Mabion has carried out the following work:

- the Company has finalised the transfer of the COVID-19 vaccine antigen production process at the laboratory scale – both the cell culture stages and the vaccine antigen purification process;
- the Company has completed the analysis of Novavax's process and analytical documentation and a quality system for the purposes of implementing the new process and analytics have been put in place.
- the cell culture process in bioreactors on a commercial scale has been scaled up, and the double implementation of this process planned under the agreement has been carried out;
- following the aforementioned activities, the product was successfully purified and subjected to analytics based on Novavax's procedures and requirements which were likewise part of the earlier transfer tasks; the results of these analyses show that the Company has obtained a desirable high-quality product in a reproducible manner;
- tasks were also performed to secure the possibility of regular commercial production of the vaccine antigen, consisting in purchasing, installing, and qualifying the necessary process and analytical equipment; process materials for next periods have been secured.

Summing up, all the preparatory work that was planned in the current period has been completed. Currently, the Company is reporting and accounting for the completed work. It is worth mentioning that the communication channels between the Mabion and Novavax teams responsible for particular areas are in place, and in the Company's opinion the infrastructure and material resources are ready for further stages of cooperation.

On 23 June 2021, the Company received a second order from Novavax under the framework agreement. The order was placed in conjunction with ongoing negotiations for a potential manufacturing agreement under which the Company could produce the active ingredient on a commercial scale for Novavax. To facilitate the Company's future production process, the parties signed an order allowing the Company to procure key raw materials for production in advance within a budget agreed by the parties and funded by Novavax. The order concerns the procurement of raw material volumes sufficient for the future commercial production of the active substance involving the Company's full production capacity by the end of the first half of 2022 (as estimated by the Company). Immediately following the order, the Company started to procure materials and reagents necessary for the future possible commercial production of the active substance. On 15 July 2021 (an event after the balance-sheet date), the Company received a payment from Novavax Inc. amounting to USD 15,226 thousand as part of the aforementioned order, in accordance with mutually agreed terms and conditions.

Contracting raw materials for production at this stage of cooperation, i.e. in advance, will enable commercial manufacturing services to commence more promptly if the manufacturing agreement is concluded. Once the production agreement has been signed, the parties' intention will be to cyclically deploy similar orders for the procurement of raw materials (according to separately agreed budgets and schedules) in successive periods. However, whether the production agreement will be concluded depends primarily on the successful execution of the first order and also requires the parties to further clarify their agreements on technical, financial, quality, and scheduling issues.

Business development: innovative antibody-based therapies

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

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

As at the date of this report, the parties are not discussing the possibility of cooperation, however, they do not exclude such cooperation in the future.

Business development: products based on MabionCD20 antibody

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

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

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

Additional equipment for the existing facility

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

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

» retrofitting the existing 5000L L production line, and

» purchasing and installing production equipment for a second 5000 L production line to be located in the existing building.

As part of permit no. 301, the Company undertook to incur investment expenditure in the area of the Zone in the amount of at least PLN 20,000 thousand (within the meaning of § 6 of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit for conducting business activity in special economic zones). The time limit for incurring these expenditures and completing the investment is 31 December 2024 (decision of 10 August 2021 by the Minister of Development, Labour, and Technology). Under permit no. 301, as at 30 June 2021, the Company made investment expenditures of PLN 2,803 thousand.

Extension of the existing facility

In 2017, the Company started preparation activities connected with the expansion of the existing production facility (stage "MABION II"), with an aim to increase significantly the production as well as R&D capacity of the Company. A concept for the extension of the Scientific and Industrial Complex for Medical Biotechnology has been developed. In 2018, the Company selected an international consortium of architectural and technological companies, to which it entrusted the development of a technological and construction design. In November 2018, the Company received the decision of the Pabianice Governor approving the construction design and granting a building permit for the aforementioned investment called "Technological and Scientific Centre for Advanced Medical Biotechnology of Mabion S.A." with the necessary infrastructure in Konstantynów Łódzki.

In 2019 and 2020, work was under way to prepare detailed designs for all construction and installation sectors. Following the contractor's consideration of comments by the Company, the detailed design was completed and accepted by the Company in February 2021. Detailed specifications of user requirements were prepared for critical installations and main process lines.

In February 2020, the Company received the decision of the Pabianice Governor approving the change to the building permit, allowing to increase the cubic volume of the building to the target size necessary for the Company to implement the intended investment plans, including the increase of the Company's production and R&D capacity. The building permit allows for the commencement of works on the extension of the existing plant, however, the moment of their commencement depends on the Company's financial situation (obtaining funds, liquidity, etc.) as well as formal possibilities of entering non-European markets (signed distribution agreements, formal approvals of regulators, etc.).

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

3.2. Major events affecting Mabion S.A. in the first half of 2021 and up to the date of this report

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

On 27 January 2021, the Management Board of Mabion S.A., on the basis of an in-depth analysis of the Company's needs and estimated benefits, adopted a new long-term strategy for financing the Company's activities. The strategy covers the Company's

overall capital needs which has to be fulfilled in order to carry out all activities which, in the opinion of the Company's Management Board, are necessary to complete the registration of MabionCD20 with the EMA and to start selling MabionCD20 and generate operating cash flows thereby. The arrangements for the Company's financing strategy were positively reviewed by the Company's Supervisory Board on the same date. The financial strategy provided for parallel processes: the initiation of activities to attract a strategic investor, and two share issues of the Company.

As part of the strategy, the following directional funding decisions were taken, and then the following activities were carried out to implement them:

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

In order to effectively carry out this process, on 27 January 2021 the Company signed an agreement with the financial advisor Rothschild & Co. The scope of the advisor's responsibilities includes, inter alia, searching for a potential strategic investor, advising on the structure of a potential transaction, support in drafting transaction documentation and in negotiations with the potential strategic investor. As at the date of this report, decisions have not been made regarding the type of investor, the expected level of capital commitment, or the transaction formula. These decisions will be made in the course of a process designed to select the most beneficial way for the Company to achieve its long-term business objectives;

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

In order to put the above decision into effect, the Company's Management Board convened an Extraordinary General Meeting for 23 February 2021, which adopted Resolution no. 4/II/2021 on increasing the Company's share capital by an amount not less than PLN 0.10 and not more than PLN 243,055.40 by way of an issue of at least one and not more than 2,430,554 U series ordinary bearer shares with a par value of PLN 0.10 each ("EGM Resolution"). The purpose of the U series share issue was to generate the necessary financing for the Company's working capital, in particular for the development of MabionCD20 and activities aimed at carrying out the registration procedure at the EMA as soon as possible.

On 3 March 2021, the Company's Management Board passed a resolution on, inter alia, determining the rules of offering and conducting the book-building process, subscription, taking-up and allotment of U series shares. On 4 March 2021, the Company and mBank S.A. ("Offering Manager") entered into a conditional share placement agreement and commenced the book-building process by way of a private placement of U series shares. The book-building process was carried out between 4 and 9 March 2021. Subsequently, on 9 March 2021 the Company's Management Board resolved that the issue price of the U series shares will be PLN 55.00 per one share and the Company will make offers to investors to acquire a total of 2,430,554 U series shares. The issue of the U series shares was effected upon the execution of agreements for the taking-up of all the U series shares and upon payment in full of the contributions to cover the shares (no allotment of shares within the meaning of the Commercial Companies Code was necessary). The conclusion of the agreements for taking up U series shares was completed on 12 March 2021. Contributions for the U series shares were paid in full by 15 March 2021. 2,430,554 U shares were taken up, as a result of which the Company leveraged PLN 133.7 million.

The U series shares were offered by way of private placement within the meaning of the Act of 15 September 2000 – Commercial Companies Code in a public offering on the basis of the exceptions from drawing up and publishing a prospectus referred to in Article 1(4)(a) and (d) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market and repealing Directive 2003/71/EC ("Prospectus Regulation"). The U series shares have been offered exclusively to: (a) qualified investors as referred to in Article 1(4)(a) of the Prospectus Regulation; or (b) investors who acquire securities with an aggregate value of at least EUR 100 thousand per investor as referred to in Article 1(4)(d) of the Prospectus Regulation, including Eligible Investors (as defined in the EGM Resolution). The Company's shareholders meeting the criteria indicated in the EGM Resolution ("Eligible Investors"), who participated in the book-building process, were entitled to priority take-up of the U series shares under the rules set out in the Resolution. Pursuant to the EGM Resolution, upon meeting the requirements

set forth therein, the Eligible Investors were entitled to pre-emptively take-up the U series shares in a number allowing them to maintain a share in the total number of votes at the General Meeting of the Company not lower than the share held at the end of the day on the date of adoption of the Resolution. Moreover, under the terms of the EGM Resolution, the Eligible Investors, being Qualified Investors, holding, at the end of the preference day, shares in the Company with an aggregate nominal value of at least 0.5% of the Company's share capital, were given a pre-emptive right to acquire U series shares before the other investors.

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

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

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

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

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

and assigned it with code PLMBION00016. On 15 April 2021, the KDPW published a notice on the registration, as of 19 April 2021, in the depository of securities under ISIN PLMBION00016 code, of 2,430,554 U series ordinary bearer shares of the Company. Thus, the condition for the introduction of the shares to trading on the WSE primary market on 19 April 2021 was fulfilled. The U series shares were registered with the KDPW in connection with the closure of the accounts maintained for the RTS. On 14 April 2021, the WSE's Board adopted a resolution on determining the last day of listing the RTS on the WSE Main Market, pursuant to which it resolved that the RTS will be listed on 16 April 2021 for the last time. The admission of shares and the rights to U series shares to trading on the regulated market did not require the Company to make a prospectus, or any other information or offering document within the meaning of the relevant legal regulations, available to the public;

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

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

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

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

At the same time, in January 2021 the Company informed that it also does not exclude the use of other sources of financing such as external debt financing, grants, subsidies from EU funds, earmarked funds for the implementation of new projects, or other sources depending on the needs and capabilities of the Company. As at the date of the current report (CR 3/2021 of 27 January 2021), the Company's Management Board is in the process of negotiating agreements with several biotechnology companies that could potentially bring the Company profits from cooperation in the area of development and production of biological drugs or vaccines. The Company is also continuing talks with the European Investment Bank to align the terms of the financing agreements with the current regulatory strategy for MabionCD20.

The Company informed about the above events in Current Reports no. 3/2021 and no. 4/2021 of 27 January 2021, no. 11/2021 of 22 February 2021, no. 12/2021 of 23 February 2021, no. 19/2021 of 4 March 2021, no. 20/2021 of 8 March 2021, no. 21/2021 of 9 March 2021, no. 23/2021 of 15 March 2021, no. 25 of 16 March 2021, no. 26/2021 and no. 27/2021 of 22 March 2021, no. 28/2021 and no. 29/2021 of 23 March 2021, no. 31/2021 of 2 April 2021, no. 33/2021 of 14 April 2021, and no. 34/2021 of 15 April 2021.

Conclusion of a borrowing agreement with Twiti Investments Limited

On 5 February 2021, the Company entered into a borrowing agreement with Twiti Investments Ltd. – a related party and shareholder holding 17.33% of the Company's share capital ("Lender"), for the total amount of up to PLN 10,000 thousand. The Company's Supervisory Board approved the conclusion of the Borrowing Agreement. The borrowing may be disbursed in tranches, in amounts and on dates agreed by the parties in a separate disbursement schedule, with the Lender required to disburse each tranche upon written request by the Company. The borrowing agreement does not specify the purpose of the funds, and it was the Company's intention to use the funds raised to cover current expenses. The interest rate on the Borrowing has been agreed on an arm's length basis as a variable interest rate based on WIBOR 3M plus a margin. The principal receivable under both of the above borrowing was repaid in March 2021 in a portion amounting to PLN 1,200 thousand by way of conversion into U series ordinary bearer shares issued by the Company pursuant to a resolution of the Extraordinary General Meeting of 23 February 2021. To this end, the Company performed a contractual set-off of part of the claim against Twiti Investments Limited for payment of the issue price for the U series shares subscribed for by Twiti Investments Limited as part of the issue with the claim of Twiti Investments Limited under the said borrowing agreement. On 15 April 2021, the Company settled the remaining unpaid liabilities under the above-mentioned agreement, i.e. the amount of PLN 2,300 thousand of principal and interest, and therefore the borrowing was repaid in full as used. The borrowing represented a further step in the implementation of the declaration of support for the Company by key shareholders made to the Company in letters of support. At the date of this report, the Company is not utilising the borrowing.

The Company informed about the events in Current Reports no. 5/2021 of 5 February 2021, no. 20/2021 of 8 March 2021, and no. 23/2021 of 15 March 2021.

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

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

On 23 February 2021, the Extraordinary General Meeting of Mabion S.A. also adopted Resolution No. 5/II/2021 on amending the Company's Articles of Association by changing the Company's scope of business. The change concerned the extension of the Company's scope of business to include freight transport by road (PKD 49.41.Z) and other postal and courier activities (PKD 53.20.Z). The amendment of the Company's Articles of Association in the above scope was registered with the National Court Register on 2 April 2021.

On 22 June 2021, the Ordinary General Meeting of Mabion S.A. adopted resolution no. 20/VI//2021 on another amendment to the Company's Articles of Association by further extending the Company's scope of business. The amendment concerned the expansion of the scope of business by, inter alia, warehousing and storage of goods, activities of agents engaged in the sale of goods, wholesale and retail sales, professional, scientific and technical activities. The amendment of the Company's Articles of Association in the above scope was registered with the National Court Register on 10 August 2021.

The aforementioned changes in the Company's scope of business were introduced as a result of the Company's analysis of opportunities to increase the efficiency of its operations using its resources, particularly within its available transport network, and additional operations consisting in the provision of new services, considered by the Company. The above changes will allow the Company to undertake operations in additional and complementary areas, and thus they will not have a material impact on the Company's main business; therefore, the General Meeting resolved to implement the change without redeeming the shares of shareholders who do not agree thereto.

The Company informed about the above events in Current Reports no. 12/2021 of 23 February 2021, no. 31/2021 of 2 April 2021, no. 42/2021 of 22 June 2021, and no. 51/2021 of 10 August 2021.

Conclusion of a framework agreement with Novavax, Inc. and orders for contractual services received from Novavax, Inc. as part of the COVID-19 vaccine programme

On 3 March 2021, the Company entered into a framework agreement (Framework Agreement) with Novavax, Inc. based in the United States (Novavax), pursuant to which the Company, with the participation of Novavax, has undertaken activities related to the transfer of technology concerning the manufacturing process of the vaccine candidate antigen for COVID-19 under the working name of NVX-CoV2373 and to technical runs of the process on a commercial scale at the Company's plant. The Framework Agreement will be in force until 31 December 2023. It is the intention of the parties to the Framework Agreement that, if the manufacturing collaboration continues, the Company's facility may be integrated into the Novavax manufacturing chain for the commercial production of the active substance of the vaccine for Novavax. Novavax is a biotechnology company focused on delivering new products and using its proprietary, innovative, patented recombinant nanoparticle vaccine technology to prevent a wide range of infectious diseases.

The Framework Agreement does not specify minimum order quantities. Based on the Framework Agreement, at this stage it is too early to determine the target scale of the cooperation initiated with Novavax and the target scope of work that will ultimately be performed, and thus to estimate the impact of the cooperation with Novavax on the Company's financial results. Such an estimate will be possible once the partners have agreed on the terms and conditions of the commercial agreement. In the opinion of the Management Board, the Company has the right team, production experience, knowledge and technology together with the production line to carry out the work commissioned by Novavax. Based on the conditions set out in the Framework Agreement, in the opinion of the Management Board the work performed by the Company as part of this Agreement, as opposed to a Commercial Agreement, will have a moderately positive impact on the Company's results and will support the implementation of the Company's strategic plans. At the same time, Novavax retains the right to terminate the Framework Agreement in whole or in part, at any time without giving a reason. Moreover, pursuant to the Framework Agreement, the Company's undertaking of potential cooperation with other entities in the area of COVID-19 vaccine manufacturing will require prior approval by Novavax.

On 3 March 2021, with the conclusion of the Framework Agreement, the parties agreed on the scope and budget of the work contracted to the Company as part of the first order to carry out the technology transfer and a technical run for the NVX-CoV2373 protein antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order includes technology transfer from Novavax to the Company. In addition, it comprises: the transfer and verification of analytical methods, together with integration of the transferred methods and documentation related to the manufacturing process into the Company's quality system, completion of one technical run and one confirmatory run demonstrating the repeatability in batch production of the product in the Company's facility. The Company estimates that no significant expenditure is required to complete the first order. The technical run is funded by the non-returnable consideration that the Company has received from Novavax in connection with the first order. On 25 March 2021, the Company

received the first payment from Novavax, Inc. as part of the execution of the aforementioned order placed under the framework agreement, amounting to USD 1,030 thousand. The funds received represent the first tranche of remuneration amounting to USD 530 thousand and an advance on materials and reagents amounting to USD 500 thousand.

On 23 June 2021, the Company received a second order from Novavax to carry out defined activities under the framework agreement. The order was placed in conjunction with ongoing negotiations for a possible manufacturing agreement under which the Company could manufacture for Novavax the active ingredient of a COVID-19 vaccine candidate under the working name of NVX-CoV2373, on a commercial scale. To facilitate the Company's future production process, Novavax and the Company have signed the second order under the existing framework agreement, allowing the Company to procure key raw materials for production in advance within a budget agreed by the parties and funded by Novavax. The order concerns the procurement of raw material volumes sufficient for the future commercial production of the active substance involving the Mabion's full production capacity by the end of the first half of 2022 (as estimated by the Company). In line with the arrangements outlined in the order, on 15 July 2021 (an event after the balance-sheet date) the Company received a full prepayment from Novavax for the raw materials to be procured, amounting to USD 15,226 thousand. Contracting raw materials for production at this stage of cooperation, i.e. in advance, will enable commercial manufacturing services to commence more promptly if the manufacturing agreement is concluded. Once the production agreement has been signed, the parties' intention will be to cyclically deploy similar orders for the procurement of raw materials (according to separately agreed budgets and schedules) in successive periods.

The conclusion of the production agreement requires the parties to further clarify their arrangements on technical, financial, quality, and scheduling issues and depends primarily on the successful execution of the first order. Accordingly, the Company points out that signing the second order does not determine whether the manufacturing agreement will ultimately be concluded. Should the manufacturing agreement not be concluded, the procured raw materials for production will be transferred to Novavax or settled with Novavax in cash.

The Company informed about the events in Current Reports no. 15/2021 of 3 March 2021, no. 30/2021 of 25 March 2021, and no. 45/2021 of 23 June 2021.

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

On 3 March 2021, the Company entered into an agreement with Polski Fundusz Rozwoju S.A. ("PFR") regarding the entry conditions for PFR's investment of up to PLN 40,000 thousand ("PFR's Investment" and "Agreement") for the purpose of increasing the Company's production capacity, in particular for the Company's potential broader cooperation with Novavax, Inc. regarding serial production of a COVID-19 vaccine active substance which is currently pending registration. Further details of the framework agreement signed with Novavax are contained in this section above.

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

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

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

On 29 April 2021, the Company signed an annex ("Annex") to the cooperation agreement ("Agreement", "Development and Commercialization Agreement"), of which the Company informed in Current Report no. 31/2016 of 8 November 2016. Under the Annex, the parties decided to continue cooperation, but the territorial scope of the agreement has been changed. Mylan will remain Company's non-exclusive distribution partner for MabionCD20 in selected countries in regions such as, in particular, Australia, New Zealand, Mexico, Central America, southern Africa, south-east Asia. At the same time, it was decided that Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries, as well as Mylan's priority right to enter into a commercialization agreement for MabionCD20 in the United States (USA), shall expire. The change in the scope of cooperation with Mylan will enable the Company to acquire a new partner or partners interested in commercializing MabionCD20 on the European and American markets and to establish cooperation taking into account the potential of MabionCD20 and the current market conditions. Importantly, the Annex in force does not affect the activities currently carried out by the Company in order to obtain the marketing authorisation for MabionCD20 from the European Medicines Agency, or their schedule. At the same time, the parties have agreed that the Company will reimburse to Mylan part of the advances, in an amount lower than the advance payments received by the Company under the Agreement before the date of the Annex, constituting repayable advances for distribution rights, which is tantamount to the final settlement of all payments made so far between the Parties. Owing to the Annex, the Company has obtained the necessary flexibility in the commercialization of MabionCD20 in its key markets in Europe and in the United States (USA). The Company informed about the above event in Current Report no. 35/2021 of 29 April 2021.

On 20 July 2021 (an event after the balance-sheet date), the Company reimbursed Mylan for the first tranche (of two) of the advances received on account of the distribution rights, amounting to USD 6,000 thousand.

Adoption of a joint work programme for the marketing authorisation of MabionCD20 on the European and US markets and definition of the final scope of data and clinical trial for the purposes of the registration application on the European market

On 30 July 2021 (an event after the balance-sheet date), following a round of interactions with the European regulatory agencies as part of the Scientific Advice procedure (two consulting sessions with the EMA and two consulting sessions with PEI, the German national regulator that closely cooperates with the EMA) and with the FDA, the Company established a strategy for the co-development of MabionCD20 for registration in the European and US markets. The essential elements of the Company's regulatory strategy have not changed and include:

1. A three-arm bridging clinical trial in patients with rheumatoid arthritis ("RA")

2. A three-arm analytical bridging trial

3. Implementing the aforementioned tasks using MabionCD20 originating from the target, i.e. large, commercial production scale (5000L)

4. Including, in the registration procedure for the European market, the results of the already completed Phase III clinical trial with MabionCD20 originating from a small manufacturing scale (500L); the trial was carried out with participation of 709 patients for the RA indication and 143 patients with NHL (non-Hodgkin's lymphoma).

At the same time, following a round of interactions with the regulators over the past several months, the Company has completed the reconciliation process and developed the final scope of data (including the scope of the bridging clinical trial) for the application for registration and marketing authorisation of MabionCD20 under the central procedure for the European market. Considering the outcome of the arrangements with the European regulators, the Company's Management Board expects – under the base scenario – to maintain the assumed schedule, i.e. to complete the trials and submit the registration dossier to the EMA for the European market in the second half of 2022. The three-arm clinical and analytical bridging trials referred to above include: (a) MabionCD20 originating from large-scale production, (b) MabThera, being the European reference, and

(c) Rituxan, being the US reference, which all in all is the basic assumption of the co-development strategy for MabionCD20. At a further stage, the Company will clarify with the FDA the scope of additional trials (which may, as expected by the Company, include a clinical trial in an oncology indication) required for MabionCD20 to be approved for the US market and will report on these arrangements once they have been made. The three-arm bridging clinical trial in patients with RA referred to in item 1 above is expected to include as a target a population of 280 patients, which is in accordance with the Company's assumption that it is not necessary to carry out separate new Phase III clinical trials in order to register MabionCD20 on the European market. The primary endpoint of the trial is to analyse pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. Such patient population will also allow assessment of treatment efficacy, which constitutes the secondary endpoint of the trial. The company reiterates that, to carry out the clinical trial, it has entered into an agreement with Parexel International (CRO), has qualified several dozen clinical sites, and has finalised the documentation necessary to launch the trial. Furthermore, the Company has initiated the process of applying to local bioethics committees for approval of the clinical trial. With respect to item 2, the Company has defined with the EMA and the PEI the target quality profile of MabionCD20 based on data obtained from validation batches of MabionCD20 produced at the target manufacturing scale and has established the scope of analytical trials for MabionCD20 produced on a commercial scale. The analytical trials are aimed at confirming analytical similarity to reference drugs and comparability to MabionCD20 originating from small-scale manufacturing, used in earlier clinical trials. In the Company's opinion, the aforementioned trials and the scope of data (items 1–4) developed as part of the arrangements with the EMA and the PEI are sufficient for the submission of a registration application to the EMA. With the aforementioned arrangements and assumptions in mind, the Company's Management Board estimated the budget for marketing authorisation of MabionCD20 (the target product manufactured on a commercial scale) on the European market, including the costs of the trial arm in the RA indication for the US market and the costs accompanying it and, based on the best estimates, determined the expected net expenditure at PLN 105–115 million over the period assumed (i.e. until the expected registration of the product on the European market). The estimated budget includes the costs already incurred by the Company for the project starting from Q1 2020. The estimates include the expenditures required for the development of the medicine, including the costs of the three-arm bridging clinical trial, the three-arm analytical trial, manufacturing costs, operational maintenance costs, costs of the regulatory procedures (before the EMA and the FDA), and expenditures for quality assurance and control. The aforementioned budget items reflect the estimated full costs to be incurred in connection with authorising MabionCD20 on the European market, while for the US market they reflect the project budget with the exception of the costs of the additional trial in the oncology indication (which, in the Company's opinion, is a necessary element of the registration application in the US market). The estimates outlined above do not take into account the costs of day-to-day operations of the Company and capital expenditure associated with increased production capacity. The above assumptions may be subject to change in the future (due to the fact that they are based on a number of factors that may affect the time-frame, including factors beyond the Company's control such as the speed of clinical trial recruitment). Moreover, the assumptions made and actions performed do not guarantee the registration of the product. In planning the scope and timing of the clinical trial, the foreseeable constraints of the COVID-19 pandemic were taken into account. The activities related to the development of MabionCD20 do not collide with other projects run by the Company, including in particular the cooperation programme with Novavax in the area of production of the active substance for a vaccine against COVID-19.

The Company informed about the above event in Current Report no. 49/2021 of 30 July 2021.

3.3. Transactions with related parties

In H1 2021, the Company did not enter into transactions with related parties on terms other than arm's length.

3.4. Guarantees and sureties granted for a loan or borrowing

In H1 2021, the Company did not provide any loan or borrowing sureties or guarantees in aggregate to any 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 the main 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 and/or the schedules of projects carried out by the Company. In addition, such random events as fires, floods and other extraordinary natural disasters may cause failures or destruction of material property belonging to Mabion S.A., as well as disruptions to the Company's operations, which may adversely affect the Company's financial results.

Risk related to operations carried out on an international scale

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

- multiple, conflicting and changing laws and regulations, including those relating to privacy, tax, export and import restrictions, labour law, regulatory requirements and other administrative consents, permits and licences;
- failure to obtain or to keep by co-operating entities the regulatory permits for use of the Company's products in various countries;
- additional potentially significant patent rights of third parties;
- complex and difficult aspects of obtaining protection and pursuing intellectual property rights;
- difficulties in filling positions and management of foreign operations by the Company or by entities cooperating with the Company;
- complex aspects related to the management of multiple reimbursement systems, public payers or patient payment systems by cooperating entities;
- limitations of Company's capabilities and the possibilities of cooperating entities in the scope of entering international markets;
- financial risks such as long payment cycles, debt collection difficulties, the impact of local and regional financial crises on demand and payment for products, as well as exposure to the risk of exchange rate fluctuations;

» natural disasters, political and economic instability, including war, terrorism, civil unrest, outbreak of disease, boycotts, restriction of freedom of trade and other business constraints;

» certain expenses, including travel, translation and insurance expenses;

» regulatory and compliance risks that relate to reliable information and control over sales and operations.

Risk related to the coronavirus (COVID-19) pandemic

As regards the coronavirus (SARS-CoV-2) epidemic threat, which started to increase with the beginning of 2020, there was a risk of delays in the schedule of work or suspension of work for an unspecified period of time due to the possible or actual restrictions indicated below:

» reduced staff availability (quarantine, childcare in case of school closures, risk of falling ill);

» limiting the mobility of the Company's employees – suspension of the participation of the Company's representatives in meetings and conferences, both foreign and domestic;

» suspension of meetings with external companies, including consultants;

» delays in deliveries resulting in the inability to conduct certain processes in the Company;

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

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

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

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

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

All the above mentioned phenomena may have a direct impact on the financial situation of the Company. In order to prevent the aforementioned risk, the Management Board monitors the global situation on an ongoing basis, trying to adapt the Company's strategy to changes in the threats in the areas described above in advance. With regard to the epidemic risk, the Management Board has taken steps to significantly reduce the risk both through the education of employees and the implementation of solutions to protect workers' health (e.g. a resolution was adopted on the introduction of countermeasures, together with later updates, by the Management Board in connection with the entry into force of the Act of 2 March 2020 on special solutions related to the prevention, counteracting and combating of COVID-19, other infectious diseases and crisis situations caused by them. The Management Board is monitoring the situation on an ongoing basis and in the event of significant new circumstances related to SARS-CoV-2 coronavirus pandemic and affecting the Issuer's operations, the Company will introduce appropriate solutions, adapting to administrative decisions

Risk related to changes in legal regulations and their interpretation

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

Risk related to the tax policy

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

Risk related to administrative decisions

The Company is unable 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, or 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. Due to the fact that Mabion intends to sell its medicines in foreign markets (with sales transactions denominated mainly in EUR and USD), the risk associated with exchange rate fluctuations may be limited in the future.

Bio-tech drug 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 hundreds of companies and the

estimated expenditure will have a CAGR of 11–14% (until 2023).[1] 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 this report, biosimilars to MabThera/Rituxan have been marketed in the EU by Celltrion, Sandoz, and Pfizer, and in the USA – by Celltrion, Pfizer and Amgen.

The above mentioned activities of competitors do not affect Mabion's schedule. Even if the commercialisation of a biosimilar drug to MabThera/Rituxan is successful for several players, the analyses show that this market has a growth potential. For the sustainable development of the market for biosimilar medicines, it is essential that more manufacturers emerge. Even within the EU, where the market penetration of biosimilar medicines is the highest, some countries still have low access to biosimilar treatments. Currently, demand for medicines for oncology and autoimmune diseases exceeds the production capacity of suppliers and is limited by the financial capacity of national health systems. The market for biosimilar drugs is one with high entry barriers. These include very high requirements for clinical trials, particularly in the US and other developed countries, to prove that a medicine is biosimilar to the original medicine. This is supported by the fact that in November 2018, Sandoz abandoned its attempt to apply for marketing authorisation in the US for its biosimilar drug MabThera/Rituxan, after the regulator requested additional data[2].

Partnering risk

In 2016, the Company signed a long-term cooperation agreement with Mylan. The agreement had ensured that Mylan would have had exclusive rights to sell the drug under the working name of MabionCD20 in all EU and Balkan countries. In addition, under the agreement, Mylan provided support to the Company in the process of registration of MabionCD20 by the EMA. In April 2021, the Company signed an annex to the cooperation agreement with Mylan, under which the parties decided that Mylan will remain Company's non-exclusive distribution partner for MabionCD20 in selected countries in regions such as, in particular Australia, New Zealand, Mexico, Central America, South Africa, South East Asia, deciding at the same time that Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries, as well as Mylan's priority right to enter into a commercialization agreement for MabionCD20 in the United States (USA), shall expire.

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

1 Global Oncology Trends 2019, IQVIA Institute
2 http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681

Risk related to the research and development process

The biotechnology industry, especially the production of modern biosimilars, is characterised by high labour intensity and the need to incur significant expenditure on research and development. Not only the possibility of launching the developed medicines on the market but also the efficiency of production processes and therefore also the manufacturing costs depend on the results of the conducted research and development work. The Company uses most of the funds so far obtained for research and development. There is a risk that some of or all of the Company's research objectives will not be achieved to the full extent planned or within the scheduled time, and so it will be unable to recover some or all of the research outlays. This can have a significant negative impact on the feasibility of the Company's strategic plans and thus its financial performance.

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

Risk of underestimating the costs of MabionCD20 manufacture and launch

According to assumptions very generally adopted by the biotechnological industry, the development and production of a single biosimilar which meets global standards lasts about 10 years[3] and costs between USD 100 and 300 million[4]. Guidelines relating to biosimilars are only now being formed and each case is analysed by market regulators individually, therefore, the scope of requirements relating to the technology, documentation, analytics and clinical development is not strictly specified. Therefore, the exact scope of research and development work cannot be determined and the development costs of the medicines cannot be precisely anticipated. It cannot be ruled out that the actual costs of manufacturing and marketing of developed drugs (including MabionCD20) will be significantly higher than currently assumed. A significant increase in the costs of production and introduction of the developed drugs to the market may adversely affect the financial results achieved by the Company.

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

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

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

Risk related to the work schedule – MabionCD20

The achievement of the Company's strategic goal, which is the registration and market launch of biosimilars as soon as possible after the expiry of patent protection of the original medicines, is connected with the need to develop a detailed work schedule

3 https://gabionline.net/biosimilars/research/Development-of-biosimilars
4 https://ec.europa.eu/docsroom/documents/38461/attachments/1/translations/en/renditions/native

for several years. The possibility of pursuing this schedule depends on many various factors, both internal and external. Potential unexpected delays in the adopted time schedule may lead to not achieving the planned sales revenue in the expected period and have a negative impact on the Company's financial results. The Management Board monitors all works related to the development of medicines and if necessary implements the required operating solutions to minimize the impact of unexpected events on adopted time schedules.

In 2017, the company initiated the research and development process for MabionCD20, which is a medicine directly competing with the existing market drug MabThera / Rituxan from Roche. The basic patent protection in Europe for this drug expired in the period: end of 2013 – before the end of 2014, while in the United States of America, it expired in July 2018.[5] The Company's goal was to market MabionCD20 as soon as possible after patent expiration, which would allow the Company to achieve a temporarily favourable competitive position. In order to prevent registration risks, the Company, since the start of work on the development of MabionCD20, has cooperated with EMA regarding compliance with guidelines and procedures related to the registration process in the European Union. It has held scientific advice sessions to eliminate doubts and to refine the activities related to the preparation of registration documentation. However, the EMA has a number of tools at its disposal to ensure the regulator's discretion and the possibility of adjusting the solution individually to the needs of a specific registration procedure. The Company has no influence on the EMA's assessment of applications and responses.

There are a number of possible events in the registration process – positive or negative decisions, obtaining a list of additional questions (once or more), filling in a round of oral answers (once or more), withdrawal of the application by the Company and its resubmission after supplementing, or other events not envisaged by the Company. The schedule of work on the part of the Company also depends to a large extent on the recommendations of the regulator, which the Company may receive during the aforementioned Scientific Advice sessions.

For the US market, the Company is actively pursuing a consultative process with the FDA, the purpose of which is to determine and perform activities consistent with the FDA's expectations and necessary for the registration of MabionCD20 in the United States. However, there is a risk that after analysis of data presented by the Company in the consultation process, FDA will indicate the need for additional work to be carried out by the Company, which may affect the schedule of drug registration in the USA.

Risk related to the work schedule – NVX-CoV2373

In March 2021, Mabion entered into a framework agreement with Novavax, Inc. based in the United States, pursuant to which the Company, with Novavax's participation, will undertake activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate protein antigen under the working name of NVX-CoV2373 and conduct technical trial runs of the process on a commercial scale at the Company's facility. The parties agreed on the scope and budget of the work contracted to the Company as part of the first order to carry out the technology transfer and a technical run for the NVX-CoV2373 protein antigen. However, the risk that the planned timetable may change due to a number of factors of a technological and logistical nature at the level of supply of materials and substances necessary for the planned work, as well as those related to the currently re-emerging COVID-19 pandemic, cannot be excluded. Due to a number of factors, there is a significant risk of delays in the implementation of the work and the need to postpone the originally adopted work schedule.

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

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

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

Risk related to low quality or loss of biological material

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

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

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

Risks related to the production process and quality control process

One of the key elements in the production of biotechnological medicines is the production process, which must be carried out in compliance with the previously planned parameters. The process of producing such medicines consists of several stages and even the smallest change in any of them may negatively affect the properties of the drug (e.g. in terms of efficacy or safety). An extremely important element of the medicine manufacturing process is the transition from a small laboratory scale to the scale of industrial production (up-scaling). It is very important to ensure continuity, stability and purity of the entire production process. The Company's quality control laboratories are equipped with state-of-the-art equipment that ensures maximum accuracy and repeatability of the obtained results. A panel of validated analytical methods ensures maximum accuracy, precision, specificity and reproducibility of the results. Designed in accordance with the regulator's guidance requirements, it enables reliable product inspection. A key parameter of analytical methods is their variability, which is influenced by a number of factors determined during validation. Continuous control of method variability over time is critical for research where results are collected over years (e.g. product stability, biosimilarity and bioequivalence studies). The absence of a reliable analysis of method trends may adversely affect the final assessment of both production processes and the bioequivalence of tested and reference products. The materials used in the production zone have appropriate certificates for use in the pharmaceutical industry. The installed production line is based on sterile materials. The managing staff of the Company's departments are high-ranking specialists with a major education background, trained and properly prepared to carry out their scope of duties, both by internal and external experts.

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

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

An extremely important factor in the Company's operations is maintaining appropriate conditions on the premises where the Company's products are being developed. Currently, Mabion holds all required approvals for the equipment and laboratory and manufacturing premises in both plants. The production process is monitored on a continuous basis and verified in accordance with the procedures adopted at the company, owing to which the Company systematically seeks to reduce the level of risk in this area. The company meets the requirements of Good Manufacturing Practice (GMP), holds the necessary approvals and permits (including a GMP Certificate for the Complex in Konstantynów Łódzki, issued by the Main Pharmaceutical Inspector).

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

Currently, it is difficult to estimate the precise demand for Mabion CD20, but the plans to sell the medicine on the US market and other markets are connected with the need to increase production capacity above the level possible at the present plant in Konstantynów Łódzki. The company is aware of these needs and it took care of the possibility of erecting another building in the same location, on the same plot. This building can be used to a greater extent for the production process (the current building also has an office part). The final date and scope of such an investment will depend on arrangements with distribution partners regarding the planned delivery of MabionCD2.

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

Risk related to clinical trials

One important preparation stage related to the registration and marketing of medicines are clinical trials. Conducting clinical trials involves risks that can be grouped as follows:

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

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

Being aware of the possible risk, the Company undertakes a number of activities leading to its minimisation. As part of these activities, all clinical trials planned by the Company, once an internal strategy has been established, are consulted with experienced, external, independent specialists and regulatory agencies in order to obtain a validated trial protocol designed to ensure the desired results with adequate statistical power. In addition, the product is evaluated with a broad panel of biological and physicochemical analyses before it is used in a clinical trial. These analyses are a more sensitive model for the characterisation of a medicinal product than a biological model in the form of a patient, and therefore the studies significantly reduce the risk of inadequate efficacy or safety of a Company's product used in a clinical trial.

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

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

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

Risk related to drug registration

The primary objective of the Company is the introduction of the developed biosimilars to global markets, primarily the EU and US markets, which involves the obligation to register such drugs with the EMA and Food and the FDA, respectively.

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

The scope and format of the MabionCD20 registration application concerning the large, target scale of production is being consulted with the representatives of the EMA and national agencies (e.g. German Paul Ehrlich Institut) under the Scientific Advice procedures to align it with the Agency's expectations, which the Company believes should streamline the registration process.

In July 2020, the Company received a written response from the EMA as part of the Scientific Advice procedure to the Company's specific assumptions regarding the new product registration process for MabionCD20, in particular to the scope of data to be included in the registration application, as well as the actions proposed to generate such data. With the help of external regulatory

experts, the Company analysed the documents received and adopted a preliminary framework for the scope and schedule of work required to submit a new marketing authorization application (MAA) for the product. However, due to the specific responsibilities of the regulatory authorities, the content of the document is subject to interpretation, which poses some risk of discrepancies in interpretation.

In September 2020, the Company held consultations (under the national Scientific Advice procedure) with the German Paul Ehrlich Institut (PEI) to clarify the details of the study for the registration of the 5000L-scale produced MabionCD20 with the EMA; Following these arrangements, it was decided, inter alia, to change the assumptions of one of the analytical methods. The Company has also confirmed with the European regulators the target quality profile based on data obtained from validation batches produced at the target manufacturing scale and has established the scope of analytical trials for MabionCD20 produced on a commercial scale.

The Company has also requested another analytical Scientific Advice procedure from the EMA to further clarify the details of the assumptions for the analytical methods employed in the biosimilarity and bioequivalence trials.

As part of the discussions on the RA clinical trial design, the Company continued to consult with the FDA and the EMA. Following an additional consultation with the German Paul Ehrlich Institut, a programme was devised to minimise regulatory risks on the premise of providing an additional clinical data package in the form of a treatment effectiveness evaluation (on a population of 280 patients).

Nevertheless, although the registration process takes place in accordance with the adopted regulations and according to specific guidelines, the regulators (both the EMA and the FDA) have a number of tools at their disposal which provide them with considerable decision-making freedom and the possibility of individual adaptation of solutions to the needs that occur, in the regulator's assessment, in a given registration procedure. The process of registration and authorisation of a medicine is multi-stage, which the final position of the regulator being developed throughout the whole process. Even if the regulator provides guidance and guidelines on the shape and scope of the data currently required, it cannot be ruled out that additional requirements for product approval may arise in the future as part of the registration procedure for MabionCD20 manufactured on 5000L scale or independently of that procedure.

Risk related to launching and maintaining medicines on the market

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

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

Upon signing an Annex with Mylan in April 2021, under which it was decided to terminate Mylan's exclusive right to sell MabionCD20 in the EU and the Balkan countries, the Company will start seeking a strategic partner through Rothschild & Co. and Plexus Ventures LLC. The process is complex and multi-stage and the Company will inform the market of its progress on an ongoing basis.

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 key Mabion's 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 relationships among senior management. If it is not possible to integrate these people and establish good employee relations between them and other members of management, this may have a negative impact on the Company's performance.

In order to counteract the above risk, the Company's Management Board pursues an active HR policy aimed at retaining the most valuable specialists in the company and supporting their development. The success of the Company depends, among other things, on the continuous ability to attract, maintain and motivate highly qualified management and scientific staff. The Company implements activities aimed at supporting the professional development of its employees, e.g. through their participation in internal and external training, support in undertaking doctoral studies, as well as including in the promotion procedure. The rules governing these benefits are formalised, open and objective (e.g. promotion procedures, implementation of bonus programmes for employees with a certain seniority – "Mabion's Ambassador"). In addition, in 2018 the Company adopted the Incentive Scheme for persons of key importance to the Company, implemented over a period of up to 4 financial years, i.e. for the financial years 2018–2021. The aim of the Scheme is to ensure optimal conditions for the growth of the Company's financial results and long-term growth of the Company's value, by means of a permanent relationship between the persons participating in the Incentive Scheme and the Company and its objectives.

Risk related to disclosure of trade secrets

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

Risks related to patent protection

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

However, it cannot be ruled out that there is a risk that patent offices will undermine the legitimacy of patent protection in applied for by the Company, and the arguments presented by the Company will be insufficient to grant this protection. In order to prevent this and other risks associated with the granting of patent protection, the Company's Management Board cooperates with professional advisers and experts in the field in question.

Risk related to industrial and intellectual property disputes

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

Risk related to the funding obtained

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

» *"Development and scaling of the innovative process for manufacturing the therapeutic recombined monoclonal antibody to enable the industrial implementation of the first Polish biotechnological medicine for oncological and autoimmune therapies"*
  - Value of the project: PLN 54,188 thousand
  - Value of co-financing (contribution from the EU Funds): PLN 27,094 thousand
  - Project implementation period: 01.11.2016 – 29.12.2020.

The initial deadline for the project was set for 31 December 2019. In December 2019, the NCBR, at the Company's request, agreed to extend the project time-frame until 30 September 2020. In view of the SARS-CoV-2 pandemic, in accordance with the Act of 3 April 2020 on special arrangements to support the implementation of operational programmes in connection with the COVID-19 outbreak in 2020, the deadlines for the completion of projects under the Operational Programme Smart Development were extended by 90 days, and as a consequence the deadline for the Company's project has been extended to 29 December 2020. In September 2020, the implementation of the first stage of the project was completed, and was positively evaluated by NCBR. In accordance with the assumed deadline (December 2020), the Company has completed all the tasks provided for in the aforementioned project and has submitted the relevant documentation to the NCBR. On 3 August 2021, the Company signed an annex to the co-financing agreement with the NCBR, providing for final settlement of both the project value (PLN 53,896 thousand) as well as the value of obtained co-financing (PLN 26,948 thousand). At present, the Company is anticipating the formal closure of the project, which includes the acceptance of the Final Report and the final payment request.

» *"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 thousand
  - Value of co-financing (contribution from the EU Funds): PLN 28,354 thousand
  - Project implementation period: 01.08.2017 – 30.07.2022.

As at the date of publication of this report, the project is being implemented according to the schedule agreed with the NCBR. The Company has completed Phase I of the project and has received NCBR's approval for the 2019 and 2020 project report.

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

In 2017, the Company decided to end the above mentioned project at its current stage of implementation due to the high scientific risk related to the implementation of research and the analysis of the competitive environment. From the received funding, the Company used funds in the amount of PLN 177 thousand. In 2019, the Company received information from the NCBR on the obligation to repay the amount of PLN 149 thousand together with interest, as reimbursement of funding under the INNOMED project, following which it paid the above liabilities in full. In 2020 March 2020, the Company received a letter from the NCBR informing that after the verification of the cash flows under the subsidy agreement, the amount of liability under the adjustment amounting to PLN 24 thousand and interest remained to be repaid. The Company has paid the amount and has no liabilities arising from the project in question. On 24 February 2021, the Company received a letter from the NCBR confirming that the final report on the project was assessed negatively and that the project was deemed in its entirety not to have been completed.

» *"Expansion of the Research and Development Centre of Mabion S.A. - research on the new generation of medicines"*
  - Value of the project: PLN 172,876 thousand
  - Value of European Regional Development Fund co-financing: PLN 63,247 thousand
  - Project implementation period: 20.01.2018 – 31.12.2021

The objective of the Project is to develop the Company's research and development facilities by preparing the necessary infrastructure: the building of the Research and Development Centre, and the purchase of research equipment to conduct research on innovative medicines. Currently, the Company is in the process of implementing the project in question, however, due to issues related to the financing of its own contribution, the project work is delayed with respect to the originally assumed schedule. The implementation of the project in its full, originally assumed scope will require extending its implementation period, for which the Company will probably apply. At present, the Company is in ongoing contact with the Ministry of Funds and Regional Policy.

All the above indicated co-financing agreements stipulate in detail the dates and scope of tasks which may be subsidized. There is a risk that if the Company fails to complete the planned work within the deadlines set by the intermediary body, uses all or part of the subsidy contrary to its intended purpose or without complying with the applicable procedures, collects all or part of the subsidy in an undue or excessive manner, it will be obliged to reimburse part or the full amount of the subsidy plus interest. There is also a risk that the Intermediate Body does not grant consent in the event of further problems related to substantive or financial progress, which may be related to the termination of co-financing agreement(s) and the necessity to return the funds collected together with interest.

As a result, if the conditions giving rise to the liability are met, the Company's financial position may deteriorate significantly, which in the long run may jeopardise the achievement of the Company's strategic objectives. In order to counteract the above risk, the Company has put in place internal procedures for the ongoing monitoring of project expenditures – the spending methods used and the schedule of spending implementation, as well as closely cooperates with intermediary institutions, informing on the ongoing basis on any possible risks.

Liquidity risk

In the first half of this year, the Company has generated revenue from the sales of market products, but its operations are also financed by funds raised from share issues, shareholder borrowings, available credit facilities, public funding and proceeds from distribution partners.

In January 2021, Mabion adopted a new long-term strategy for financing its operations. The strategy includes the overall capital needs of the Company that should be satisfied to carry out all activities necessary to complete the registration of MabionCD20 with the EMA and to commence sales of MabionCD20, which will allow the Company to generate operating cash flows. The adopted financial strategy consists of parallel processes: commencement of activities aimed at acquiring a strategic investor and two issues of the Company's shares. At the same time, as a result of the successful completion of the first issue (U shares) and the conclusion of the framework agreement with Novavax, Inc. for the COVID-19 vaccine programme in March 2021, the Company cancelled the Extraordinary General Meeting which was to pass a resolution on the second of the above-mentioned

issues of the Company's shares. The decisions to update the Company's financial strategy, including whether or not to carry out a further share issue, will be taken after detailed analyses.

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

Risk related to operations in the Łódź Special Economic Zone

Mabion S.A. conducts research and development, and production operations, and has built a fully-equipped Scientific-Industrial Complex in the Łódź Special Economic Zone (LSEZ). In accordance with the Act on Special Economic Zones, the income earned on business activities in a special economic zone, under the permit received, is exempt from Corporate Income Tax. Mabion S.A. is exempt from the tax until 31 December 2026. There is a risk of changes in law provisions concerning the operation of special economic zones or in tax advantages applicable in those zones. There is also a risk that the Company will cease meeting the conditions specified in the permit which entitles it to avail itself of these advantages. Upon the expiry of the permit or if the Company loses the permit before its expiry Mabion's further operations in the LSEZ may become unfavourable and increase tax burden.

4. Analysis of the financial condition and assets of Mabion S.A.

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

The condensed semi-annual financial statements of the Company for the period from 1 January 2021 to 30 June 2021 have been drawn up in conformity with the International Financial Reporting Standards (IFRS) as approved by the European Union at the reporting date. The financial statements cover a comparative period from 1 January to 30 June 2020, and comparative data as at 31 December 2020. The financial statements have been drawn up on the historical cost basis except for derivative financial instruments, available-for-sale financial assets which have been measured at fair value. The condensed semi-annual financial statements, with the exception of the cash flow statement, have been prepared on an accruals basis.

The accounting policies applied to draw up the condensed semi-annual financial statements are the same as those applied to draw up the 2020 annual financial statements. The condensed semi-annual financial statements do not include all the information required in the full financial statements compliant with IFRS as adopted for application in the European Union ("IFRS") and should be read in conjunction with the audited financial statements of the Company for the financial year ended 31 December 2020, published on 30 April 2021.

There were no changes in the rules for measuring assets and liabilities and financial result in H1 2021.

The condensed semi-annual financial statements have been drawn up in accordance with the going concern principle, which provides that the Company will continue to operate in the foreseeable future.

As at 31 December 2020, the Company generated a cumulative loss which resulted in negative equity. On 23 February 2021, the Extraordinary General Meeting of the Company adopted Resolution No. 3/II/2019 concerning confirmation of further existence of the Company in connection with the occurrence of the circumstances provided for in Article 397 of the Code of Commercial Companies.

After the issue of U series shares in March this year, the Company's equity as at 30 June 2021 totalled PLN 31.8 million.

The condensed semi-annual financial statements of the Company for the period from 1 January 2021 to 30 June 2021 have not been audited. However, they have been reviewed by the audit firm PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k.

4.2. Financial condition of Mabion S.A. after the first half of 2021.

Sales, costs, and financial result

The table below presents an analysis of the results generated by the Company in H1 2021 (in PLN thousand):

	01.01-30.06.2021	01.01-30.06.2020	Change (%)
Net income from sales and equivalent income	1,590	0	not applicable
Costs of sold products, commodities, and materials	0	0	not applicable
Gross profit (loss) on sales	1,590	0	not applicable
General administration costs	-9,568	-9,882	-3%
Costs of research and development work	-10,788	-20,050	-46%
Other operating income and costs, net	256	901	-72%
Operating profit (loss)	-18,510	-29,031	-36%
Gross profit (loss)	-19,572	-30,829	-37%
Income tax	0	0	not applicable
Net profit (loss)	-19,572	-30,829	-37%

In H1 2021, the Company generated revenues from the provision of services (development of the antibody production technology) for Celon Pharma S.A. in the amount of PLN 1,590 thousand. In the period of 6 months ended 30 June 2021, the Company incurred a tax loss of PLN 6,150 thousand. The Company has not recognised a deferred tax asset on this loss due to the conditions of IAS 12 not being met as to the probability of taxable income allowing the loss to be utilised before the expiry of the period for its utilisation. The amount of tax losses carried forward is presented in the financial statements for the financial year ended 31 December 2020.

Company's assets and related funding

Assets	30.06.2021		31.12.2020		Change (%)
	Value (PLN thousand)	Structure	Value (PLN thousand)	Structure	
Fixed assets	**71,142**	**31%**	**66,546**	**85%**	**7%**
Intangible assets	930	0%	1,071	1%	-13%
Property, plant and equipment	70,006	31%	65,280	84%	7%
Long-term receivables	206	0%	195	0%	6%
Long-term investments	0	0%	0	0%	not applicable
Long-term prepayments and accruals	0	0%	0	0%	not applicable
Current assets	**156,276**	**69%**	**11,775**	**15%**	**1,227%**
Inventories	11,913	6%	5,976	8%	99%
Trade and other receivables	66,633	29%	2,641	3%	2,423%
Prepayments and accrued income	429	0%	763	1%	-44%
Cash and cash equivalents	77,301	34%	2,395	3%	3,128%
Total assets	**227,418**	**100%**	**78,321**	**100%**	**190%**

The value of Mabion S.A.'s assets as at 30 June 2021 totals PLN 227,418 thousand, which represents 190% of the assets' value as at 31 December 2020.

Liabilities and equity	30.06.2021		31.12.2020		Change (%)
	Value (PLN thousand)	Structure	Value (PLN thousand)	Structure	
Equity	**31,827**	**14%**	**-77,388**	**-99%**	**-141%**
Liabilities and provisions for liabilities	**195,591**	**86%**	**155,709**	**199%**	**26%**
Bank loans	15,593	7%	31,380	40%	-50%
Long-term liabilities	57,376	25%	51,138	65%	12%
Short-term liabilities	138,215	61%	104,571	134%	32%
Prepayments and accruals	57,815	25%	50,856	65%	14%
Total liabilities and equity	**227,418**	**100%**	**78,321**	**100%**	**190%**

Cash flow statement

The table below presents a summary of the Company's cash flows (in PLN thousand):

	01.01.2021 -30.06.2021	01.01.2020 -30.06.2020	Change (%)
Net cash flows from operating activities	-29,397	-15,613	88%
Net cash flows from investing activities	-7,977	-2,667	199%
Net cash flows from financing activities	112,280	-1,516	-7,506%
Total net cash flows	**74,906**	**-19,796**	**-478%**

In H1 2021, the Company generated a negative cash flow balance from operating activities. The most significant factor affecting the value of generated cash flows from operating activities were research and development costs incurred by the Company.

Selected indicators of the Company's financial condition

In 2020, the Company did not make any sales of products or services as part of its core business, while in 2021, it sold services (development of the antibody production technology) to Celon Pharma S.A. in the amount of PLN 1,590 thousand. At the same time, the Company incurred operating expenses in connection with the costs of conducted development work, investments in machines and equipment used for conducting development work and for the production of medicines in the future, as well as general administration costs related to, among others, obtaining funds for current operations.

Therefore, both in 2020 and 2021, the Company recognised a loss on operating activities and a net loss, and therefore it is not possible to determine financial ratios for the Company related to profitability.

4.3. Description of factors and events of a significant impact on the condensed financial statements

In H1 2021, there were no factors or events, including those of an unusual nature, other than those indicated in the other sections of the report, which would have a significant impact on the Company's condensed financial statements.

4.4. Factors to affect the results to be achieved within at least the next quarter

The main factors to affect the Company's performance in the coming quarters are:

- the scope and timing of the work required to conduct the bridging clinical trial and submit a new marketing authorisation application (MAA) for MabionCD20 on the basis of the Scientific Advice procedure with the EMA;
- implementation of the work related to product stability tests and similarity and comparability tests for the product originating from the large-scale validation batches and achievement of the expected results;
- costs of ongoing research and development for MabionCD20 and other medicines in the Company's pipeline;
- results of work related to the transfer of manufacturing process technology for the COVID-19 vaccine candidate antigen under the working name of NVX-CoV2373 and the possibility of commercial manufacturing for Novavax at the Company's facility;
- the implementation of the Company's financing strategy adopted on 27 January 2021, including the possibility of acquiring a strategic investor and/or conducting a prospectus issue;

- possibility of establishing cooperation with new partners for the development of the Company's current or future therapeutic projects;
- possibility of acquiring a distribution partner or partners for the EU and US markets for MabionCD20;
- proceeds from the assistance granted from European funds and the possibility of obtaining additional funds from the EU;
- timely disbursement of funds by state institutions dealing with the distribution of means under projects co-financed from EU funds;
- staff costs and general administration costs of the Company;
- completion of research and development work on and registration of MabionCD20 on key markets: European and American;
- funding the planned increase in production capacity, taking into account the intensification of activities related to the new production plant construction project;
- exchange differences resulting from changes in foreign currency exchange rates;
- renegotiating the change in the conditions for disbursement of loan tranches by the European Investment Bank.

Receipts/refunds of costs incurred may be affected by possible delays in ongoing discussions or unforeseen departures from the schedules of agreements already signed.

As the global epidemiological emergency related to coronavirus (SARS-CoV-2) continues, additional risks and factors have been identified, of which the financial risks have been identified concerning the liquidity disruption in the markets resulting from the spread of the virus and the consequent possible restriction of the Company's access to funding may prove to be particularly important. The 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, as indicated below, remains valid, as further elaborated in sections 3.5. and 6.2. of this report.

All the above mentioned phenomena may have a direct impact on the financial situation of the Company.

4.5. Position of the Management Board on the feasibility of previously published forecasts for the year

The Company has not published financial result forecasts for 2021.

5. Shares and shareholders

5.1. Share capital structure

As at 30 June 2021 and as of the date of this report, the Company's share capital amounts to PLN 1,616,132.60 and is divided into 16,161,326 shares with a nominal value of PLN 0.10 each, including:

- 450,000 A series registered preference shares,
- 450,000 B series registered preference shares,
- 450,000 C series registered preference shares,
- 450,000 D series ordinary preference shares,
- 100,000 E series registered preference shares,
- 100,000 F series registered preference shares,
- 20,000 G series registered preference shares,

- 2,980,000 H series ordinary preference shares,
- 1,900,000 I series ordinary preference shares,
- 2,600,000 J series ordinary preference shares,
- 790,000 K series ordinary preference shares,
- 510,000 L series ordinary preference shares,
- 360,000 M series ordinary preference shares,
- 340,000 N series ordinary preference shares,
- 300,000 O series ordinary preference shares,
- 1,920,772 P series ordinary bearer shares,
- 10,000 S series ordinary bearer shares.
- 2,430,554 U series ordinary bearer shares,

Registered shares of A, B, C, E, F and G series are privileged in such a way that each of them entitles to two votes at the General Meeting. The total number of votes resulting from all issued shares of the Company is 17,731,326 votes.

Release of 500 S series ordinary bearer shares

On 18 February 2021, 500 S series ordinary bearer shares with a nominal value of PLN 0.10 each issued by the Company on 23 June 2020 were released (recorded in the securities accounts) in connection with the exercise by the eligible persons of their rights under the B series subscription warrants granted to those persons as part of the Incentive Scheme for 2019. Accordingly, the Company's share capital was increased to PLN 1,373,077.20. The shares were taken up for cash contributions made in full before the shares were released. The Company informed about the event in Current Report no. 10/2021 of 18 February 2021.

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

On 16 February 2021, the Board of Giełda Papierów Wartościowych w Warszawie S.A. (Warsaw Stock Exchange S.A., "WSE") adopted a resolution on the admission and introduction to exchange trading on the WSE Main Market of S series ordinary bearer shares of the Company, in which the WSE's Board stated that 500 S series ordinary bearer shares of the Company, of a nominal value of PLN 0.10 each, are admitted to trading on the main market. At the same time, the WSE's Board decided to introduce, as of 18 February 2021, the above mentioned Company's shares to trading on the primary market, provided that Krajowy Depozyt Papierów Wartościowych S.A. ("KDPW") has registered these shares on 18 April 2021 and assigned it with code PLMBION00016. On 16 February 2021, the KDPW published an announcement on the registration of the above shares under code "PLMBION00016" in the securities depository as of 18 February 2021. Thus, the aforementioned condition was fulfilled and the shares were introduced to trading on 18 February 2020. The Company informed about the above events in Current Reports no. 8/2021 of 16 February 2020, no. 8/2021 and no. 9/2021 of 17 February 2021.

Issue and admission to trading of 2,430,554 U series ordinary bearer shares

On 23 February 2021, the Extraordinary General Meeting of the Company adopted resolution on increasing the Company's share capital by not less than PLN 0.10 and not more than PLN 243,055.40 up to not less than PLN 1,373,077.30 and not more than PLN 1,616,132.60 through the issue of not less than 1 but not more than 2,430,554 ordinary bearer shares with a par value of PLN 0.10 each. Then, as a result of the accelerated book-building process carried out as part of the offering of new issue shares by way of private subscription within the meaning of Article 431 § 2.1 of the Commercial Companies Code, on 15 March 2021 agreements were concluded for the taking up of all 2,430,554 U series ordinary bearer shares of the Company at the issue price of PLN 55 per share.

The share capital increase through the issue of U series was been registered with the National Court Register on 2 April 2021. Following the registration, the share capital of the Company amounts to PLN 1,616,132.60 and will be divided into 16,161,326 shares with a nominal value of PLN 0.10 each, and the total number of votes resulting from all issued shares of the Company amounts to 17,731,326 votes.

On 14 April 2021, the WSE's Board adopted a resolution on the admission and introduction to trading on the WSE Main Market of the U series shares of the Company, pursuant to which it stated that 2,430,554 U series ordinary bearer shares of the Company are admitted to trading on the main market, and decided to introduce as of 19 April 2021 to trading on the main market the aforementioned shares of the Company, provided that the KDPW, on 19 April 2021, has registered these shares and designated them with the code PLMBION00016. On 15 April 2021, the KDPW published a notice on the registration, as of 19 April 2021, in the depository of securities under ISIN PLMBION00016 code, of 2,430,554 U series ordinary bearer shares of the Company, and therefore the condition for the listing of the shares on the WSE main market on 19 April 2021 has been met. For further information on the issue of U shares, please refer to section 3.2 of this report.

5.1. Shareholders with at least 5% of the total number of votes

To the best knowledge of the Management Board, as at the date of the report for H1 2021 (16 September 2021), the following shareholders held at least 5% of votes in the total number of votes at the General Meeting of the Company.

No.	Shareholder	Number of shares	Number of votes	Participation in the share capital	Share in the total number of votes
1.	Twiti Investments Limited	2,674,617	3,268,917	16.55%	18.44%
2.	Maciej Wieczorek through*:	1,717,485	2,210,335	10.63%	12.47%
	Glatton Sp. z o.o.	1,097,135	1,097,135	6.79%	6.19%
	Celon Pharma S.A.	620,350	1,113,200	3.84%	6.28%
3.	Polfarmex S.A.	1,474,346	1,957,196	9.12%	11.04%
4.	Funds managed by Investors TFI S.A.**	1,502,649	1 502,649	9.30%	8.47%
5.	Other	8,792,229	8,792,229	54.40%	49.59%
	Total	**16,161,326**	**17,731,326**	**100%**	**100%**

* *Mr Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 66.67% of the share capital of Celon Pharma S.A. and 75.01% of the total number of votes in Celon Pharma S.A.*

** *Based on the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 15 June 2020 and agreements on taking up the U shares of the Company concluded on 15 March 2021.*

To the best knowledge of the Management Board, as at the date of the previous interim report, i.e. report for Q1 2021 published on 20 May 2021, the following shareholders held at least 5% of votes in the total number of votes at the General Meeting of the Company:

No.	Shareholder	Number of shares	Number of votes	Participation in the share capital	Share in the total number of votes
1.	Twiti Investments Limited	2,674,617	3,268,917	16.55%	18.44%
2.	Maciej Wieczorek through*:	1,717,485	2,210,335	10.63%	12.47%
	Glatton Sp. z o.o.	1,097,135	1,097,135	6.79%	6.19%
	Celon Pharma S.A.	620,350	1,113,200	3.84%	6.28%
3.	Polfarmex S.A.	1,474,346	1,957,196	9.12%	11.04%
4.	Generali Otwarty Fundusz Emerytalny	1,714,263	1,714,263	10.61%	9.67%
5.	Funds managed by Nationale-Nederlanden PTE S.A.**	1,467,649	1,467,649	9.08%	8.28%
6.	Funds managed by Investors TFI S.A.***	1,502,649	1 502,649	9.30%	8.47%
7.	Other	5,610,317	5,610,317	34.71%	31.64%
	Total	**16,161,326**	**17,731,326**	**100%**	**100%**

* *Mr Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 66.67% of the share capital of Celon Pharma S.A. and 75.01% of the total number of votes in Celon Pharma S.A.*

** *Based on the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 18 June 2019 and agreements on taking up the U shares of the Company concluded on 15 March 2021.*

*** *Based on the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 15 June 2020 and agreements on taking up the U shares of the Company concluded on 15 March 2021.*

5.1. Number of shares held by managing and supervising persons

	Number of shares held by managing and supervising persons as at the date of submitting the report for H1 2021 (i.e. as at 16 September 2021)	Number of shares held by managing and supervising persons as at the date of submitting the report for H1 2021 (i.e. as at 20 May 2021)
Management Board		
Krzysztof Kaczmarczyk	holds directly 2,998 shares of the Company, constituting 0.02% of the Company's share capital and entitling to 0.02% of votes at the General Meeting.	holds directly 1,500 shares of the Company, constituting 0.01% of the Company's share capital and entitling to 0.01% of votes at the General Meeting.
Sławomir Jaros	holds directly 4,043 shares of the Company, constituting 0.03% of the Company's share capital and entitling to 0.02% of votes at the General Meeting.	holds directly 4,043 shares of the Company, constituting 0.03% of the Company's share capital and entitling to 0.02% of votes at the General Meeting.
Adam Pietruszkiewicz	holds directly 4,600 shares of the Company, constituting 0.03% of the Company's share capital and entitling to 0.03% of votes at the General Meeting.	holds directly 3,200 shares of the Company, constituting 0.02% of the Company's share capital and entitling to 0.02% of votes at the General Meeting.

	Number of shares held by managing and supervising persons as at the date of submitting the report for H1 2021 (i.e. as at 16 September 2021)	Number of shares held by managing and supervising persons as at the date of submitting the report for H1 2021 (i.e. as at 20 May 2021)
Supervisory Board		
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., a 66.67% participation in the share capital) – a total of 1,717,485 shares in the Company constituting 10.63% of the Company's share capital and entitling to 12.47% of votes at the General Meeting.	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., a 66.67% participation in the share capital) – a total of 1,717,485 shares in the Company constituting 10.63% of the Company's share capital and entitling to 12.47% of votes at the General Meeting.

In the period from the date of the previous interim report to the date of this report, the other managing and supervising persons did not hold any shares in the Company. Members of the Management Board and Supervisory Board of Mabion S.A. do not hold any title to the Company's shares other than indicated below.

In 2018, an Incentive Scheme for the period 2018-2021 was adopted. As part of the Incentive Scheme, the persons participating in it - the eligible persons, i.e. the key persons in the Company – may obtain the right to take up A and B series subscription warrants. The subscription warrants are issued free of charge. Each A and B series subscription warrant entitles to subscribe, respectively, for 1 R and 1 S series share. The issue price of shares for holders of A series subscription warrants is PLN 91 per each R series share, and for holders of B series warrants, it is PLN 0.10 per each S series share. The rights attached to the subscription warrants may be exercised until 31 July 2022. The Incentive Scheme allows for settlement in the form of an offer, extended by the Company to persons who have taken up the warrants, to purchase them against payment for the purpose of redemption. The decision on the form of exercising the rights is taken by the Supervisory Board of the Company after verification of the fulfilment of the criteria specified in the Incentive Scheme and on the basis of the recommendation of the Management Board.

In accordance with existing resolutions of the Company's (of February 2019 and 2020, and of January 2021) Supervisory Board of February 2019, February 2020, and January 2021, the persons entitled to take up subscription warrants for different years in the period 2018–2020 include, as at the date of this report, persons sitting on the Management Board of the Company:

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

» Mr. Grzegorz Grabowicz (Member of the Management Board) – for 2019: the right to take up a maximum of 3,300 A series warrants; for 2020: the right to take up a maximum of 5,101 A series warrants.

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

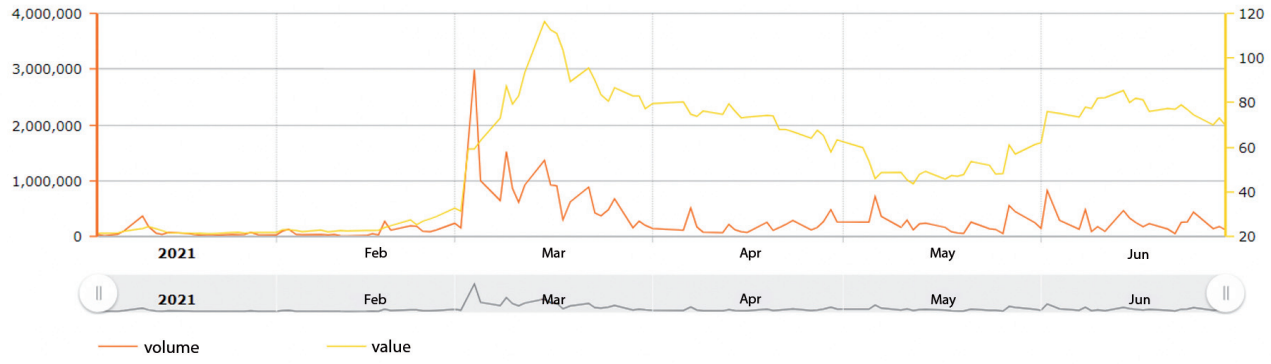
As regards the implementation of the Incentive Scheme for 2020, in February 2021 the Supervisory Board stated that in 2020, with respect to A series subscription warrants, the market objective constituting one of the two conditions for the right to take up and exercise the rights attached to A series warrants to become applicable was not met, while with respect to B series

subscription warrants, the condition for the right to take up and exercise the rights attached to B series subscription warrants was met. Therefore the Supervisory Board vested, all in eligible persons, the right to subscribe for a total of up to 500 B series subscription warrants for 2020. On 10 August 2021, the B series subscription warrants vested under the Incentive Scheme for 2020 have been credited to the investment accounts of the eligible persons.

5.2. Share quotations on the Warsaw Stock Exchange

For the first half of 2021:

Reference price:	PLN 20.75 (30.12.2020)
Start date:	2021-01-04
End date:	2021-06-30
Change:	236.39%
Change:	PLN +49.05
Minimum:	PLN 19.90 (2021-01-28)
Maximum:	PLN 126.20 (2021-03-15)
Average:	PLN 55.44
Total trading volume:	34,883,040 pcs.
Average daily trading volume:	283,602 pcs.
Total turnover:	PLN 2490.162 million
Average daily trading turn-over:	PLN 20.245 million



Source: www.gpw.pl

6. Other material information and events

6.1. Proceedings pending before a court, an authority competent to conduct arbitration proceedings, or a public administration body

In H1 2021 as well as at the date of this report, no material proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority, or public administration authority.

6.2. Other information trelevant for the assessment of the staff, property, financial condition, financial result and changes thereof, as well as information that is relevant for the assessment of the possibility of Mabion S.A. fulfilling its obligations.

The Company's future success depends, in particular, on securing the funds necessary to finance its operations and its ability to register and commercialise medicines, as well as winning orders for contract manufacturing and development of pharmaceutical products.

As at 31 December 2020 and in the preceding periods, the Company's equity showed a loss exceeding the sum of its supplementary capitals and reserves and one third of the share capital. The negative equity is due to the nature of the Company's business and is typical of research and development companies. The Company's biotechnology business is marked by consistently high research costs with no sales revenue until the project is commercialised, and, as a result, the Company incurs losses from operations and generates negative cash flows from operations. It is expected that such a situation may reoccur in the foreseeable future. On 23 February 2021, the Extraordinary General Meeting of the Company adopted Resolution No. 3/II/2019 concerning further existence of the Company under Article 397 of the Code of Commercial Companies.

As at 31 March 2021, the equity as shown in the Company's balance sheet was positive. The share capital increase through the issue of U series was been registered with the National Court Register after the balance-sheet date, i.e. on 2 April 2021.

Following the analyses, as at the date of this report, no uncertainties as to the going concern were identified. The Company actively monitors its environment as part of the prospects for obtaining new financing opportunities to cover expenses related to its basic R&D and investment activities.

The funds raised in March 2021 from the issue of U series shares and the fact of concluding an agreement with Novavax Inc. enabled the Company to potentially access additional, not yet fully available sources of financing, including potential debt financing from Polski Fundusz Rozwoju S.A. (PLN 30,000 thousand), a granted and unused subsidy from the European Regional Development Fund (approximately PLN 63,000 thousand). The Company is also holding talks with the European Investment Bank to amend the terms and conditions of the agreement and on the possibility of releasing funds as part of individual tranches up to a total of EUR 30,000 thousand, i.e. approximately PLN 137,000 thousand. The collaboration with Novavax, Inc., under a certain scenario (including the initial stage currently being implemented, i.e., inter alia: effective technology transfer, completion of one technical run and one confirmatory run, followed by another stage of continued collaboration on a commercial basis), may bring additional operating flows to the Company, while the Company's current financial condition is not based on and does not depend on the success of this project.

In September 2021, the Company's Management Board received from Polfarmex S.A., Glatton Sp. z o.o., and Twiti Investments Ltd. – the major (founding) shareholders ("Shareholders") of the Company – support documents pursuant to which the Shareholders declared their financial support for the Company for a period of at least 13 months from the date of the support document. In the Company's opinion, the declaration of the major Shareholders regarding the recapitalisation confirms and provides important support in terms of the possibility to implement the adopted registration strategy for the key project.

At the same time, in accordance with the long-term financing strategy for the Company's activities as adopted in January 2021, the Company is taking steps to attract a strategic investor and also does not exclude conducting a prospectus-based share offering within the meaning of the relevant legislation. The Company's Management Board assumes that these actions, depending on their success, will provide the Company with the financing necessary to complete the registration process and commercialisation of MabionCD20.

In addition, the necessary funds can be also ensured through the change in the terms of the currently binding debt financing agreements and further leveraging of financing available on the market, including financing available from EU projects and projects supporting research and development, and exclusive agreements with future distribution partners or support from shareholders (both strategic and stock market participants).

In connection with the WHO (World Health Organization) announcement of the COVID-19 coronavirus pandemic worldwide, additional financial risks have been identified in relation to the liquidity disruption in the markets resulting from the spread of the COVID-19 virus and the consequent possible restriction of the Company's access to funding. Potential shifts in administrative processes also cannot be ruled out, including both in the area of decisions of the authorities regulating the authorisation of medicinal products and in the area of decisions of public authorities awarding and accounting for grants and subsidies or VAT refunds. At the time of submission of the report, no information on the redeployment of ongoing processes was received from these authorities. The persisting state of pandemic, including, among other things, passenger traffic limitations, may also contribute to the temporary need to reduce the Company's marketing activity in business development area, as well as the suspension of key business decisions as part of the conducted talks.

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

Other events that occurred in H1 2021 include:

» Termination of the collaboration with Vaxine Pty Ltd. under a Memorandum of Understanding ("MoU") entered into in September 2020 to work out arrangements in relation to the process development, manufacturing and commercialisation of Covax-19™, a potential vaccine for COVID-19 disease. During the period of validity of the MoU, the parties worked on agreeing the terms of the possible agreements, as a result of which in January 2021 the Company prepared and sent to the partner a cooperation offer fulfilling the provisions of the memorandum. Despite the expiry of the offer, Vaxine Pty Ltd. has not taken any further steps in relation to the above offer. Therefore, having regard to the purpose of the MoU as set out above, the Company assumed that the other party to the MoU did not consider it appropriate to enter into agreements relating to the Covax-19™ with Mabion, which was permissible under the MoU.

» Receiving, on 31 March 2021, the statement of claim filed by Altiora d. o.o., based in Zagreb ("Altiora"). As set out in the statement of claim, Altiora seeks an award against the Company of the amount of EUR 359 thousand in respect of the remuneration charged by Altiora in connection with one of the agreements between the parties concerning the performance of clinical trials ("Master Service Agreement" of July 2013) which, according to the statement of claim and the opinion of Altiora, is still in force. In the opinion of the Company, the disputed value is not significant and, moreover the agreement is not strategically important to the Company as there are other CRO companies that can provide such services. Possible litigation costs, as per estimates carried out to the best knowledge, have been appropriately recognised in the financial statements of the Company drawn up as at 30 June 2021, therefore the litigation is not expected to have a negative financial impact on the Company. The Company contests the claim both in principle and in amount. The Company is of the opinion that the action filed against it is groundless and the claims submitted therein have no legal or factual basis. The Company filed a response to the lawsuit, in which it presented claims and evidence together with allegations proving that the lawsuit is groundless. The Company also intends to take its own claims held against Altiora for compensation for damages caused by the improper performance of the Agreement to court. On 8 June 2021, the Regional Court in Łódź issued a decision to refer the case to mediation and to appoint a mediator, and set the duration of the mediation for 4 months.

» The scheduled GMP inspection conducted in January 2021 at the Company's premises by the Chief Pharmaceutical Inspectorate to verify the compliance of the manufacturing conditions of the medicinal products under the trials and to assess the Company's activities with respect to the extended scope of the Authorisation to Manufacture and Import Tested Medicinal Products. The inspection concluded with a positive recommendation for certification of the Company in both areas. On 13 April 2021, the Company received a GMP certificate covering the manufacture and import of studied medicinal products.

As of the date of this report, there is no other information that is relevant for the assessment of the staff, property, financial condition, financial result and changes thereof, as well as information that is relevant for the assessment of the possibility of Mabion S.A. fulfilling its obligations.

Management Board of the Company

Krzysztof Kaczmarczyk
President of the Management Board

Sławomir Jaros
Member of the Management Board

Grzegorz Grabowicz
Member of the Management Board

Adam Pietruszkiewicz
Member of the Management Board

Konstantynów Łódzki, 16 September 2021