Other information to the quarterly report of Mabion S.A. for Q3 2021

Konstantynów Łódzki, 29 November 2021

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1 Selected financial data

SELECTED FINANCIAL DATA	in PLN thousand		in EUR thousand	
	from 01.01.2021 to 30.09.2021	from 01.01.2020 to 30.09.2020	from 01.01.2021 to 30.09.2021	from 01.01.2020 to 30.09.2020
Net income from sales of products, commodities, and materials	1,590	0	349	0
Operating profit (loss)	-34,840	-39,217	-7,643	-8,829
Gross profit (loss)	-35,203	-39,948	-7,722	-8,993
Net profit (loss)	-35,203	-39,948	-7,722	-8,993
Net cash flows from operating activities	-10,995	-26,037	-2,412	-5,862
Net cash flows from investing activities	-17,778	-3,314	-3,900	-746
Net cash flows from financing activities	111,456	4,263	24,450	960
Total net cash flows	82,683	-25,088	18,138	-5,648
	30.09.2021	**31.12.2020**	**30.09.2021**	**31.12.2020**
Total assets	192,120	78,321	41,469	16,972
Liabilities and provisions for liabilities	175,919	155,709	37,972	33,741
Long-term liabilities	57,443	51,138	12,399	11,081
Short-term liabilities	118,476	104,571	25,573	22,660
Equity	16,201	-77,388	3,497	-16,770
Share capital	1,616	1,373	349	298
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)	-2.18	-2.91	-0.48	-0.65

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 September 2021 (4.6329 PLN/EUR) and 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 being the arithmetic average of the average exchange rates announced by the National Bank of Poland for the euro effective as at the last day of each month in the period of nine months ended 30 September 2021 and the period of nine months ended 30 September 2020 (respectively: 4.5585 PLN/EUR and 4.4420 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 its registered office in Kutno. On 29 October 2009, the legal form of the Company changed 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 medicines used in the treatment of neoplastic, autoimmune, metabolic, and neurological diseases, including rare diseases. In the area of prevention of SARS-CoV-2 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 medicines and thereby, a high degree of similarity to the proteins of the patient's body, makes the immune system treat the therapeutic antibody as its own protein. This guarantees a possible lower toxicity of the therapies developed by the Company and is a significant benefit for the patient. Currently, the Company's most advanced product is a biosimilar medicine, MabionCD20, a reference drug to MabThera/ Rituxan (Roche).

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

2.2 Bodies of the Company

2.2.1 Management Board

As at 30 September 2021 and as the date of submitting this report, the composition of the Company's Management Board was 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

No changes in the composition of the Company's Management Board occurred in Q3 2021 and up to the date of submitting this report.

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.

2.2.2 Supervisory Board

As at 30 September 2021 and as the date of submitting this report, the composition of the Company's Supervisory Board was 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.

No changes in the composition of the Company's Supervisory Board occurred in Q3 2021 and up to the date of submitting this report.

2.3 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 bearer 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 bearer shares,
- 1,900,000 I series ordinary bearer shares,
- 2,600,000 J series ordinary bearer shares,
- 790,000 K series ordinary bearer shares,
- 510,000 L series ordinary bearer shares,
- 360,000 M series ordinary bearer shares,

- 340,000 N series ordinary bearer shares,
- 300,000 O series ordinary bearer shares,
- 1,920,772 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.

No changes in the amount and structure of the Company's share capital occurred in Q3 2021 and up to the date of submitting this report.

2.4 Shareholding structure

To the best knowledge of the Management Board of the Company, as at the date of this report, i.e. 29 November 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., 58.84% of the share capital of Celon Pharma S.A. and 68.20% 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.*

In the period from the date of submitting the previous interim report, i.e. the report for H1 2021 published on 16 September 2021, to the date of this report, there were no changes in the ownership structure of significant blocks of shares of the Issuer.

2.5 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 Q3 2021 (i.e. as at 29 November 2021)
Management Board		
Krzysztof Kaczmarczyk	held 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.	held directly 5,640 shares of the Company, constituting 0.03% of the Company's share capital and entitling to 0.03% 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 Q3 2021 (i.e. as at 29 November 2021)
Management Board		
Sławomir Jaros	held 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.	held directly 4,829 shares of the Company, constituting 0.03% of the Company's share capital and entitling to 0.03% of votes at the General Meeting.
Adam Pietruszkiewicz	held directly 6,000 shares of the Company, constituting 0.04% of the Company's share capital and entitling to 0.03% of votes at the General Meeting*	held directly 9,000 shares of the Company, constituting 0.06% of the Company's share capital and entitling to 0.05% of votes at the General Meeting.
Grzegorz Grabowicz	-	held directly 700 shares of the Company, constituting 0.004% of the Company's share capital and entitling to 0.004% of votes at the General Meeting.
Supervisory Board		
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., a 58.83% 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 58.84% 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.

* *the report for the H1 2021 erroneously indicated 4,600 shares*

Other managing and supervising persons, to the best of the Company's knowledge, do not hold any shares in the Company as at the date of this report.

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 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 January 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. Up to the date of this report, the rights attached to the above-mentioned subscription warrants have not been exercised by the eligible persons.

2.6 Changes in the organisation of the capital group

Mabion S.A. has no subsidiaries and does not form a capital group.

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. In the current year, the Company expanded the scope of its operations to include the implementation of partnership projects and the provision of contracted services, thereby starting contract manufacturing and development activities (CDMO).

The Company analyses on an annual basis the development plan for medicinal products and modifies it according to needs, taking into account, among other things, the expiry dates of patents for reference medicines, the current and 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 biosimilar medicines.

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

Active projects

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

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

Projects involving the development and marketing of new medicinal products

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).

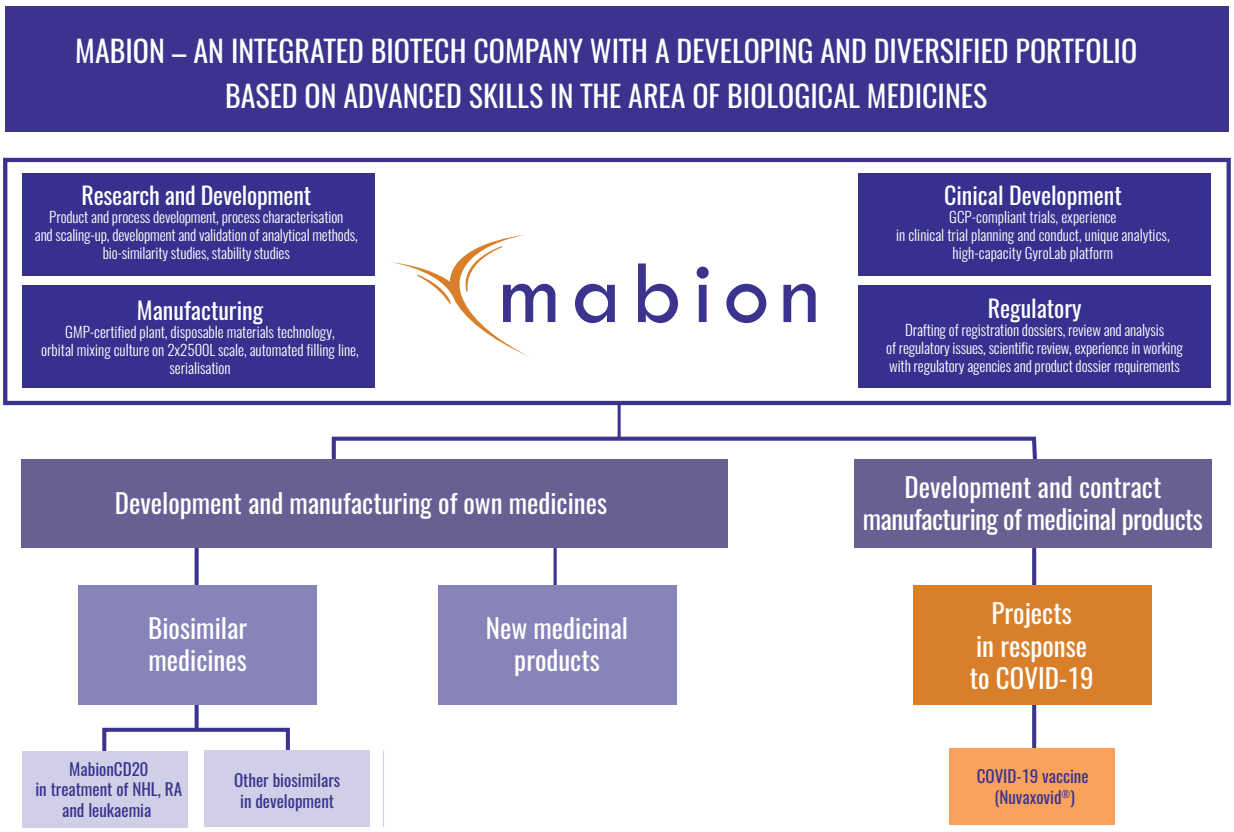
Partnership projects

This group of projects includes all operations related to the development and marketing of new products (or therapies), as well as contract manufacturing.

As part of the development of new therapies, the Company is now holding, among other things, advanced discussions under a Memorandum of Understanding entered into in October 2020 with Taxon Therapeutics Ltd. The talks concern cooperation in the research, development, and commercialisation of MabionCD20 antibodies in specific clinical indications.

Contract manufacturing projects are those for which the Company is considering commencement of implementation in the medium to long term, under an order from an external partner. The Company is currently implementing a long-term project related to the conclusion of a framework agreement (March 2021) and a commercial contract manufacturing agreement (October 2021) with Novavax, Inc. On their basis, the Company, with the participation of Novavax, carried out operations related to the transfer of the manufacturing process technology and antigen analytics of the vaccine candidate for COVID-19 called Nuvaxovid® (previous working name: NVX-CoV2373) and conducted technical trial runs of the process on a commercial scale at the Company's facility. Since October 2021, the Company has been working on the commercial production of the above antigen on Novavax's commission.

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 the development of technology, analytics, and manufacturing, medicine manufacturer	**rituximab (MabionCD20)**	oncology (NHL) and autoimmunology (RA)	biosimilar medicine in approved therapies	at the registration stage in the EU and at the phase I clinical trial stage in the USA	active business development	partnering-capable asset
partner responsible for development and delivery of a product for trials and future therapy	**rituximab (MabionCD20)**	rare diseases (autoimmunology)	innovative therapy	product ready for the clinical stage	memorandum of understanding	partnering-capable asset
strategic co-developer / CMDO	**vaccine**	COVID-19	innovative therapy	framework agreement and first order for contracted services signed	partnering	NOVAVAX USA
integrated partner for the development of technology, analytics, and manufacturing, medicine 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 the development of technology, analytics, and manufacturing, medicine manufacturer	**cetuximab (MabionEGFR)**	oncology (colorectal carcinoma, squamous cell carcinoma of the head and neck area)	biosimilar medicine in approved therapies	cell line optimisation	pre-commercial stage	partnering-capable asset
integrated partner for thedevelopment of technology,analytics, and manufacturing, medicine manufacturer	**denosumab, omalizumab**	autoimmunological diseases, metabolic diseases and oncology	biosimilar medicine in approved therapies	active development of relevant cell lines	pre-commercial stage	possible partners identified

MabionCD20 project

The Company's priority and most advanced project is MabionCD20, a proposed biosimilar to the reference drug MabThera/Rituxan (rituximab) (Roche). In 2018, the Company published the results of a clinical trial 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. Implementation of 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 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 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 as a required element of the registration application) required 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 a target 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 a 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 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.

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 clinical trial, conducting a risk analysis taking into account both the potential risks specific to research in immunological diseases, observations from previous clinical work, as well as the current situation related to the coronavirus pandemic. The documents necessary for the launch of clinical trials were also drawn up, including the IMPD (Investigational Medicinal Product Dossier) and the IB Investigator's Brochure) 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 logistical 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 clinical trial. Following the contracting of the first clinical sites in Poland, work is underway to finalise further agreements with such clinical sites. However, Mabion does not exclude that a clinical trial will be conducted in other European countries. The suppliers of reference medicines for the trial (i.e. MabThera and Rituxan) were contracted and quality audits and qualification of the suppliers 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 – in order to commence the clinical bridging trial necessary for the authorisation of MabionCD20 in the EU in the first instance – has obtained approvals for the clinical trial from certain competent authorities and bioethics committees. These authorisations allow a clinical trial to be initiated in Poland, Georgia, and Belgium. The Company intends to obtain in the near future an authorisation to conduct a clinical trial also in the last key country for the trial – Ukraine.

To sum up, in the research and development work on MabionCD20, in Q3 2021 and until the date of publication of this report, the Company considers the following activities to be successfully carried out:

» 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, as well as clinical analytics as part of the characterisation of pharmacokinetics, pharmacodynamics and immunogenicity in MabionCD20-003RA clinical trial;

» confirmation, during the scientific advice procedure with the EMA, of an optimised analytical panel for the assessment of biosimilarity and bioequivalence 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 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 Q3 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.

Nuvaxovid® (former 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, together with the antigen analytics, called Nuvaxovid (former NVX-CoV2373) and conduct technical trial 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, analytics, and technical runs for the Nuvaxovid® protein antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order included technology transfer from Novavax to the Company. In addition, it includes: the transfer and verification of analytical methods, together with implementation 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 possibility of batch production in the facility.

On 25 March 2021, the Company received the first payment from Novavax, Inc. as part of the fulfilment of the aforementioned order placed under the framework agreement, amounting to USD 1,030 thousand. The funds received represented the first tranche of remuneration for the contracted work, amounting to USD 530 thousand, and an advance on materials and reagents amounting to USD 500 thousand.

The work under the first order was carried out in accordance with the commissioned scope, with positive results.

On 23 June 2021, the Company received a second order from Novavax under the framework agreement. The order was placed in conjunction with negotiations then in progress for a potential manufacturing agreement under which the Company could manufacture 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 concerned 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, 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. After the balance sheet date, Novavax made further payments representing partial settlement of the agreement of 3 March 2021 and the arrangement to cover expenditure on the necessary machinery and equipment for a total of USD 1,830 thousand.

As a result of the successful implementation of the above, on 8 October 2021, the Company entered into a commercial contract manufacturing agreement with Novavax, together with a Terms of Reference under which the Company will commercially manufacture the Nuvaxovid® antigen, based on a-GMP standard, for Novavax. The Agreement in place is unconditional, independent of the registration procedure of Nuvaxovid® in the respective markets. It has been concluded for a fixed period of time until the end of 2025, with an option for renewal. Under the Agreement, the parties have agreed on the volume and production schedule for each year, based on which the Company will produce the number of product batches required by Novavax, although the parties may agree to modify the above, in accordance with the Agreement.

The parties to the Agreement expect the commercial-scale GMP manufacturing to commence in December 2021. Until that time, the Company will carry out the preparatory work specified in the Order, including, among other things, the installation of additional systems and equipment, the acquisition and quality control of materials, and drawing up documentation specific to commercial manufacturing.

On 19 November 2021, a quality agreement was concluded which marked an important step in the implementation of the manufacturing agreement, covering technical and regulatory arrangements for the production of Nuvaxovid® antigen, including relevant GMP standards. The agreement sets forth the obligations and technical and regulatory arrangements required for the manufacture, testing, storage and shipment of the product. It also sets out the principles of cooperation between the departments involved in the implementation of the Agreement.

On the same day, the Company submitted a notification to the Chief Pharmaceutical Inspectorate (GIF) concerning the conclusion of the aforementioned agreement. Another step will consist in a notification to the GIF of a change in the manufacturing conditions, on the basis of which the Company will be able to commence manufacturing operations.

By the date of this report, the Company has carried out or will carry 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 has conducted preparations related to the quality system for the purposes of multiproduct manufacturing and process analytics; System documentation related to validation of computerised systems, specification and release of materials and implementation of changes in waste management is being developed;

» the Company has scaled up the cell culture process in commercial-volume bioreactors, which was further confirmed by reproducing the process. The resulting product was successfully purified on a laboratory scale 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 showed that in each case, the Company obtained a desired high quality product meeting the predetermined specification requirements for the DS Novavax product;

» the Company completed the process of producing the antigen on a commercial scale (engineering trial run), obtaining the first batch of the active substance in bulk. The resulting product was analysed based on Novavax's procedures and requirements, and the results of these analyses confirm that the product complies with the specifications for the DS Novavax product;

» the Company has completed the laboratory work associated with the transfer and verification of the analytical methods necessary to confirm the quality of the manufactured product;

» the Company works 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 and analytical materials and reagents have been secured for future periods and the upgrading of the manufacturing area is underway;

» the Company is currently updating its risk analysis and carrying out preventive actions;

» the Company set up working groups and scheduled regular meetings internally and with Novavax teams. The project organisational structure and the project communication scheme are being updated.

Summing up, all the that was planned in the current period has been completed on schedule. At present, the Company is at the stage of preparatory work to commence commercial production.

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 potential long-term collaboration for the research, development, and then worldwide commercialisation of medicinal products based on a monoclonal antibody recognising the CD20 receptor on human B lymphocytes ("Products") in specific clinical indications in the area of rare diseases.

Taxon Therapeutics is an Israeli biotechnology company focused on the orphan drug segment and rare conditions for which there are currently no 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 intentional and 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. In addition, to deliver the agreed scope of work under the agreement with Novavax, the Company plans to expand its production capacity in late 2022 and early 2023 by equipping the existing facility with new bioreactors, bringing the Company to four bioreactors in subsequent years as of 2023. The commencement of commercial-scale manufacturing of the GMP-standard Nuvaxovid® protein antigen will take place in late 2021/early 2022. Until that time, the Company will carry out the preparatory work specified in the Order, including, among other things, the installation of additional systems and equipment.

Moreover, as part of permit no. 301, the Company undertook to incur investment expenditure in the area of the Łódź Special Economic 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), related to the increase of production capacity of the existing facility. 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 September 2021, the Company made investment expenditures of PLN 2803 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 capabilities, including in particular the ability to obtain adequate funding with the support of grants obtained and current operating cash flows.

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 Description of significant achievements and failures of the Company in Q3 2021 and after the balance-sheet date

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 on the European market

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, 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. Implementation of 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 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 a patient population will also allow assessment of treatment efficacy, which constitutes the secondary endpoint of the trial. To carry out the clinical trial, the Company 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 competent bodies for approval of the clinical trial, as a result of which the approvals referred to above for Poland, Georgia and Belgium, have been obtained.

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

Change of the permit to operate in the Łódź Special Economic Zone

On 10 August 2021, the Company received a decision of the Minister of Development, Labour and Technology on the amendment of permit no. 301 to conduct business activity in the Łódź Special Economic Zone ("Zone").

By virtue of the above mentioned decision, the deadline for incurring investment expenditure within the meaning of § 6.1 of the Ordinance of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit to conduct business in special economic zones, in the amount of at least PLN 20 million,

was extended from 30 June 2021 to 31 December 2024. At the same time, the investment completion date was extended from 31 December 2021 to 31 December 2024

The Company has applied to change the above dates due to the need to update the schedule of planned investments, on the basis of the Company's current needs.

The Company informed about the above event in Current Report no. 50/2021 of 10 August 2021.

Conclusion of a commercial scale manufacturing agreement with Novavax, Inc. for 2022-2025 and a quality agreement

On 8 October 2021 (an event after the balance-sheet date), the Company entered into a commercial contract manufacturing agreement (Manufacturing Agreement, Master Contract Manufacturing Agreement) with Novavax, together with a Statement of Work, pursuant to which the Company will manufacture on a commercial scale, on a GMP standard basis, a vaccine candidate antigen for COVID-19 under the name of Nuvaxovid® (formerly NVX-CoV2373), for Novavax. The resolution approving the substantially agreed provisions of the Agreement and the Statement of Work was adopted by the Management Board of the

Company on 6 October 2021. The Order was commenced as a result of the Company's activities in respect of the work related to the transfer of the manufacturing process and analytical methods based on Novavax's procedures and requirements, as well as the preparation of the Company's quality system for the implementation of the new process and product, as provided for in the framework agreement with Novavax of 3 March 2021, whose conclusion was announced by the Company in Current Report no. 15/2021. The Agreement in place is unconditional, and its conclusion and commencement are independent of the registration procedure of the Nuvaxovid® vaccine candidate in the respective markets. The Agreement has been concluded for a fixed period of time until the end of 2025, with an option for renewal. The total value of the Agreement during its term was estimated at USD 372 million i.e. PLN 1.46 billion based on the average exchange rate of the National Bank of Poland as at 7 October 2021 (the Agreement's value was estimated on the theoretical assumption of future zero inflation during the entire term of the Agreement). The Agreement will be implemented and settled per batch of the Product, at the unit price per batch specified in the Agreement (unit prices are subject to indexation based on future inflation). Under the Agreement, the parties have agreed on the volume and production schedule for each year in the period 2022–2025, based on which Mabion will manufacture the number of product batches required by Novavax. The production schedule has been set for the entire duration of the Agreement, but the parties may agree on modifications to the schedule and volume of deliveries. The possibility of completing the agreed scope of work under the Agreement in the future years depends on the Company's available production capacity, therefore the Management Board's objective will be to expand the production capacity in late 2022 and early 2023 and equipping the facility with new bioreactors, which will result in the Company having four bioreactors in the years 2023–2025. The Company's Management Board estimates that during the first two years of commercial manufacturing covered by the Agreement (i.e. 2022–2023), the Company may realise approximately 40% of the total value of the Agreement, and in the following two years, including as a result of increased production capacity, approximately 60% of the total value of the Agreement. The parties expect the commercial-scale GMP manufacturing to commence in December 2021. Until that time, the Company will carry out the preparatory work specified in the Order, including, among other things, the installation of additional systems and equipment, the acquisition and quality control of materials, and updating documentation specific to commercial manufacturing.

Then, on 19 November 2021 (an event after the balance-sheet date), the Company entered into a Quality Agreement with Novavax, covering technical and regulatory arrangements for the production of Nuvaxovid® antigen, including relevant GMP standards. The Quality Agreement remains in force until the end of the term of the Manufacturing Agreement, subject to updating if required. The Quality Agreement sets forth the obligations and technical and regulatory arrangements required for the manufacture, testing, storage and shipment of the product. It also sets out the principles of cooperation between the departments involved in the implementation of the Agreement. The Quality Agreement represented an important step in the implementation of the Manufacturing Agreement.

On the same day, the Company submitted a notification to the Chief Pharmaceutical Inspectorate (GIF) concerning the conclusion of the aforementioned Quality Agreement. Another step will consist in a notification to the GIF of a change in the manufacturing conditions, on the basis of which the Company will be able to commence manufacturing operations.

The Company informed about the above events in Current Reports no. 52/2021 of 8 October 2020 and no. 63/2021 of 19 November 2021.

Permits to conduct a bridging clinical trial of MabionCD20 in patients with rheumatoid arthritis in Poland, Georgia and Belgium

On 11 October 2021 (an event after the balance-sheet date), the Company became aware that on 6 October 2021 the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products issued a permit for the Company to conduct a clinical trial of MabionCD20 in Poland in patients with rheumatoid arthritis, entitled "A double-blind, parallel-group, randomized clinical trial to evaluate the pharmacokinetics and clinical similarity of MabionCD20 (manufactured commercially) with MabThera® approved in the European Union and Rituxan® approved in the United States in patients with moderate-to-severe rheumatoid arthritis" ("Trial").

On 14 October 2021 (an event after the balance-sheet date), the Company became aware that the President of the Medical and Pharmaceutical Regulatory Agency of Georgia had issued a permit for the Company to conduct the Trial in Georgia.

On 22 October 2021 (an event after the balance-sheet date), the Company became aware that the Federal Agency for Medicines and Health Products in Belgium has issued a permit for the Company to conduct the Trial in Belgium.

The Company also holds approvals from the competent bioethics committees in all the above countries.

The above-mentioned permits enabled the Company to commence the clinical trial necessary for MabionCD20's authorisation, in the first instance, in the EU, including the cooperation with clinical sites in Poland, Georgia, and Belgium and the recruitment of patients to the trial. The Company is currently awaiting the relevant approval to conduct the Trial in Ukraine.

The MabionCD20 clinical trial is a three-arm bridging clinical trial in RA patients using MabionCD20 originating from the target manufacturing scale, MabThera asthe European reference and Rituxan as the US reference. In accordance with the trial protocol, the bridging clinical trial will ultimately involve 280 patients from no less than 35 clinical sites located in Poland, Belgium, Georgia, and Ukraine. Also, the Company does not exclude extending the trial to other countries. The primary endpoint of the trial will be to analyse pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. Such a patient population will also allow assessment of treatment efficacy, which constitutes the secondary endpoint of the trial. The primary observation period for patients will be 6 months ("primary endpoint"). In addition, a long-term follow-up of the safety and immunogenicity of the therapy will be carried out ("follow-up period"), up to 48 weeks following the first administration of the medicine.

The Company informed about the above events in Current Reports no. 53/2021 of 11 October 2021, no. 54/2021 of 14 October 2021, and no. 57/2021 of 22 October 2021.

Termination of the cooperation agreement with Mylan Ireland Ltd.

On 17 November 2021 (an event after the balance-sheet date), the Company received, from Mylan Ireland Ltd., a statement of termination of the Development and Commercialization Agreement entered into in 2016, of which the Company informed in Current Report no. 31/2016 of 8 November 2016. The Agreement was terminated subject to 90 days' notice. Pursuant to the Agreement, as amended, inter alia, by an annex of 29 April 2021, Mylan was only a non-exclusive distribution partner of the Company for MabionCD20, only in selected countries, in areas such as, among other things, Australia, New Zealand, Mexico, Central America, southern Africa, south-eastern Asia. Accordingly, the essential rights to sell MabionCD20 in the European Union and the United States remained and remain the property of the Company and may be commercialised in the future depending on the needs and decisions of the Company.

The termination of the Agreement in question did not involve any payments or additional financial obligations on the part of the Company. All payments between the parties to date have been settled pursuant to the aforementioned annex of 29 April 2021. Pursuant to the annex, the Company repaid to Mylan the first tranche of advances received for distribution rights on 20 July 2021 in the amount of USD 6,000 thousand and on 29 October 2021 (an event after the balance-sheet event) the Company repaid the second (final) tranche in the amount of USD 3,500 thousand. As at the date of this report, the related liabilities amount to USD 0.

At present, the Company has the full and necessary flexibility to commercialise MabionCD20 in all markets, which may have a positive impact on acquiring a strategic investor.

The Company informed about the above event in Current Report no. 62/2021 of 17 November 2021.

3.3 Description of factors and events, including of unusual nature, having a significant impact on the condensed financial statements

In Q3 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.

3.4 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 MabionCD20 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;

» implementation of the commercial contract manufacturing agreement concerning the Nuvaxovid® antigen for Novavax, including its progress and schedule;

» implementation of the Company's financing strategy adopted on 27 January 2021, including the possibility of acquiring a strategic investor and/or leveraging debt financing;

» 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;

» to finance 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 lockdown, as indicated below, remains valid:

» 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.
- possible 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.

In order to prevent the aforementioned risk, the Management Board of the Company 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. The Company's 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 (inter alia, a resolution was adopted on the introduction of countermeasures, together with later updates). 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.

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

3.5 Transactions with related parties

In Q3 2021, the Company did not enter into transactions with related parties on terms other than arm's length.

3.6 Sureties and guarantees granted

In Q3 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.

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

In Q3 2021, no material proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority, or public administration authority.

3.8 Position of the Management Board on the feasibility of previously published forecasts

The Company has not published financial result forecasts for 2021.

4 Other information relevant to the assessment of the Company's condition

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. 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. This is typical of R&D companies. 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 framework agreement concluded in March 2021 together with the first order for contracted services with Novavax and the advancement of cooperation with the latter, confirmed by the commercial contract manufacturing agreement signed in October 2021, warrant that the Company will start generating revenue from this business segment in the foreseeable future. As part of the cooperation until the date of this report, Novavax made further payments representing partial settlement of the agreement of 3 March 2021 and of the arrangement to cover expenditure on raw materials and supplies for future commercial production and the necessary machinery and equipment for a total of USD 18,086 thousand. The Agreement with Novavax is unconditional, and its conclusion and commencement are independent of the registration procedure of the Nuvaxovid® vaccine candidate in the respective markets. The Agreement is for a fixed term until the end of 2025, with an extension option, and its total value over its entire term has been estimated at USD 372 million (with a theoretical assumption of future zero inflation over the Agreement's term). The Agreement will be implemented and settled per batch of the product, at the unit price per batch specified in the Agreement (unit prices are subject to indexation based on future inflation). Under the Agreement, the parties have agreed on the volume and production schedule for each year in the period 2022–2025. However, the parties may agree on modifications in this respect. The Company's Management Board estimates that during the first two years of commercial manufacturing, the Company may realise approximately 40% of the total value of the Agreement, and in the following two years, including as a result of increased production capacity, approximately 60% of the total value of the Agreement.

The funds raised in March 2021 from the issue of U series shares and the fact of concluding an agreement with Novavax Inc. also 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) and 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.

In September 2021, the Company 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 (MabionCD20).

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 acquire a strategic investor.

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). The relevant details are presented in Note 3 to the Financial Statements.

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 raising fourth 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 Q3 2021 include:

» On 10 August 2021, the District Court for Łódź-Śródmieście in Łódź, 20th Commercial Division of the National Court Register, registered amendments to the Company's Articles of Association as adopted by the Ordinary General Meeting of the Company of 22 June 2021, concerning, inter alia, extending the Company's objects of business to include, among other things, warehousing and storage of goods, activities of agents engaged in the sale of goods, wholesale and retail sales, professional, scientific and technical activities, in accordance with the Polish Classification of Business Activities (PKD 2007).

» Litigation instigated as a result of a suit filed in March 2021 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 September 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 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. This claim was partly covered by a set-off charge, which is discussed in more detail below. In June 2021, the Regional Court in Łódź issued a decision to refer the case to mediation and set the duration of the mediation for 4 months. In September 2021, the first conciliation meeting was held, at which the Company requested that the mediation be extended to include its own claims for damages caused by the improper performance of the agreement. Further mediation meetings took place in October and November 2021. The mediation has been extended until the end of December 2021 and may be extended further if the parties so agree. As at the date of this report, the Company cannot assess the possibility of a composition with Altiora. Notwithstanding the course of the mediation proceedings, in October 2021, the Company, acting pursuant to Article 499 of the Civil Code, made a statement of claim set-off in the amount of EUR 264 thousand and in the amount of PLN 1.1 million, up to the amount of Altiora's claim asserted in the lawsuit. The statement was served on Altiora. Thereafter, the Company asserted a set-off charge in respect of the above-mentioned amounts in court proceedings pending before the Regional Court in Łódź as a result of a suit filed by Altiora. The Company's strategy in the ongoing litigation is to concentrate both claims (Altiora's claim and Company's claim) in a single action in order to reduce the Company's litigation risk which would ensue from bringing a separate action against Altiora. Should the Court find Altiora's claim to be valid even in part, the Court will assess the Company's claim - and should the latter be valid, the two claims will be mutually offset to a lower value.

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.

5 Contact details

Company name:	Mabion Spółka Akcyjna
Registered office:	Konstantynów Łódzki
Address:	ul. gen. Mariana Langiewicza 60 95-050 Konstantynów Łódzki
Telecommunications numbers:	phone +48 42 207 78 90
E-mail address:	info@mabion.eu
Website	www.mabion.eu

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, 29 November 2021