Additional information to the quarterly report of Mabion S.A. for the first quarter of 2020

Konstantynów Łódzki, 25 May 2020

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1 Selected financial data

SELECTED FINANCIAL DATA	in PLN thousand		in EUR thousand	
	from 01.01.2020 to 31.03.2020	from 01.01.2019 to 31.03.2019	from 01.01.2020 to 31.03.2020	from 01.01.2019 to 31.01.2019
Net income from sales of products, commodities and materials	0	0	0	0
Operating profit (loss)	-16678	-14509	-3794	-3376
Gross profit (loss)	-19845	-14985	-4514	-3487
Net profit (loss)	-19845	-14985	-4514	-3487
Net cash flows from operating activities	-10400	-13601	-2366	-3165
Net cash flows from investing activities	-1140	-3637	-259	-846
Net cash flows from financing activities	-810	-479	-184	-111
Total net cash flows	-12350	-17717	-2809	-4122
	31.03.2020	**31.12.2019**	**31.03.2020**	**31.12.2019**
Total assets	99643	113545	21888	26663
Liabilities and provisions for liabilities	141084	135125	30992	31731
Long-term liabilities	47745	48743	10488	11446
Short term liabilities	93339	86382	20504	20285
Equity	-41441	-21580	-9103	-5068
Share capital	1372	1372	301	322
Number of shares (in pcs)	13730272	13730272	13730272	13730272
Net profit (loss) per ordinary share (in PLN/EUR)	-1.45	-4.64	-0.33	-1.08

Individual items of the balance sheet presented in EUR were translated at the average exchange rate announced by the National Bank of Poland on 31 March 2020 (4.5523 PLN/EUR) and on 31 December 2019 - 4.2585 PLN/EUR). Individual items of the income statement and cash flow statement have been converted into EUR at the exchange rate being the arithmetic average of the average exchange rates announced by the National Bank of Poland for the euro effective on the last day of each month in the period of three months ended 31 March 2020 and three months ended 31 March 2019 (respectively: 4.3963 PLN/EUR and 4.2978 PLN/EUR).

2 Information about Mabion S.A.

2.1 Introduction

Mabion S.A. ("Mabion" or "Company") was established on 30 May 2007 as a limited liability company with its registered office in Kutno. The legal form of the Company changed on 29 October 2009 as a result of transformation of the limited liability company into a joint stock company. Currently, Mabion S.A. is entered in 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 Konstantynów Łódzki.

Mabion S.A. is a biotechnology company focusing on research and development activities aimed at developing and commercially introducing biotech drugs based on monoclonal antibody technology to the market. The main objective of the Company's activity is the development, manufacture and marketing of drugs biosimilar to the existing original biotechnological drugs (so-called reference drugs), in the area of oncology, autoimmunity, neurology and metabolic diseases.

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

2.2 Company's bodies

2.2.1 Management Board

As at 31 March 2020 and the date of publication of this report, the Company's Management Board was composed of the following persons:

- Dirk Kreder – President of the Management Board,
- Sławomir Jaros – Member of the Management Board,
- Jarosław Walczak – Member of the Management Board,
- Grzegorz Grabowicz – Member of the Management Board.

Changes in the composition of the Management Board of the Company during the first quarter of 2020:

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

2.2.2 Supervisory Board

As at 31 March 2020 and as at the date of submission of this report, the Company's Supervisory Board was composed of the following persons:

- Krzysztof Kaczmarczyk – Chairman of the Supervisory Board,
- Maciej Wieczorek – Deputy Chairman of the Supervisory Board,
- Józef Banach – Independent Member of the Supervisory Board,
- Tadeusz Pietrucha – Independent Member of the Supervisory Board,
- Jacek Piotr Nowak – Member of the Supervisory Board,
- David John James – Independent Member of the Supervisory Board,
- Robert Koński – Independent Member of the Supervisory Board.

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

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

2.3 Company's share capital

As of 31 March 2020 and as of the date of publication of this report, the Company's share capital amounts to PLN 1,373,027.20 and is divided into 13,730,272 shares with a nominal value of PLN 0.10 each, including:

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

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

On 29 January 2020, 9,500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were released i.e. recorded on the securities accounts of the eligible persons. Therefore, the share capital of the Company was increased. S series ordinary bearer shares were issued by the Company as part of a conditional increase in the share capital in connection with the exercise by eligible persons of the rights carried by B series subscription warrants granted to such persons under the Incentive Scheme for 2018. The issue price of S series shares was equal to the nominal share price. The shares were taken up in exchange for a cash contribution made in full before the release of the shares. The Company has submitted a relevant application to the National Court Register to make an entry related to the increase of the share capital. As a result of releasing the above mentioned S series shares. As at the publication date of this report, the increase in consideration was not disclosed in the National Court Register. The Company informed about the event in Current Report no. 8/2020 of 29 January 2020.

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On 17 January 2020 the National Depository for Securities (KDPW S.A.) (KDPW) made a conditional registration in the securities depository, under ISIN code PLMBION00016, of 514,773 P series ordinary bearer shares of the Company and 9,500 S series

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

2.4 Shareholding structure

On the basis of information available to the Company, as at the date of submitting the report for the first quarter of 2020 (25 May 2020), the following shareholders hold at least 5% of the total number of votes at the General Meeting of the Company:

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

* *Mr Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 66.67% of the share capital of Celon Pharma S.A. and 75% of the total number of votes in Celon Pharma S.A.*

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

*** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 29.11.2019.*

In the period from the date of submitting the annual report for 2019, i.e. from 8 April 2020 to the date of publication of this report, there were no changes in the ownership structure of significant blocks of shares of the Company.

2.5 Ownership of the Company's shares by managing and supervising persons

Shares held by managing and supervising persons as at the submission date of the report for Q1 2020 (25 May 2020)	
Management Board	
Sławomir Jaros	olds directly 4,043 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.03% of the Company's share capital and entitling to 0.02% of votes at the General Meeting.
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., a 66.67% participation in the share capital) he holds a total of 1,626,576 shares in the Company with a nominal value of PLN 0.10 each, constituting 11.85% of the Company's share capital and entitling to 13.85% of votes at the General Meeting.

Other managing and supervising persons do not hold any Company shares. Members of the Management Board and Supervisory Board of Mabion S.A. do not have other rights to Company shares than those indicated below. In the period from the date of publication of the annual report for 2019, i.e. from 8 April 2020 to the date of publication of this report, there were no changes in the ownership of the Company's shares by managing and supervising persons.

In 2018, the Incentive Scheme for 2018-2021 was adopted. As part of the implementation of the Incentive Scheme, the persons participating in it - eligible persons, i.e. key persons in the Company - may obtain the right to take up A series and B series subscription warrants. Subscription warrants are issued free of charge. Each A series and B series subscription warrant entitles its holder to take up 1 share of R series and S series, respectively. The issue price of shares in the case of holders of A series warrants is PLN 91 per each R series share, while in the case of holders of B series warrants, it is PLN 0.10 per each S series share. Rights resulting from subscription warrants may be exercised until 31 July 2022. The Incentive Scheme allows for settlement in the form of offering by the Company to persons who have subscribed for warrants the possibility of purchasing them for a fee in order to redeem them. The decision on the form of exercising the rights is made by the Supervisory Board of the Company after verification 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 the resolutions of the Supervisory Board of the Company of February 2019 and February 2020, the persons eligible to take up subscription warrants for 2018, 2019 and 2020 (as at the date of publication of this report) include Members of the Management Board of the Company:

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

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

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

A series subscription warrants for 2018 and 2019 were not granted due to failure to meet the market target in 2018 and 2019. However, in accordance with the Regulations of the Incentive Scheme, these warrants may be granted to eligible persons during the term of the Incentive Scheme together with A series warrants for the year in which the market target is met. B series subscription warrants for 2019 were granted by a resolution of the Supervisory Board in February 2020, however, by the date of publication of this report no agreements on subscription for these warrants have been concluded.

2.6 Description of changes in the organization 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 Implementation of the Company's development strategy

The primary objective of Mabion is the development, manufacture and marketing of drugs biosimilar to the existing original biotechnology drugs (so-called reference drugs), in the field of oncology, autoimmunity, neurology and metabolic diseases.

Every year the Company analyses the development plan for medicinal products and modifies it as necessary, taking into account, among other things, the expiry dates of patents for reference medicines, the size of the market for reference medicines - current and forecasted, the Company's technology for producing medicines, the competence and experience of the team and competition in the field of biosimilar medicines.

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

In March 2020, the Company's Management Board started work related to the annual update of the medicinal product development strategy plan, which as at the date of publication of this report was continued.

Active projects

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

Projects launched in 2019

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

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

» Reference drug Prolia[1] and Xgeva[2] (based on denosumab) - using additional analytical methods, the presence of Leu/Ile in variable regions was verified, which allowed for 100% verification of the amino acid sequence. The results obtained will be used to develop a genetic construct encoding the protein. Work on the construction of the vector encoding the biosimilar antibody and on the creation of a reference material bank was continued.

» Reference drug Xolair[3] (based on omalizumab) - using additional analytical methods, the presence of Leu/Ile in variable regions was verified, which allowed for 100% verification of the amino acid sequence. The results obtained will be used to develop a genetic construct encoding the protein. Work on the creation of a reference material bank was continued.

[1] Reference drug Prolia - indications: osteoporosis, sales value in 2018 approximately USD 2.3 billion (based on Global Data). The patent for the drug Prolia expires in Europe in 2022. (except for France, Italy, Spain and the United Kingdom where it expires in 2025), and in the USA in 2025. Currently, several entities are working on a biosimilar version of the drug (http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab).

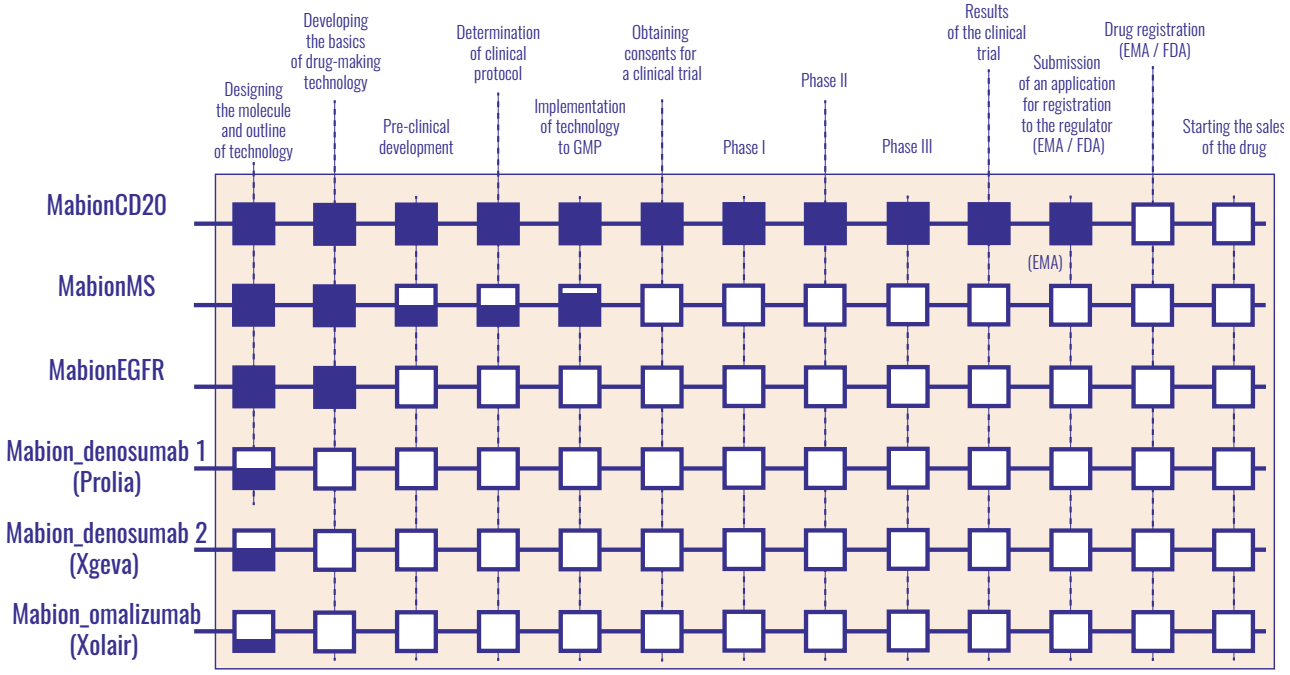
[2] Reference drug Xgeva - indications: prevention of bone complications (pathological fractures, necessity of bone irradiation, spinal cord compression or necessity of bone surgery) in adults with metastases of solid tumors to bone. Sales in 2018 are approximately USD 1.7 billion (based on Global Data). Patent for Xgeva expires in Europe in 2022 (except for France, Italy, Spain and the United Kingdom where it expires in 2025) and in the United States, where it expires in 2025. Currently, several operators are working on a biosimilar version of the drug (http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab).

[3] Reference drug Xolair - indications: asthma, sales value in 2018 about USD 3 billion (based on Global Data). Patent protection ended in 2017. Currently, several entities are working on a biosimilar version of the drug - among others, Celltrion (http://www.koreabiomed.com/news/articleView.html?idxno=6109) and BiosanaPharma (https://www.centerforbiosimilars.com/news/biosanapharma-to-start-phase-1-trial-of-biosimilar-omalizumab-in-australia).

Partnership projects

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

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



Projekt MabionCD20

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

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

Then, on 16 March 2020, on the basis of opinions of external consultants and recommendations of the Supervisory Board, the Management Board of the Company decided to modify the current regulatory strategy for MabionCD20 with the EMA. The basic change is to seek marketing authorisation for the drug on a large commercial scale, which has not yet been submitted to the EMA, as opposed to a two-step strategy pursued so far, i.e. to obtain marketing authorisation for a small production scale first, and then, on the basis of a second submission, to subsequently obtain authorisation for the product manufactured on the intended commercial scale. The change in the regulatory strategy suggested the withdrawal of the registration applications referred to above. The withdrawal of applications took place on 16 March 2020, and was subsequently confirmed

by the European Medicines Agency on 30 March 2020.

A new registration application, as part of which the Agency will assess the target (commercial) scale of MabionCD20 production, will be submitted after completion of process validation and the generation of biosimilarity data for the large scale process. The existing data originating from the large production scale already indicates reproducible quality and a high degree of analytical similarity both, to the reference products as well as to the product previously used in clinical trials. In the Company's opinion, this similarity is a significant step in the direction of waiving additional, larger clinical trials. In the Company's Management Board's opinion, the change in the regulatory strategy is the optimal path in terms of both, cost and timelines in order to register the product and to allow for commercialisation of MabionCD20 in the European Union.

As of the date of publication of this report, work on large scale production of the medicine is nearing completion. Production of the active substance MabionCD20 as part of three validation batches has already been completed. Validation of the MabionCD20 large-scale manufacturing process is planned to be carried out shortly, namely in June 2020. The scope and format of new registration applications is first of all subject to consultation with representatives of the EMA under the Scientific Advice procedure. The aim is to adapt the applications to the Agency's expectations and to streamline the registration procedure of the application on the basis of product data originating from the large, target production scale. In April 2020, the Company submitted the Briefing Package to the EMA and is currently awaiting the regulator's response, which should take place between June and July 2020.

With respect to the activities conducted for the marketing authorisation of the drug under the working name of MabionCD20 in the United States, as summarised at the BPD (Biosimilar Biological Product Development) Type 2 meeting with the U.S. Food and Drug Administration (FDA) held in June 2018, the FDA has allowed the Company's data to be used as application support. At the same time, it proposed an overall strategy to link the EU registered product (MabThera) to the US approved product (Rituxan). Based on the data available at that time, the Agency did not indicate the need for a completely separate process of developing MabionCD20 for the US market. The Agency considered that there was a need for a bridging with respect to trials performed in Europe based and using the reference drug MabThera. The bridging study should be three-armed and include the US reference product Rituxan, the European reference product MabThera and MabionCD20 produced using the large-scale, commercial manufacturing process. It will also be necessary to carry out a three-armed analytical study.

On 22 January 2020, the Company held a Type 3 BPD meeting with the Food and Drug Agency. The purpose of the meeting was to obtain confirmation of the regulatory strategy. During the meeting, there was a productive discussion on data needed to submit in an application for registration in the USA for all indications of the reference medicine. In February 2020, the Company received a summary of the meeting from the FDA and carefully analysed the document and the conclusions and guidelines provided, as well as to assess their impact on the actions planned by the Company to register and release the drug to the market in the USA. In the Company's interpretation, the FDA confirmed the possibility of submitting an application for MabionCD20 and validated the presented approach.

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

As part of continuing discussions on the application program, Mabion S.A. prepared and sent to the FDA a set of additional questions specifying the clinical parameters under investigation as well as detailed comparative analyses of MabionCD20 with the reference drug Rituxan. The actions taken will most likely result in another meeting of the Company's representatives with the FDA, as recommended by the FDA. In this meeting, it is expected that details of planned activities to complement the results from previous research and the possibility of following the Company's preferred method of registration using the Bridging Study approach will be discussed. In accordance with FDA guidelines, Type 2 meetings address specific issues for which the FDA provides a directional recommendation, while at Type 3 meetings, a comprehensive in-depth analysis of the complex data package is conducted. The date of the meeting will be defined in response to FDA submissions in June 2020. The Company assumes that this meeting may take place in the third or fourth week of August 2020.

In order to start the bridging trial referred to above, the Company, based on the trial protocol, must obtain the consent of the competent authorities and the consent of the bioethics committees. At the same time, the Company has to ensure the allocation of sufficient resources as a prerequisite for its initiation and thereby determines the timinig of the trial. Funds for the implementation of the above may come from a partner, European Union funds, or other sources. In addition to the Company's home market, partners for additional markets are actively sought. For the US market, a potential partner for the Company is Mylan. However, based on the current contractual arrangement, Mabion is free to engage in discussions with potential partners other than Mylan, under the condition that Mylan has once the right to match an offer for the US market within a certain timeframe.

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

- a preliminary study was performed to characterize the bulk product (drug substance - (MabionCD20DS) on a scale of 2x250OL for 3 batches (technical batch and 2 validation batches), confirming the bioequivalence (MabionCD20DS 250OL vs. MabionCD20DS 250L) and the biosimilarity (MabionCD20DS vs. MabThera) of the intermediate product obtained;
- a continuous process of stability testing for MabionCD20 and the reference drug MabThera was conducted;
- plans have been developed to study the bioequivalence and biosimilarity of 2x250OL MabionCD20 compared to the 2x250L product as well as the European (MabThera) and American (Rituxan) reference drug – the scope of the research and the statistical approach is currently subject to the ongoing advisory processes with the EMA and the FDA;
- the scope of work on determining the process space for the manufacturing process has been extended;
- additional analytical methods have been developed and qualified to enable a wider in-house characterisation of the MabionCD20 particle;
- a Media Fill test was carried out for automatic filling;
- the immediate packaging has been filled in sterile conditions with the technical batch;
- production of the active substance MabionCD20 as part of in three validation batches has been completed;
- physicochemical, biological and microbiological analyses of the technical batch and three validation batches were conducted according to the developed MabionCD20 manufacturing process control strategy;
- work related to the preparation of the clinical trial protocol and the Briefing Package based on the findings of the FDA has been completed;
- review of the GCP system for the clinical trial has started
- in January 2020, the Company took part in a meeting with the FDA. Then, in May 2020, the Company sent the FDA a set of further questions specifying clinical parameters, as well as detailed comparative analyses. The Company has proposed additional variants of the bridging test in connection with the restrictions caused by the SARS-CoV-2 coronavirus pandemic and currently the Company is waiting for another meeting with the regulator
- in April 2020 the Company submitted the Briefing Package to the EMA and awaits the regulator's response;
- analytical methods are being optimised, which, after their prior validation, will allow for characterisation of pharmacokinetics, pharmacodynamics and immunogenicity in subsequent clinical trials related to MabionCD20.

MabionMS

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

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

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

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

For this project, in 2019, the Company prepared both a clinical trial synopsis and a Briefing package. The content and regulatory assumptions of the project were consulted with external experts in the area of clinical trials in multiple sclerosis therapy. After the consultation and approval of the final version of these documents, the Company submitted them to the EMA in August 2019 (finally, the documentation was not submitted to the FDA due to the need to continue the work on their shape). Then, received a response from the regulator confirming part of the assumptions. The event started the process of scientific consultations with the EMA in order to confirm the compliance of the design assumptions with the Agency's requirements. The consultation with regulators is a multi-stage process, which may consist of research and development reports and a round of Scientific Advice enquiries. A consensus in the course of the consultation may be difficult to predict in relation to the timing of the consensus.

MabionEGFR

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

- determining the scope of the quality target product profile (QTPP) for qualitative attributes of protein;
- developing a reference material bank;
- optimising subsequent versions and verification of the genetic construct;
- optimisation of the conditions for introducing the vector into host cells;
- obtaining a cell line producing an antibody biosimilar to Cetuximab;
- verification of the productivity and stability of the cell line producing the antibody biosimilar to Cetuximab;

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

» initial optimisation of the antibody purification conditions.

3.2 Description of significant achievements and failures of the Company in Q1 2020 and after the balance sheet date

On 13 January 2020, the Management Board of Mabion S.A. informed that as a result of telephone consultations with the EMA, it plans to submit in January 2020 an answer to the list of questions received in December 2019. This was to enable the Company to continue to process its registration application at the meeting of the Committee for Medicinal Products for Human Use (CHMP) on 24-27 February 2020. The Company stressed that the regulator has a number of tools at its disposal to ensure its discretion and the possibility of adjusting the solution individually to the needs of a given registration procedure. The Company also informed that it has no influence on the assessment of the EMA and that there are a number of possible events - positive or negative decision, receiving a list of additional questions (once or more), invitation to a round of oral answers (once or more), withdrawal of the application by the Company and its resubmission after additions or other events not envisaged at that stage by the Company. The Company informed about the above event in Current Report no. 2/2020 of 13 January 2020.

On 22 January 2020, a Type 3 BPD (Biosimilar Biological Product Development) meeting with the Food and Drug Administration (FDA) was held on the registration and marketing authorisation of MabionCD20 in the USA. The purpose of the meeting was to obtain confirmation of the regulatory strategy for the possibility of applying for registration of MabionCD20 in the United States of America. During the meeting, there was a productive discussion on the data needed to apply for registration in the USA for all indications of the reference drug. The company was invited to contact the FDA on a regular basis in order to smoothly implement activities aimed at filing the registration application in the USA. The Type 3 BPD meeting was a stage of implementation of activities aimed at obtaining registration of MabionCD20 in the USA, however, holding it does not guarantee a positive effect of these activities. The Company informed about the above event in Current Report no. 4/2020 of 22 January 2020.

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

On 7 February 2020, the Company received the decision of the Minister of Development on the change of permit no. 301 obtained in January 2017 to conduct business activity in the Łódź Special Economic Zone ("Zone"). By virtue of the above mentioned decision, at the request of the Company, the deadline for incurring investment expenses in the amount of at least PLN 20 million in the Zone within the meaning of § 6 (1) of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit to conduct business activity in the areas of special economic zones was extended from 31 December 2019 to 30 June 2021. The application for the above change resulted from the change in the schedule of the Company's investment commencement. At the same time, the deadline for completion of the investment planned for 31 December 2021 did not change. The Company informed about the event in Current Report no. 9/2020 of 7 February 2020.

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

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

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

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

On 16 March 2020, the Company's Management Board decided to modify the regulatory strategy for MabionCD20 pursued in the procedures carried out with the EMA. The main change is to obtain a marketing authorisation in the EMA directly for the medicine manufactured on a large commercial scale as opposed to the two-year strategy planned so far, i.e. obtaining a small scale marketing authorisation and then on the basis of a variation, obtaining large scale authorisation. The Company's Management Board made its decision on the basis of the opinion of external consultants received on 16 March 2020 and the recommendation of the Company's Supervisory Board. The change of strategy is related to the withdrawal of registration applications submitted on 1 June 2018 and 6 May 2019. The new application, in which the target scale will be evaluated by the Agency, will be submitted after obtaining validation and biosimilarity data of the product coming from the large production scale. For procedural and formal reasons, the Company could not proceed with its previously submitted and pending applications with additional data on the large scale. In the opinion of the Company's Management Board, the change of strategy was the most optimal path in terms of both cost and time of product registration and the possibility of commercialising MabionCD20 in the European Union. The scope and format of the new applications will first be consulted with EMA representatives as part of the Scientific Advice procedure in order to adapt them to the Agency's expectations, which will streamline the registration procedure for the application concerning the large-scale, targeted production. In April 2020 (an event after the balance-sheet date), the Company submitted the Briefing Package to the EMA and is currently awaiting the regulator's response, which should take place, depending on the path taken by the Agency, between June and July 2020.

The decision to withdraw applications for registration of MabionCD20 in the EMA did not affect the adopted schedule of work on the large-scale manufacturing and bridging trial validation as well as work on registering MabionCD20 in the US market. At the time of the decision to change the strategy, work was underway to launch the 3rd large scale production validation batch. Currently, production of the active substance MabionCD20 has been completed as part of three validation batches. The Company plans to carry out the validation of the large-scale product manufacturing process in June 2020. However, the current plan of work necessary to submit the new application to the EMA may be changed as a result of guidelines obtained from the regulator. The Company informed about the event in Current Report no. 15/2020 of 16 March 2020.

On 16 March 2020, the Supervisory Board held a meeting with representatives of the Management Board of the Company, at which a discussion took place on the financing of the Company's activities in light of the new regulatory strategy for MabionCD20 as part of the procedures carried out with the EMA. The Company's Management Board received supporting documents from the Company's main (founding) shareholders ("Shareholders"), according to which the Shareholders declared to inject capital in the Company in an amount not lower than PLN 15 million in 2020. The capital injection, in accordance with the Shareholders' declaration of 16 March 2020, will take place in 2020 in tranches, in response to the Company's financial needs. The recapitalisation of the Company, in accordance with the declarations received, may take place by taking up new issue shares or using debt instruments. The Management Board of the Company adopted supporting documents from the Shareholders and decided to start activities aimed at obtaining debt financing, which will enable effective implementation of the new strategy of

registration of MabionCD20 with the EMA. In the opinion of the Company's Management Board, it should be possible to obtain external debt financing thanks to the strong support it received from the Company's major shareholders. In addition, the Company does not preclude seeking and using other sources of funding such as grants, subsidies from the EU funds, targeted funds for new projects or other options depending on the Company's needs and capabilities. The Company informed of the event in Current Report no. 16/2020 dated 16 March 2020.

On 16 March 2020, in connection with the epidemic emergency introduced in Poland and the SARS-CoV-2 coronavirus pandemic announced by the WHO (World Health Organization) worldwide, the Management Board of Mabion S.A. provided information on the possible impact of this situation on the Company's operations. The Management Board identified that the Company's operations may be temporarily affected by reduced availability of employees and, consequently, delays in research and development processes, due to the need to introduce home office for certain positions. The Management Board indicated that it has some control over the pace and continuity of manufacturing processes, but it cannot be ruled out that the introduction of home office for certain positions and the potential for disturbances in the supply chain integrity of certain components, materials and machinery and equipment will temporarily slow down R&D and manufacturing processes. At the same time, the Company's Management Board stressed that the Company's processes are focused on maintaining progress and completing work on the MabionCD20 validation, enabling the transition to the next stages of research on the medicinal product manufactured on a large scale (i.e. stability and analytical similarity studies). At the time of publication of the current report, this work was proceeding smoothly, according to the planned schedules, and there were no delays in the delivery of components, materials, machinery or equipment. However, it could not be excluded that such delays may occur in the future. The Management Board of the Company also recognized the risks associated with the liquidity disruption in the markets resulting from the spread of the SARS-CoV-2 virus and the consequent possible restriction of the Company's access to funding. In addition, the Company has noted potential shifts in administrative processes, including both in the area of decisions of the authorities regulating the release of medicinal products to the market and in the area of decisions of public bodies granting and settling subsidies and grants or VAT refunds. At the moment of submitting the current report, as well as until the date of publication of this interim report, the Management Board did not receive any information from the indicated authorities concerning any shifts in the processes underway. The persisting pandemic, including, among others, passenger traffic limitation, may also contribute to a temporary need to reduce the Company's marketing activity in the area of business development, as well as the suspension of key business decisions as part of ongoing talks. Due to the high dynamics of the events, the Company's Management Board monitors the situation on an ongoing basis. The Company also declared that it will comply with all applicable administrative decisions. The Company informed about the impact of the SARS-CoV-2 virus spread on the operations of Mabion S.A. in Current Report no. 17/2020 of 16 March 2020. Information on the current impact of SARS-CoV-2 on the Company's operations is presented in point 4 of this report.

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

(an event after the balance-sheet date), the Management Board of the Company made a decision on the intention to issue up to 1,907,281 U series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each, to increase the Company's share capital by an amount not lower than PLN 0.10 and not higher than PLN 190,728.10. The above decision was also approved by the Company's Supervisory Board on 18 May 2020.

The aim of the planned issue is to obtain additional funding for working capital of the Company and, in particular, to accelerate the ongoing development of MabionCD20 and to achieve the milestones envisaged to submit the application for marketing authorisation for MabionCD20 to the EMA as soon as possible. In addition, the funds raised will support the Company's development work required to obtain registration in the USA.

The acquired capital will allow Mabion S.A., a fully integrated company with GMP-certified facilities, to conduct further development based on the previous experience of the Company, robust quality process, experienced and qualified workforce, as well as technological capacity.

The intention of the Company's Management Board is that the issue is effected in the form of a private placement within the meaning of Art. 431 §2 (1) of the Commercial Companies Code, carried out by way of a public offering exempt from the obligation to publish a prospectus within the meaning of the relevant provisions of law or another information or offering document for the purpose of such an offering, and in particular that the selection of investors to whom offers to subscribe for U series shares is made with account taken of the book-building process or another process aimed at acquiring entities subscribing for new issue shares. In the opinion of the Management Board of the Company, the issue of U series shares should be carried out with the full exclusion of the existing shareholders' pre-emptive right to all U series shares, which is in the interest of the Company and its shareholders and serves to ensure efficient provision of its capital. The issue price of U series shares will be determined by the Management Board of the Company within the limits set by the General Meeting.

In view of the above, the Management Board of the Company, when convening the Ordinary General Meeting of the Company (OGM) on 19 May 2020 (an event after the balance-sheet date) for 15 June 2020, included in the planned agenda of the OGM an item providing for the adoption of a resolution on increasing the Company's share capital through the issue of U series ordinary bearer shares.

As a consequence of the above, in the planned agenda, the Ordinary General Meeting also took into account the adoption of a resolution on a conditional increase in the share capital by an amount not exceeding PLN 5,595.40 through the issue of not more than 55,954 V series ordinary bearer shares and not more than 55,954 D series subscription warrants, entirely addressed to the European Investment Bank (EIB), in order to implement the agreements concluded with the EIB in 2019 (financing agreement and warrant agreement), obliging the Company to issue and offer to the EIB a specified number of subscription warrants if the Company's share capital is increased. According to the provisions of the warrant agreement, the issue price of one V series share should be PLN 0.10 and the subscription warrants should be issued free of charge.

The Company informed about the above mentioned events in Current Reports no. 21/2020 of 18 May 2020 and no. 22/2020 of 19 May 2020.

3.3 Indication of factors and events, including those of atypical nature, having a material impact on the condensed financial statements

In the first quarter of 2020, there were no factors and events other than those indicated in other points of the report, including those of an untypical nature, having a significant impact on the condensed financial statements of the Company.

3.4 Factors that will affect the results achieved at least in the next quarter

The main factors that will affect the Company's results in the following quarters include:

» outcome of the Scientific Advice procedure with the EMA on the marketing authorisation of the drug under the working name of MabionCD20;

- finalisation of the work on the validation of large scale manufacturing in accordance with the adopted work schedule and achievement of the expected results;
- costs of research and development work on MabionCD20 and other drugs in the Company's pipeline;
- the capacity to finance projects undertaken in accordance with the approved strategy, including the launch of a bridging trial;
- staff costs, taking into general management costs of the Company;
- financing the planned capacity increase taking into account the intensification of activities related to the new production plant construction project;
- exchange rate differences resulting from changes in foreign exchange rates;
- market risk - competitive environment and price developments for reference and biosimilar medicines;
- changes in the terms and conditions of financing of the Company under loan agreements, currently under negotiation, including those concerning the extension of the Santander financing and the modification of the conditions for the release of tranches by the European Investment Bank;
- possibility of termination of the agreement by the distribution partner - Mylan - and consequently the possible need to return most of the advances received in case the conditions of the current agreement cannot be changed;
- proceeds from aid granted from EU funds;
- decision of the General Meeting of the Company on the increase of the share capital through the issue of shares and to carry out the issue in accordance with the Company's assumptions.

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

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

All the aforementioned phenomena may have a direct impact on the Company's financial situation. Detailed information on the impact of the effects of the SARS-CoV-2 virus spread on the Company's operations has been described in point 3.2. of this report.

3.5 Transactions with related parties

In the first quarter of 2020, the Company did not conclude any transactions with related entities on terms other than market terms.

In the first quarter of 2020, the surety granted by Glatton Sp. z o.o. to the Company in 2018, in the amount up to PLN 45 million, was in force. The surety relates to the revolving loan agreement of 17 July 2018 concluded with Santander Bank Polska S.A. (formerly Bank Zachodni WBK S.A.) for a period of two years to finance the Company's operations. In 2020, the Company signed an agreement on arm's length with the above mentioned related entity, governing the rules of payment for the surety referred to above.

3.6 Sureties and guarantees granted

In the first quarter of 2020, the Company did not grant any borrowing or loan sureties or guarantees to a single 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 court, arbitration authority or public administration body

In the first quarter of 2020, there were no significant proceedings pending before court, arbitration authority or public administration authority concerning liabilities or receivables of the Company.

3.8 Management Board' s position on the feasibility of previously published forecasts

In 2012, the Company decided to cancel the financial forecasts prepared for the years 2010-2020 in connection with the application for the introduction of I series shares to trading in the alternative trading system and to abandon the financial forecasts.

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

In the first quarter of 2020, the Company's activity was comparable to previous periods. The success of the Company in the future depends in particular on the provision of funds necessary to finance its operations and its ability to register and commercialise medicines.

The level of the Company's equity as at 31 December 2019, as well as at 31 March 2020, shows a loss exceeding the sum of supplementary capitals and reserves and one third of the share capital. In view of the above, the Management Board of Mabion S.A. in the planned agenda of the next Ordinary General Meeting of the Company will take into account an item providing for the adoption of a resolution on the continued existence of the Company in accordance with Article 397 of the Commercial Companies Code *(„If the balance sheet drawn up by the management board shows a loss exceeding the aggregate of the supplementary and the reserve capitals and one third of the share capital, the management board shall immediately convene the general assembly so that a resolution on the continued existence of the company can be adopted")*.

The occurrence of negative equity, which is a prerequisite specified in Article 397 of the Commercial Companies Code, results from the nature of the Company's operations and is typical for research and development companies. The Company's biotech operations are characterized by the constant incurrence of high research costs with no sales revenues until the project is commercialized, as a result of which the Company incurs losses on its operating activities and generates negative cash flows from operating activities. This situation is expected to continue in the foreseeable future. To date, the Company has financed its operating activities with cash received from shareholder loans, capital issues, bank loans, grants and proceeds from distribution partners.

As a strategic partner of the Company, Mylan decided to support the Company financially and provide strategic development support. In turn, the Company undertook to grant Mylan, subject to the approval of MabionCD20, the right to distribute in Europe for contracted countries. In previous periods, the Company has pursued, in cooperation with Mylan, a strategy consisting in registering its product with the European Medicines Agency based on a small batch production. In March 2020, the Company decided to change its registration strategy - it decided to move directly to the registration of the drug produced on a large scale (2x2500L), which results in a postponement of the possibility of registering the drug, which in turn is related to the inability to receive the expected next payment from the partner, conditional on this event in the short term. The existing agreement with Mylan also provides for the possibility of its termination after 2020 if the drug is not registered by that time. In the absence of registration by the end of 2020, Mylan will have the opportunity to terminate the agreement and consequently demand from the Company the reimbursement of most of the advances received. In this case the Company will have to acquire a new distribution partner or partners. The process of registration of MabionCD20 is longer than originally expected and goes beyond the current period provided for in the agreement with Mylan. The Company, after changing its registration strategy, remains in ongoing contact with the partner and took actions to continue the existing agreement and introduce appropriate changes to its relevant terms.

The change in the registration strategy also requires the Company to provide additional funding for current liabilities and costs necessary to implement the updated strategy in the long term.

As at 31 March 2020, the Company used part of the available loan of PLN 15 million from Santander Bank Polska S. A. The remaining amount of financing, totalling PLN 15 million, is available for use and is subject to the fulfilment of the conditions contained in the agreement with the Bank, in particular the EMA's consent to the registration of MabionCD20. In accordance with the agreement in force, the date of its completion and the loan repayment is July 2020. The Company has taken steps to establish and change the terms and conditions, including the extension of financing.

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

Extending the registration process for MabionCD20 may affect the continuation of the agreement with Mylan and requires additional funding. The Company's strategy is to continue to work with Mylan and to obtain or maintain the required funding. However, the extension of the registration process creates a risk that the cooperation with Mylan will not be continued, and the Company may fail to attract other partners and will not obtain the required funding.

As at the date of publication of this report, the Company has letters of support from key shareholders (Twiti Investments Limited, Glatton Sp. z o. o., Polfarmex S. A.), in which they express their willingness and ability to continue financial support for the current operations of the Company in the near future. In addition, in March 2020, the Company received supporting documents from the main (founding) shareholders, according to which they declared to recapitalise the Company with the amount of not less than PLN 15 million in 2020 (described in more detail in point 3.2.). The change in the terms of current debt financing agreements and further acquisition of financing available on the market, including exclusive agreements with future distribution partners or declared support from shareholders (both strategic and stock market participants), should provide the Company with the financing necessary to complete the registration process and commercialise MabionCD20.

The Company actively monitors its environment in terms of the prospects for obtaining new funding opportunities, which will enable it to cover expenses related to its core R&D and investment activities. In particular, current activities are focused on including support from the National Centre for Research and Development in the planned bridging clinical trial. The Company has also undertaken activities aimed at acquiring a distribution partner for the US market and other markets not covered by the existing agreements. However, risks related to limited access to funding cannot be excluded due to the global liquidity situation and the situation caused by the SARS-CoV-2 pandemic and its impact on capital markets (see also section 3.2).

The SARS-CoV-2 pandemic affects the functioning of both Mabion S.A. and external entities cooperating with it. Most companies in the world are limiting their activities due to the epidemic. Delays in the execution of orders are increasingly frequent. Many suppliers of the Company are representatives of European companies that have warehouses in many countries in Europe, which makes it impossible to deliver at the declared time. Delays on the part of courier companies are also a frequent cause of late deliveries. Apart from the delivery dates, limitations occur caused by the lack of possibility of carrying out e.g. calibration of equipment by a representative of a foreign company at the Company's premises, without which the equipment cannot be started up and its acceptance finalised. There are also situations when materials and process substances are delivered at the last minute, which causes a delay in the process of transferring materials for testing. In addition, it is not ruled out that the company's inventories may be depleted, and the production limitation will contribute to the reduced supply of products, and thus potential problems with guaranteeing all the resources necessary to conduct research.

The above risk may have an impact on the timeliness and scope of implementation of projects co-financed by the European Union.

There is a risk that if the Company fails to carry out the planned work within the deadlines set by the intermediary body, it will be obliged to return part or the entire amount of the grant plus interest. There is also a risk that the intermediary body may not grant the approval in the event of further problems related to substantive or financial progress, which may involve the termination of the grant agreement(s) and the need to reimburse the funds collected, together with interest.

Therefore, if the conditions giving rise to the liability are fulfilled, the Company's financial situation may significantly deteriorate, which in the long run may threaten the achievement of the Company's strategic objectives.

In order to prevent the above mentioned risk, the Management Board of the Company monitors the course of cooperation with contractors and the internal situation of the Company on an ongoing basis, trying to proactively adjust the strategy to the existing threats in the areas described above and to cooperate with intermediary bodies closely. The Management Board also analyses the situation caused by the pandemic in terms of its possible impact on the implementation of clinical trials. It cannot be ruled out that the restrictions introduced by government administrations in individual countries may hinder the launch of the study or affect its organisation and duration. In order to minimize this risk, the Management Board monitors potential threats on an ongoing basis to adapt the Company's plans to the epidemic situation.

In order to limit the negative effects of the pandemic, the Management Board, acting on the basis of the relevant provisions of law, submitted applications for granting tax reliefs, which constitute income for the State Treasury, and for postponing the date of payment of contributions due to the Social Insurance Institution (ZUS). The Company also decided to take advantage of the deferred deadline for the payment of advance payments for personal income tax and to submit an application for a tax relief for real estate tax. The Management Board of the Company is currently monitoring the enacted and drafted legislation, aimed at providing aid of a public-law nature for companies suffering from negative economic effects, caused by the SARS-CoV-2 pandemic.

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

5 Contact details

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Management Board of the Company

Konstantynów Łódzki, 25 May 2020

Dirk Kreder
President of the Management Board

Jarosław Walczak
Member of the Management Board

Sławomir Jaros
Member of the Management Board

Grzegorz Grabowicz
Member of the Management Board

May 25, 2020

Oświadczenie

Niniejszym oświadczam, że z uwagi na pandemię koronawirusa COVID-19 powodującą ograniczenia w przemieszczeniu pomiędzy krajami UE jak również wewnątrz Państwo Członkowskich UE nie udało się mi się w pełni zakończyć procedury uzyskania podpisu elektronicznego w terminie do zatwierdzenia Śródrocznego Skróconego Sprawozdania Finansowego za okres 3 miesięcy zakończony 31 marca 2020 r. wraz z Pozostałymi Informacjami do raportu kwartalnego Mabion S.A. za I kwartał 2020 r. w związku z czym nie miałem możliwości podpisania ww. dokumentów.

Jednocześnie oświadczam że wedle mojej najlepszej wiedzy, Śródroczne Skrócone Sprawozdanie Finansowe za okres 3 miesięcy zakończony 31 marca 2020 r. i dane porównywalne zostały sporządzone zgodnie z Międzynarodowymi Standarami Sprawozdawczości Finansowej i odzwierciedlają w sposób prawdziwy, rzetelny i jasny sytuację majątkową i finansową Spółki oraz jej wynik finansowy.

Ponadto oświadczam, że Pozostałe Informacje do raportu kwartalnego Mabion S.A. za I kwartał 2020 r. zawierają prawdziwy obraz rozwoju i osiągnięć oraz sytuacji Spółki, w tym opis podstawowych zagrożeń i ryzyka.

Statement

I hereby declare that, due to the COVID-19 coronavirus pandemic causing restrictions on movement between EU countries as well as within an EU Member State, I have not been able to complete the procedure of obtaining electronic signature in time for the approval of the Interim Condensed Financial Statements for the period of 3 months ended March 31, 2020, alongside with Other Information to the quarterly report of Mabion S.A. and, as a result, I have not been able to sign the above-mentioned documents.

Simultaneously, I declare that to the best of my knowledge, the Interim Condensed Financial Statements for the period of 3 months ended March 31, 2020 and the comparative data have been prepared in accordance with the International Financial Reporting Standards and they give a true and fair view of the Company's financial position and its financial performance.

Moreover, I declare that the Other Information to the quarterly report of Mabion S.A. contains a true view of the development, achievements and situation of the Company, including the description of basic threats and risks.

Dirk Kreder – Prezes Zarządu Mabion S.A./

President of Management Board of Mabion S.A.