Other information to the quarterly report of Mabion S.A. for the third quarter of 2019

Konstantynów Łódzki, 14 November 2019

Other information to the quarterly report of Mabion S.A. for the third quarter of 2019

1 Selected financial data

	in PLN thousand		in EUR thousand	
	from 01.01.2019 to 30.09.2019	from 01.01.2018 to 30.09.2018	from 01.01.2019 to 30.09.2019	from 01.01.2018 to 30.09.2018
Net revenues from sales of products, goods and materials	0	0	0	0
Profit (loss) on operating activities	-46 656	-48 693	-10 829	-11 448
Gross profit (loss)	-48 429	-52 286	-11 240	-12 292
Net profit (loss)	-48 429	-52 286	-11 240	-12 292
Net cash flows from operating activities	-24 753	-32 726	-5 745	-7 694
Net cash flows from investing activities	-7 878	-3 608	-1 828	-848
Net cash flows from financial activities	-1 907	103 286	-443	24 283
Total net cash flows	-34 538	66 952	-8 016	15 740
	30.09.2019	31.12.2018	30.09.2019	31.12.2018
Total assets	107 595	144 717	24 601	33 655
Liabilities and provisions for liabilities	113 884	102 578	26 039	23 855
Long-term liabilities	45 487	36 069	10 400	8 388
Short-term liabilities	68 397	66 509	15 639	15 467
Equity	-6 289	42 139	-1 438	9 800
Share capital	1 372	1 372	314	319
Number of shares (in pcs.)	13 720 722	13 720 722	13 720 722	13 720 722
Profit (loss) per ordinary share (in PLN/EUR)	-3.53	-4.06	-0.82	-0.95

Selected balance-sheet items presented in EUR were converted according to the average EUR exchange rate announced by the National Bank of Poland on 30 September 2019 (4.3736 PLN/EUR) and 31 December 2018 (4.3000 PLN/EUR). Selected items in the profit and loss account and cash flow statement were converted into EUR at the exchange rate being the arithmetic mean of average exchange rates for EUR announced by the National Bank of Poland, in force on the last day of each month in the period of 9 months ended 30 September 2019 and 9 months ended 30 September 2018 (4.3086 PLN/EUR and 4.2535 PLN/EUR, respectively).

2 Information about Mabion S.A.

2.1 The Company' s authorities

2.1.1 Management Board

In 2019 Q3 and until the date of submitting this report, the composition of the Company's Management Board did not change and as at 14 November 2019, the Company's Management Board is composed of 3 members:
» Sławomir Jaros - Member of the Management Board,
» Jarosław Walczak - Member of the Management Board,
» Grzegorz Grabowicz - Member of the Management Board.

2.1.1 Supervisory Board

In 2019 Q3 and until the date of submitting this report, the composition of the Company's Supervisory Board did not change and as at 14 November 2019, the Company's Supervisory Board was composed of 8 members:
» Maciej Wieczorek - Chairman of the Supervisory Board,
» Józef Banach - Deputy Chairman of the Supervisory Board, 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,
» Krzysztof Kaczmarczyk - Independent Member of the Supervisory Board,
» Dirk Kreder - Independent Member of the Supervisory Board.

2.2 Structure of the share capital

As at 30 September 2019 and as at the submission date of this report, the share capital of the Company amounts to PLN 1,372,077.20 and is divided into 13,720,772 shares with a nominal value of PLN 0.10 each, including:
» 450 000 registered preference A shares,
» 450 000 registered preference B shares,
» 450 000 registered preference C shares,
» 450 000 ordinary bearer D shares,
» 100 000 registered preference E shares,
» 100 000 registered preference F shares,
» 20 000 registered preference G shares,
» 2 980 000 ordinary bearer H shares,
» 1 900 000 ordinary bearer I shares,
» 2 600 000 ordinary bearer J shares,
» 790 000 ordinary bearer K shares,
» 510 000 ordinary bearer L shares,
» 360 000 ordinary bearer M shares,
» 340 000 ordinary bearer N shares,
» 300 000 ordinary bearer O shares,
» 1 920 772 ordinary bearer P shares.

Registered shares of A, B, C, E, F and G series are preference shares, which means that each of them entitles to two votes at the General Meeting. The total number of votes resulting from all the issued shares is 15 290 772.

2.3 Shareholders' Structure

To the knowledge of the Company as at the date of submitting the report for the third quarter of 2019 (14 November 2019), the following shareholders hold at least 5% of the total number of votes at the Company's General Meeting:

I.P.	Shareholder	Number of shares	Number of votes	Participation in the share capital	Share in the total number of votes
1.	Twiti Investments Limited	2 380 072	2 974 372	17.35%	19.45%
2.	Maciej Wieczorek through*:	1 626 576	2 119 426	11.85%	13.86%
	- 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	10.48%	12.56%
4.	Funds managed by Generali PTE S.A.	1 629 847	1 629 847	11.88%	10.66%
5.	Funds managed by Nationale Nederlanden PTE S.A. Funds**	1 140 600	1 140 600	8.31%	7.46%
6.	Funds managed by Investors TFI S.A. ***	1 068 007	1 068 007	7.78%	6.98%
7.	Others	4 437 687	4 437 687	32.34%	29.02%
	TOTAL	**13 720 772**	**15 290 772**	**100%**	**100%**

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

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

*** *According to the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 28.06.2018*

As of the date of submitting the previous interim report, i.e. as of 12 September 2019 until the date of submitting this report, no changes in the ownership structure of significant Issuer's stakes took place.

2.4 Number of shares held by managing and supervising persons

	Shares held as at the submission date of the report for the third quarter of 2019 (14 November 2019)
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., 66.67% of the share capital) holds 1 626 576 shares of the Company in total with a nominal value of PLN 0.10 each, constituting 11.85% of the share capital of the Company and 13.86% of votes at the General Meeting.

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

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

In February 2019, the Supervisory Board, acting on the basis of the authorisation granted by the Ordinary General Meeting of 28 June 2018, established the lists of persons entitled to subscribe for A and B subscription warrants for 2018 and 2019, together with the maximum number of warrants that each of these persons may subscribe for, provided that the criteria set forth in the Incentive Scheme are met. In accordance with the resolution of the Supervisory Board, the persons entitled to subscribe for subscription warrants for 2018 include Members of the Management Board of the Company:

» Mr. Jarosław Walczak - the right to subscribe for up to 1 411 A warrants,
» Mr. Sławomir Jaros - the right to subscribe for up to 5 644 A warrants and granted 4,043 B warrants.

The A subscription warrants for 2018 were not granted due to the fact that in 2018, the market objective specified in the Incentive Scheme in relation to A warrants was not met; however, pursuant to the Incentive Scheme Rules and Regulations, these warrants may be granted to eligible persons during the period of the Incentive Scheme together with A warrants for the year in which the market objective is met. With respect to B warrants, the condition for the right to subscribe for them and exercise the rights carried by B warrants has been met. As at the date of publication of this report, no agreements to subscribe for B warrants have been made.

2.5 Description of changes in the organisation of the capital group

Mabion S.A. ("Company", "Issuer", "Mabion") does not have any subsidiaries and does not form a capital group.

3 Activity of Mabion S.A.

3.1 Implementation of the Company' s development strategy

The main objective of Mabion is to develop, manufacture and market medicines biosimilar to the original biotech medicines existing on the market (reference drugs), in the field of oncology, autoimmulogy, neurology and metabolic diseases.

On 3 April 2019, following the annual review and update of the development strategy for medicinal products, the Company's Management Board adopted a resolution approving changes to the existing development strategy. In accordance with the resolution, the catalogue of projects which the Company is interested in implementing, now or in the future, either independently or with partners, has been changed. The Company has also qualified research and development projects into three groups of projects, i.e. active projects, new projects that were planned for 2019, and partnership projects.

Active projects

A group of projects of the greatest importance for the Company, for which the Company conducts work and invests funds. This group includes the following current projects: MabionCD20, MabionMS and MabionEGFR.

New projects planned for 2019

Projects for which the Company started research and development work in the second half of 2019 include projects related to development of three medicines biosimilar to the following reference drugs: Prolia[1] and Xgeva[2] (both based on denosumab antibody) and Xolair[3] (based on omalizumab antibody).

In respect of the above-mentioned antibodies, the following works were carried out in the 3rd quarter of 2019:

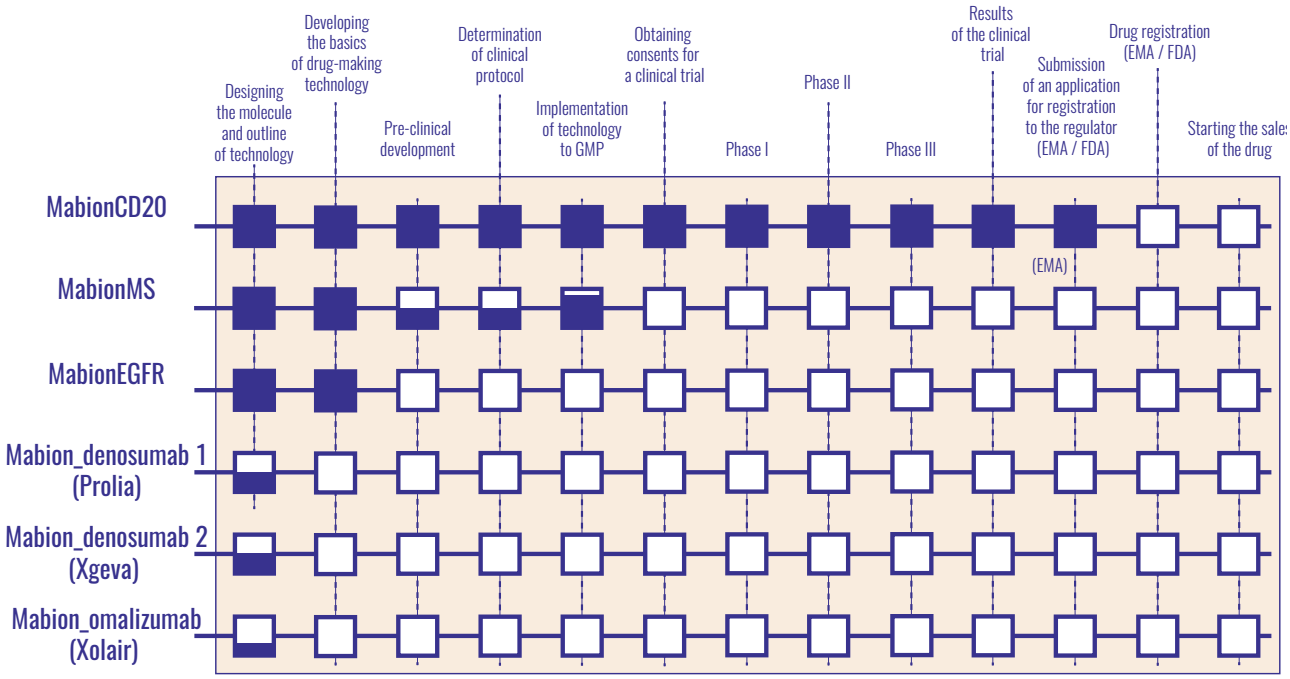
» Reference drug Prolia and Xgeva (based on denosumab antibody) - the amino acid sequence of the reference drug was verified and confirmed and work on the construction of a vector encoding biosimilar antibody was started. The creation of a reference material bank was initiated.

» Reference drug Xolair - the amino acid sequence of the reference drug was verified and the creation of a reference material bank was started.

Partnership projects

Projects for which the Company is considering commencement of implementation in the medium or long term, preferentially in cooperation with a partner. They will include projects concerning, among others, autoimmune and oncological diseases.

The graphs below show in detail the already completed stages of development of projects underway.



[1] Prolia reference drug - indications: osteoporosis, value of sales in 2018 approx. USD 2.3 billion (based on Global Data). The patent for 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. Several entities are currently working on a biosimilar version of the medicine (http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab).

[2] Xgeva reference drug - indications: prevention of bone complications (pathological fractures, necessity to irradiate bones, spinal cord pressure or necessity to perform bone surgery) in adults with metastases of solid tumors to bone. Sales value in 2018: approx. USD 1.7 billion (based on Global Data).The 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 USA in 2025. Several entities are currently working on a biosimilar version of the medicine (http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab).

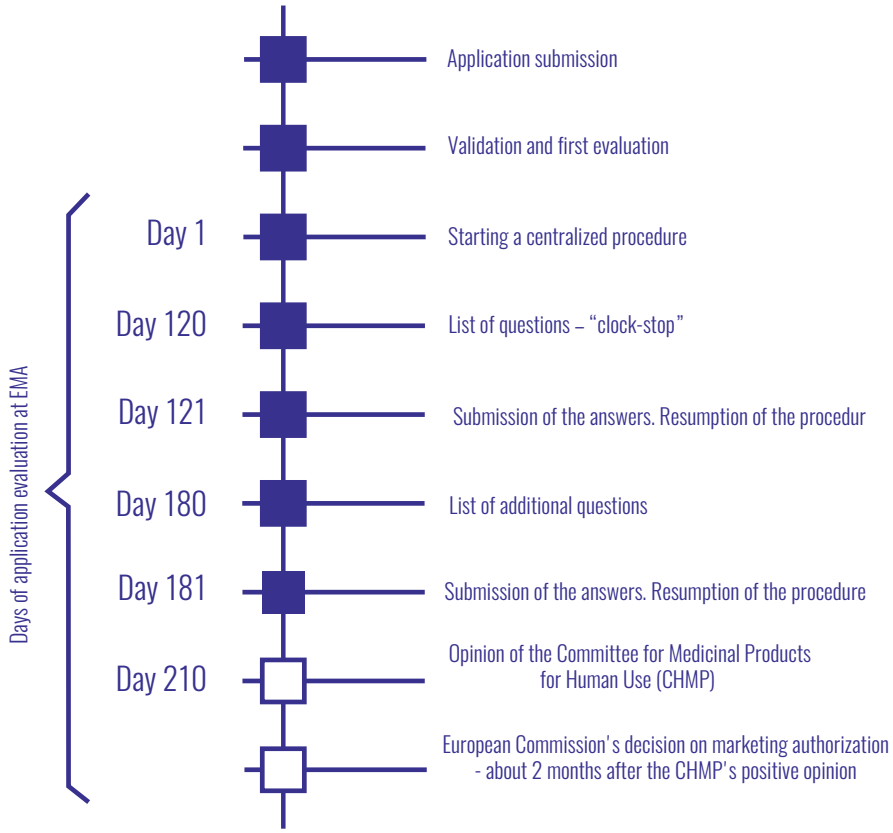
[3] Xolair reference drug - indications: asthma, sales value in 2018 approx. USD 3 billion (based on Global Data). Patent protection ended in 2017. Currently, several entities are working on a biosimilar version of the medicine, including Celltrion (http://www.koreabiomed.com/news/articleView.html?idxno=6109)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

The MabionCD20 project

The Company's priority and most advanced project is the admission to trading of a drug under the working name of MabionCD20. On 1 June 2018, the Company filed a marketing authorisation application (MAA) with the European Medicines Agency for admitting to the market regulated by the EMA of a drug under the working name of MabionCD20. On 21 June 2018, the Company received information on the positive completion of the validation of the application and thus its acceptance into the assessment procedure.

On 24 April 2019, it submitted answers to the EMA's questions received under the Day 120 stage of the registration procedure for MabionCD20 in the EMA. The submission of answers to the EMA questions allows the procedure to resume and the Agency to continue its assessment of the application. On 1 July 2019, the EMA submitted to the Company the second round of questions under the drug registration procedure (Day 180). On 10 November 2019, the EMA received the Company's answers to the second round of questions concerning the registration procedure for MabionCD20 (Day 181). Providing answers to these questions will be one of the last stages on the way to obtaining the final decision of the European regulator. On 10 November 2019, the EMA received answers to the second round of questions (Day 180) of the registration procedure for MabionCD20. The submission of the answers allows the Agency to continue its evaluation of the application. The Company is currently awaiting the opinion of the Committee for Medicinal Products for Human Use (CHMP).

The chart below shows the procedure for assessing an application for registration of a medicine in the EMA together with indication of the stage at which the Company's application remains as at the date of publication of this report:



Should a favourable decision of the European Commission on the marketing authorisation be obtained, the Company will apply for a post-registration change in the form of a dossier to increase the scale of production to 2x2500 l of culture volume in a bioreactor. The application submitted to the EMA in 2018 concerned the clinical scale of bioreactor breeding, however it covered the manufacturing process after the transfer from the plant at Fabryczna Street to the commercial manufacturing plant in Konstantynów Łódzki. Post-registration changes are a typical element of cooperation with the regulatory authority after obtaining the original registration, and may concern changes in scale, manufacturing sites, process improvements, additional manufacturing sites, etc. This is a customary practice of pharmaceutical companies (e.g. MabThera has undergone 44 post-registration reviews[4]).

[4] https://www.ema.europa.eu/en/medicines/human/EPAR/mabthera#authorisation-details-section

In June 2018, the Company received a summary from the U.S. Food and Drug Administration following a Type 2 BPD (Biosimilar Biological Product Development) meeting. The meeting was aimed at providing an initial, general presentation of the MabionCD20 development data collected by the Company with respect to the reference drug MabThera, as well as at identifying key issues regarding the feasibility of starting cooperation with the Agency on the basis of these data to obtain MabionCD20 registration in the United States. According to the summary, the Agency allowed for the possibility of using the data held by the Company to support the application process. At the same time, it proposed an overall strategy to link the product registered in the European Union (MabThera) to the product authorised in the USA (Rituxan). On the basis of data available at that time, the Agency did not indicate the need for a completely separate process for the development of MabionCD20 for the US market.

The Agency considered that there was a need for a bridging study to be carried out on the basis of the reference drug MabThera in relation to the trials carried out in Europe. The bridging study should be trilateral and include the American Rituxan, the European MabThera and MabionCD20. It will also be necessary to perform a three-arm analytical study. The US registration and authorisation process for MabionCD20 is a multi-step process and it cannot be excluded that additional requirements for FDA approval may arise in the future.

On the basis of the current recommendation of the Agency, the Company prepared a study protocol and, together with "Briefing Package", transferred it to the FDA in September 2019.

On 23 October 2019, the Company was informed that the FDA granted the Company the opportunity to hold a Type 3 BPD meeting and set the date of the meeting for 22 January 2020. The purpose of the meeting is to obtain confirmation of the regulatory strategy regarding the possibility of applying for registration of MabionCD20 in the USA. Setting a Type 3 meeting is the next step in the implementation of activities aimed at obtaining MabionCD20 registration in the USA. It is the result of FDA's assessment of the documentation package submitted by the Company, including full reports on clinical trials of MabionCD20 conducted with the European reference drug MabThera in patients with rheumatoid arthritis (RA) and non-Hodgkin's lymphoma (NHL), results of the analytical similarity study of MabionCD20 (clinically tested drug batches) and European reference (MabThera) to the American (Rituxan) reference and the clinical (bridging) trial protocol.

In order to commence the bridging study, the Company, based on the study protocol, must obtain the consent of competent authorities and the consent of bioethics committees. At the same time, the Company must ensure financing for the study, which is a necessary condition for its commencement and thus determines the date of its performance. The funds for the implementation of the above assumptions may originate both from a potential distribution partner, from EU funds or other sources.

As far as US partners are concerned, the potential partner is Mylan, and depending on the company's decision, Mabion will be able to consider other partners who can co-finance research and activities leading to the commercialisation of the drug in the US market. Until Mylan has made a decision on this issue (which should be 30 days after the final minutes of the FDA Type 3 meeting are issued), the Company may not make any commitments to other partners.

In 2018, the Company received permission from the European Medicines Agency to submit a duplicate application ("Duplicate application") for a medicine under the working name of MabionCD20. On 6 May 2019, the Company received confirmation of the correct submission of the aforementioned duplicate registration application to the EMA from the partner, and on 27 May 2019, the Company was informed about the positive completion of the validation of the aforementioned application by the EMA and thus its acceptance into the assessment procedure. The assumption of the duplicate application is that the Company will obtain an additional trade name for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). This action may accelerate the commercialisation of the medicine under the working name of MabionCD20 in markets where RA is still protected by MabThera patent.

On 11 November 2019, the EMA received answers from the Company under the registration procedure for the duplicate application for MabionCD20 (Day 181). From Day 181 of the procedure, both applications will be processed in parallel.

The submission of the answers allows the Agency to continue its assessment of the duplicate application. The Company is currently awaiting the opinion of the Committee for Medicinal Products for Human Use (CHMP).

To sum up the research and development work on MabionCD20, the following activities were successfully completed in the third quarter of 2019:

- bioequivalence and biosimilarity studies (MabionCD20 vs. MabThera) were completed;
- the stability of MabionCD20 and the reference drug were continuously examined;
- the degradation studies of MabionCD20 and the reference drug have been completed;
- the answers were developed as part of the ongoing registration process with the European Medicines Agency (day 180); confirmation of submission of the responses to the electronic EMA system was received by the Company on 10 November 2019 for the original application and on 11 November 2019 for the duplicate application for registration of MabionCD20 ("Duplicate application");
- the scope of work related to the determination of the process space for the manufacturing process of MabionCD20 was extended;
- strategy for controlling the manufacturing process of MabionCD20 on a 2x2500L scale has been developed;
- technological and validation documentation was developed for the manufacturing process of MabionCD20 on a 2x2500L scale;
- preparations were made to launch the process of manufacturing the first batch of validation on a 2x2500L scale
- the preparation of the clinical trial protocol and the Briefing Package was completed based on the existing arrangements with the FDA. On 12 September 2019, the Briefing Package was handed over to an external company (the Company's project representative in the USA) for submission to the FDA. After the analysis of the above documentation, the FDA confirmed that the Company was granted a type 3 meeting, which was scheduled for 22 January 2020.

The MabionMS project

With respect to the MabionMS innovative therapy project, the Company has so far filed 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, based on which it applied 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 patients suffering from multiple sclerosis with a combination of MabionCD20 and other substances (the MabionMS combination therapy project). In 2018, the Company filed an application with the European Patent Office in the Hague for the extension of patent protection under the PCT procedure for the aforementioned invention. In order to avoid a dangerous situation in which the Patent Office alleges an attempt at double patenting of the same scope of protection, in March 2019 the Company withdrew the originally filed European application in order to benefit from the protection granted under the international application (also covering the European area). This is a procedural solution to optimise this process.

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, from the area of application of MabionCD20 in the treatment of patients with MS, entitled "Low aggregate anti CD20 ligand formulation". This is a second patent application for the use of MabionCD20 to treat multiple sclerosis as an innovative indication for the molecule. The application concerns the monotherapy use of MabionCD20. Currently, the Company is looking for partners for further work related to the development of the above mentioned therapies.

Within the scope of the above project, in the first half of 2019 the Company prepared both a synopsis of clinical trials as well as a Briefing Package. The substantive content and regulatory assumptions of the project were consulted with external specialists in clinical trials in the treatment of multiple sclerosis. After consultation and approval of the final version of the documents, the Company submitted them to the EMA on 9 August 2019. On 12 September 2019, the Briefing Package was handed over to an external company (the Company's project representative in the USA) for submission to the FDA. Both events initiate the process of scientific consultations with regulators in order to confirm the compliance of project assumptions with the requirements of both Agencies. Consultation with regulators is a multi-stage process, which may include research and development reports and rounds of scientific advice queries. It is difficult to predict when a consensus in such consultation can be reached.

The MabionEGFR project

As regards 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 by EU.

Within the scope of the above project, in the third quarter of 2019 the Company conducted activities related to:
» determination of the quality target product profile for the reference product (QTPP) for critical protein attributes;
» creation of a reference material bank;
» optimisation of subsequent versions and verification of the genetic structure;
» development of analytical methods for characterising the protein obtained;
» optimisation of the conditions for introducing the vector into host cells;
» preselection of chromatographic deposits and preliminary optimization of conditions for antibody purification.

Cooperation with Plexus Ventures LLC

In the reporting period, the Company continued cooperation with Plexus Ventures LLC - an experienced advisor supporting the Company in the field of business development. Plexus conducts activities aimed at acquiring partners who can effectively sell medicines included in the above mentioned Mabion pipeline. The process is complex and lengthy - it involves contacting companies, signing confidentiality agreements and presenting data at various detail levels, depending on the stage of the process. At the same time, companies are updating their offers.

Production capacity

The current production capacity enables the Company to start selling the drug under the working name of MabionCD20. The implementation of long-term plans requires the Company to increase its production capacity, which involves the need for investments. A necessary stage in the Company's development is retrofitting of the existing production line in order to meet the potential demand from EU countries.

Retrofitting an existing plant

The investment, which is the subject of permit No. 301 for conducting business activity within the Łódź Special Economic Zone, consists in increasing the production capacity of the current plant and includes:
» retrofitting of the existing production line 2x2500 L, and
» purchase and installation of production equipment for the second production line 2x2500 L, which will be located in the existing building.

Under permit No. 301 until 31 December 2019, the Company undertook to incur investment expenditures within the Zone amounting to at least PLN 20 million (within the meaning of § 6 of the Regulation of the Council of Ministers of 10 December 2008 on public aid granted to entrepreneurs operating on the basis of a permit to conduct business activity in the areas of special economic zones). In accordance with the previous announcement, in June 2019 the Company submitted a request to the Minister of Investment and Development to extend the deadline for disbursement of these funds until 30 June 2021. The Company is awaiting a decision in this respect. The investment is planned to be completed by 31 December 2021. On account of permit No. 301 as of 30 September 2019, the Company made expenses in the amount of PLN 2.8 million.

Extension of an existing plant

In 2017, the Company commenced preparatory activities related to the expansion of the existing plant (MABION II), which will result in a significant increase in the Company's production and research and development capacities. The MABION II project is complex in nature and will be implemented as part of a project or projects co-financed from EU funds, own resources and covered by the next zonal permit.

In 2017, a concept for the expansion of the Scientific-Industrial Complex for Medical Biotechnology was developed. In 2018, the Management Board of the Company selected an international consortium of architectural and technological companies, to which it entrusted the development of a technological and construction design. As at the date of publication of this report, the project consortium is finalizing work on executive designs for all construction and installation works.

In 2018, the Company also received a decision of the Starost of Pabianice to approve the construction design and grant a building permit for the above mentioned investment, entitled "Centrum Naukowo Technologiczne zaawansowanej biotechnologii medycznych Mabion S.A." together with the necessary infrastructure in Konstantynów Łódzki.

Obtaining a building permit enables the commencement of work on the expansion of the existing plant; however, the moment of its commencement depends on the situation of the Company (including status of current projects in the field of investment co-financing, as well as leveraging new sources of financing, cash flow of the Company, guidelines of the regulators - EMA, FDA and actions necessary to be performed by the Company in connection with these guidelines, etc.). The Company's investment plans may be extended in the future in relation to the investments covered by the currently obtained permit.

3.2 Description of significant achievements and failures of the Company in the first quarter of 2019 and after the balance-sheet date

On 1 July 2019, the Company received the second round of questions under the drug registration procedure from the European Medicines Agency (Day 180). The Company informed about the event in current report no. 20/2019 of 1 July 2019.

On 23 July 2019, the Company became aware that as a result of an inspection conducted by the Chief Pharmaceutical Inspectorate (GIF), it obtained a GMP (Good Manufacturing Practice) certificate for the Mabion S.A.'s Scientific-Industrial Complex for Medical Biotechnology in Konstantynów Łódzki for the production of an active substance (Rituximab). The GIF inspection was commissioned by the EMA as part of the assessment of the Company's marketing authorisation application for MabionCD20. The GMP certificate confirms that the Company conducts production processes in accordance with GMP principles for the production of the active substance (Rituximab) used to obtain the finished product. This is the first certificate in the above mentioned scope that the Company has obtained so far. The certificate is valid for 3 years from the date of the last day of inspection (i.e. 17 May 2019). The Company informed about the event in its current report no. 21/2019 of 23 July 2019.

On 25 July 2019, the Company received a letter from the EMA informing that on the basis of the inspection carried out by GIF on behalf of the EMA, classified as a pre-authorization inspection concerning the drug with the working name of MabionCD20, the Inspectorate recognizes that the manufacturing processes conducted in the Company are in accordance with the principles and guidelines of Good Manufacturing Practice (GMP) set out in Directive 2003/94/EC. The findings of the inspection enable the inspectors to recommend the EMA to establish the Mabion S.A's Scientific-Industrial Complex for Medical Biotechnology in Konstantynów Łódzki in Konstantynów Łódzki as a manufacturing site for the medicine with the working name of MabionCD20. It is one of the milestones necessary to obtain marketing authorisation for MabionCD20, but it is not an event that guarantees registration. The Company informed about the event in its current report no. 22/2019 of 25 July 2019.

On 14 August 2019, the Company was informed by the Mylan legal department that, in connection with the information on the intention to merge Mylan NV (Mylan) with Upjohn - an entity separated from the Pfizer group, at this time they do not anticipate any impact of the planned merger on the cooperation of the Mabion and Mylan teams with respect to the registration of MabionCD20 in the European market and the agreement binding upon the Mabion and Mylan (Development and Commercialization Agreement). The Company informed about concluding the Development and Commercialization Agreement in current report No. 31/2016 of 8 November 2016. This is confirmed by the fact that the cooperation between the Company and Mylan is in line with the adopted assumptions, and that working group meetings are held regularly and adequately to the needs of the work related to the registration process of MabionCD20 with the EMA. It cannot be excluded that Mylan's position may change in the future. Mabion has no influence on the scope of third party cooperation and it may happen that the new entity's strategy for the development of medicinal products competes with the Mabion's offer. In the Company's opinion, any changes in the scope of cooperation with Mylan should not affect sales of MabionCD20 in the future due to the form of distribution of this medicine (cyclically changing lists of products reimbursed by health care systems) and market potential.

The Company remains in current contact with representatives of Mylan. The Company informed about the event in its current report no. 24/2019 of 14 August 2019.

On 19 August 2019, the Company became aware that as a result of a GIF inspection, it obtained a GMP certificate for the Mabion S.A.'s Scientific-Industrial Complex for Medical Biotechnology in Konstantynów Łódzki for the following manufacturing operations: production of sterile forms of biotechnological products, quality control research, batch release and packaging of medicinal products. This is the second GMP certificate obtained by the Company as a result of a GIF inspection commissioned by EMA as part of the assessment of the marketing authorisation application for MabionCD20 submitted by the Company. This GMP certificate confirms that the Company conducts production processes in accordance with the GMP principles in this respect. The certificate is valid for 3 years from the last day of inspection (i.e. 17 May 2019). Obtained GMP certificates are necessary for the manufacture, registration and commercialisation of MabionCD20, however, GMP certificates do not guarantee product approval by EMA. The Company informed about the event in its current report no. 25/2019 of 19 August 2019.

On 21 October 2019, the Management Board of Mabion S.A. and the European Investment Bank (EIB) agreed on financing conditions for granting the Company an unsecured loan disbursed in three tranches, mobilised after meeting certain conditions, up to the total amount of EUR 30 million, after concluding the relevant documentation, including the financing agreement (Financing Agreement) and the agreement on the issue of subscription warrants for the EIB (Warrant Agreement). On the same day, the Management Board of Mabion S.A. adopted a resolution to conclude financing documentation, including the Financing Agreement and the Warrant Agreement, on terms and conditions agreed with the EIB. Concerning the adoption of the said resolution on 21 October 2019, the Supervisory Board of the Company gave the Management Board a positive recommendation. The Financing Agreement, based on the agreed terms of financing, was signed on 24 October 2019.

On 31 October 2019, the Company signed the Warrant Agreement on terms and conditions agreed with the EIB.

The funds raised under the loan will be used to finance investment and research and development projects, including the development of biosimilars and innovative biological drugs in Poland and the enhancement of the Company's research and development infrastructure and production capacity. The terms and conditions of the Financing Agreement provide that individual tranches of financing will be repaid within 5 years from the date of disbursement of a given tranche. The loan availability period is 36 months from the date of conclusion of the Financing Agreement. The loan bears interest at a fixed interest rate not higher than 2.7% per annum. The Financing Agreement provides for provisions imposing restrictions on the Company, inter alia with respect to the disposal of material assets and their encumbrance, granting loans and guarantees, as well as with respect to the payment of dividends and incurring financial liabilities in excess of the agreed amounts. Violation of the Company's obligations under the Financing Agreement will entitle the EIB to demand immediate repayment of the loan.

The condition for making the EIB financing available (disbursement) is, among others, the issue by the Company of C series subscription warrants, which will be taken up by the EIB and will entitle to take up T series shares of the Company constituting 2.85% of the share capital of the Company as at the date of issue. For this purpose, the Company convened for 29 November 2019, an Extraordinary General Meeting in order to adopt a resolution on the conditional increase of the Company's share capital through the issue of ordinary bearer shares of T Series with simultaneous exclusion of the pre-emptive right of the existing shareholders of the Company in full, issue of subscription warrants of C Series with simultaneous exclusion of the pre-emptive right of the existing shareholders of the Company in full and amendment of the Company's Articles of Association. The issue of subscription warrants for the EIB constitutes an element of remuneration for the EIB for making the financing available and enables a significant reduction of current debt service costs in relation to standard credit products offered by financial institutions. Pursuant to the Warrant Agreement, the main terms and conditions of the issue of subscription warrants and subscription for shares are as follows:

1. the warrants will be taken up by the EIB free of charge and will entitle to take up T series shares of the Company at the issue price of PLN 0.1 per share;

2. the subscription warrants will be freely transferable to entities affiliated with the EIB, and to other entities only under a sales agreement;

3. in cases specified in the agreement resulting in a reduction of the share of T shares in the Company's share capital below 2.85%, the Company will be obliged to issue additional warrants to the EIB in such a number that the shares subscribed for on the basis of warrants represent such a percentage of the Company's share capital.

The Warrant Agreement regulates cases in which rights carried by subscription warrants may be exercised and the rights and obligations of the parties with respect to the sale and purchase of subscription warrants and T series shares (including limitation of the transferability of T series shares within 6 months from the date of their acquisition, subject to exceptions specified in the Warrant Agreement). The Company informed on agreeing on financing terms and conditions in current report no. 26/2019 of 21 October 2019, and about convening the Extraordinary General Meeting in current report no. 28/2019 of 30 October 2019. In view of the best interest of the Company, the Supervisory Board of Mabion S.A. recommended that the General Meeting of Mabion S.A. adopt resolutions included in the agenda of the Extraordinary General Meeting convened for 29 November 2019, including Resolution No. 3/XI/2019 of the Meeting on: (a) conditional increase of the Company's share capital by the amount not higher than PLN 40 283.50 (b) issue of 402 835 subscription warrants to the European Investment Bank ("warrants") taken up free of charge and entitling to subscribe for 1 share of the Company (c) exclusion of the existing shareholders' pre-emptive rights to Subscription Warrants and pre-emptive rights to T shares of the Company in full, and (d) appropriate amendment of the Company's Articles of Association.

On 23 October 2019, the Management Board of Mabion S.A. informed that it had received information from an agent representing the Company before the FDA that the Company had been granted the opportunity to hold a Type 3 BPD meeting with the FDA and that the date of that meeting had been set for 22 January 2020. The purpose of the meeting is to obtain confirmation of the regulatory strategy regarding the possibility of filing an application for registration of MabionCD20 in the United States of America. Setting a Type 3 meeting is the next step in the implementation of activities aimed at obtaining MabionCD20 registration in the United States. It is the result of FDA's assessment of the documentation package submitted by the Company, including full reports on clinical trials of MabionCD20 conducted with the European reference drug MabThera in patients with RA and NHL, the results of the analytical similarity study of MabionCD20 (clinically tested drug series) and the European reference (MabThera) to the American reference (Rituxan) and the clinical (bridge) trial protocol. Setting the meeting does not guarantee a positive effect of these activities. The Company also reserves the right to change the date of the meeting. The Company informed about the event in its current report no. 27/2019 of 23 October 2019.

On 10 November 2019, the Company obtained confirmation from a company contracted to deposit answers to the second round of questions of the registration procedure for MabionCD20 that they had been effectively received by the EMA electronic system (Day 181). The submission of the answers allows the Agency to continue its assessment of the duplicate application. The Company will now await the opinion of the Committee for Medicinal Products for Human Use (CHMP). The submission of answers does not guarantee the approval of the product by the European Medicines Agency. The Company informed about the event in its current report no. 29/2019 of 10 November 2019.

On 11 November 2019, the company received confirmation from the contracted company that answers had been effectively received in the EMA electronic system as part of the registration procedure for the duplicate application ("Duplicate application") for MabionCD20. Rheumatoid arthritis (RA) will not be included in the list of indications for this product. From Day 181 of the procedure, both applications will be treated in parallel.

The submission of answers allows the Agency to continue the evaluation for the Duplicate application. The Company will now await the opinion of the Committee for Medicinal Products for Human Use (CHMP). The submission of answers does not guarantee the approval of the product by the European Medicines Agency. The Company informed about the event in its current report no. 30/2019 of 11 November 2019.

3.3 Indication of factors and events, including untypical ones, having a significant impact on the condensed financial statements

In the third quarter of 2019, there were no factors or events other than those specified in other sections of the report, including unusual ones, that would materially affect the condensed financial statements of the Company.

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

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

- EMA Decision to authorise marketing of the medicine with the working name of MabionCD20
- costs of conducted research and development work concerning MabionCD20 and other drugs in the Company's pipeline, including costs of manufacturing validation batches (possible repetitions depending on the results achieved);
- the possibility of financing the projects undertaken in line with the approved strategy, including the launch of the bridging study;
- financing of the planned capacity increase, taking into account the intensification of activities in the new plant construction project;
- personnel costs including the increase in the number of employees and general administrative costs of the Company;
- foreign exchange differences resulting from changes in foreign exchange rates;
- market risk - competitive environment and changes in prices of reference and biosimilar drugs;
- proceeds from funds obtained in the event of meeting the conditions for disbursement of individual tranches of the loan granted by the European Investment Bank;
- proceeds from the aid granted from EU funds;
- proceeds from expected fees from distribution partners for MabionCD20.

The amount of proceeds / reimbursement of the costs incurred may depend on possible delays in talks or unforeseen deviations from the schedules of contracts already signed.

3.5 Transactions with related parties

In the third quarter of 2019, the Company did not enter into any transactions with related parties on terms other than arm's length.

In the third quarter of 2019, a gratuitous surety granted to the Company in 2018 by Glatton Sp. z o.o. (a significant shareholder of the Company) was in force in the amount of up to PLN 45 million. The surety relates to the revolving loan agreement of 17 July 2018 entered into with Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) for a period of two years to finance the Company's operating activities. As at 31 March 2019, the Company did not use the credit line granted.

3.6 Sureties and guarantees granted by the Company

In the third quarter of 2019, the Company did not grant any credit or loan sureties or guarantees to one entity or its subsidiary where the total value of the existing sureties or guarantees would be significant for the Company.

3.7 Proceedings before court, arbitration authority or public administration authority

In Q3 2019, no material court, administrative or arbitration proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority or public administration authority.

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

The Management Board of the Company decided to revoke the financial forecasts published in 2010 (drawn up in connection with the application for the introduction of I shares to trading in the alternative trading system) and to resign from providing financial forecasts.

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

In the third quarter of 2019, the Company's activity was comparable to the previous periods.

On 11 September 2019 the Company received information from NCRD concerning the reimbursement of PLN 149 thousand and interest calculated as for tax arrears from the date of transfer of funds, i.e. from 10.12.2014, as a return of co-financing under the INNOMED project. Taking into account the completion of the project covered by the subsidy without achieving the assumed objectives and planned ratios and high probability of the need to return the received funds, in previous reporting periods the Company created an appropriate provision entirely covering the potential amount to be returned with interest. On 19 September 2019, the Company settled these liabilities.

In accordance with the preliminary version of the report confirmed by the finally approved semi-annual condensed financial statements of Mabion S.A. as at and for the period of 3 and 9 months ended on 30 September 2019, the level of the Company's equity as at 30 September 2019 shows a loss exceeding the sum of the supplementary and reserve capitals and one third of the share capital. Therefore, the Management Board of Mabion S.A. included in the agenda of the Extraordinary General Meeting of the Company convened for 29 November 2019 an item providing for the adoption, pursuant to Article 397 of the Commercial Companies Code, of a resolution on the continued existence of the Company.

The occurrence of negative equities being a premise specified in art. 397 of the Commercial Companies Code (*"If the balance sheet prepared by the Management Board shows a loss exceeding the sum of supplementary and reserve capitals and one third of the share capital, the Management Board is obliged to immediately convene a General Meeting in order to adopt a resolution on the continued existence of the company"*) results from the nature of the Company's business. The Management Board emphasizes that in the first three quarters of 2019 there were no one-off events and the Company's activity was comparable to previous periods. The achievement of the above mentioned level of equity capital results from the specific nature of the Company's biotechnological activity (constant incurring of high research costs with no sales revenues until the commercialisation of the project) and is typical for research and development companies. In the opinion of the Management Board of the Company, support from shareholders (both strategic and stock market participants), a long-term cooperation agreement with Mylan Ireland Limited, available bank financing, subsidies and a loan agreement for EUR 30 million signed with the European Investment Bank should provide the Company with financing necessary to complete the development work related to MabionCD20 and justify the continuation of the Company's operations in accordance with the continued business model and the adopted development strategy.

The Supervisory Board of Mabion S.A., taking into account the best interest of the Company, recommended that the General Meeting of Mabion S.A. adopt resolutions included in the agenda of the Extraordinary General Meeting convened for 29 November 2019, including Resolution No. 4/XI/2019 on the continued existence of the Company pursuant to Article 397 of the CCC.

There is no other information that would be significant for the assessment of the personnel, property, financial and financial standing, financial result and their changes, and information that would be significant for the assessment of the possibility of Mabion S.A. meeting its obligations.

5 Dane kontaktowe

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Management Board of the Company

Konstantynów Łódzki, 14 November 2019

Sławomir Jaros	Grzegorz Grabowicz	Jarosław Walczak
Member of the Management Board	Member of the Management Board	Member of the Management Board