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

Konstantynów Łódzki, 16 May 2019

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

Table of contents

1 Selected financial data

Selected balance sheet items presented in EUR were converted according to the average EUR exchange rate announced by the National Bank of Poland on 31 March 2019 (4.3013 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 3 months ended 31 March 2019 and 3 months ended 31 March 2018 (4.2978 PLN/EUR and 4.1784 PLN/EUR, respectively).

	in PLN thousand		in EUR thousand	
SELECTED FINANCIAL DATA	from 01.01.2019 to 31.03.2019	from 01.01.2018 to 31.03.2018	from 01.01.2019 to 31.03.2019	from 01.01.2018 to 31.03.2018
Net revenues from sales of products, goods and materials	0	0	0	0
Profit (loss) on operating activities	-14 509	-14 067	-3 376	-3 367
Gross profit (loss)	-14 985	-14 349	-3 487	-3 434
Net profit (loss)	-14 985	-14 349	-3 487	-3 434
Net cash flows from operating activities	-13 601	-18 804	-3 165	-4 500
Net cash flows from investing activities	-3 637	-726	-846	-174
Net cash flows from financial activities	-479	191 830	-111	45 910
Total net cash flows	-17 717	172 300	-4 122	41 236
	31.03.2019	31.12.2018	31.03.2019	31.12.2018
Total assets	128 291	261 202	29 826	62 065
Liabilities and provisions for liabilities	101 162	329 709	23 519	78 344
Long-term liabilities	35 216	15 738	8 187	3 740
Short-term liabilities	65 946	313 971	15 332	74 604
Equity	27 129	-68 507	6 307	-16 278
Share capital	1 372	1 180	319	280
Number of shares (in pcs.)	13 720 772	11 800 000	13 720 772	11 800 000
Profit (loss) per ordinary share (in PLN/EUR)	9,35	22,14	2,17	5,26

2 Information about Mabion S.A.

2.1 The Company' s authorities

2.1.1 Management Board

From 2 January 2019 until the date of submitting this report, the composition of the Company's Management Board did not change and as at 16 May 2019, the Company's Management Board is composed of 4 members:

» Artur Chabowski - 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.

On 24 December 2018, the Supervisory Board of the Company adopted a resolution on appointing Mr. Grzegorz Grabowicz as Member of the Company's Management Board of the first joint term of office as of 2 January 2019.

On 25 April 2019, Mr. Artur Chabowski tendered his resignation from the position of President of the Company's Management Board. The resignation will enter into force on 30 June 2019.

2.1.2 Supervisory Board

During the reporting period and until the date of submitting this report, the composition of the Company's Supervisory Board did not change and as at 16 May 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 31 March 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 series A, B, C, E, F and G are preference shares, which means that each of them entitles to two votes at the General Meeting. The total number of votes resulting from all the issued shares is 15,290,772.

On 2 April 2019, the Management Board of the Company adopted a resolution on conversion of 514,773 ordinary registered P shares into ordinary bearer P shares, issuing a collective certificate for the above shares and depositing it in a brokerage house, and on entering into an agreement with the National Depository for Securities (Krajowy Depozyt Papierów Wartościowych S.A.) on registration of the above shares in the deposit of securities and applying for their admission and introduction to trading on the official stock exchange quotation market of the Warsaw Stock Exchange (Giełda Papierów Wartościowych w Warszawie S.A.). The resolution was adopted in accordance with the motion of a shareholder – Twiti Investments Limited – submitted pursuant to Article 334 § 2 of the Commercial Companies Code. The shares subject to conversion constitute 3.75% of the share capital and 3.37% of the total number of votes in the Company. The P shares are not preference shares. After the conversion, all P shares of the Company, i.e. 1,920,772 shares, are ordinary bearer shares, of which 1,405,999 P shares are admitted to trading on the official WSE quotation market, and the remaining 514,773 shares, in accordance with the aforementioned resolution of the Management Board of the Company, will be covered by an application for admission to trading. The Company informed about the event in current report no. 7/2019 of 2 April 2019.

2.3 Shareholders' Structure

To the knowledge of the Management Board, as at the date of submitting the report for the first quarter of 2019 (16 May 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*:	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 Investors TFI S.A. **	1 068 007	1 068 007	7,78%	6,98%
6.	Nationale Nederlanden PTE S.A. Funds**	938 031	938 031	6,84%	6,13%
7.	Others	4 640 256	4 640 256	33,82%	30,35%
	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 28.06.2018*

To the knowledge of the Management Board, as at the date of submitting the previous periodic report, i.e. the annual report for 2018 published on 10 April 2019, the following shareholders held 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*:	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.	1 490 545	1 490 545	10,86%	9,75%
5.	Funds managed by Investors TFI S.A. **	1 068 007	1 068 007	7,78%	6,98%
6.	Nationale Nederlanden PTE S.A. Funds**	938 031	938 031	6,84%	6,13%
7.	Others	4 779 558	4 779 558	34,83%	31,26%
	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 General Meeting of Mabion S.A. on 28.06.2018*

2.4 Number of shares held by managing and supervising persons

	Shares held as at the submission date of the report for the first quarter of 2019 (16 May 2019)
Management Board	
Artur Chabowski	holds directly 13,718 shares in the Company with a nominal value of PLN 0.10 each, constituting 0.10% of the Company's share capital and 0.09% of votes at the General Meeting
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., 66.67% of the share capital) holds 1,626,576 shares of the Company in total with a nominal value of PLN 0.10 each, constituting 11.85% of the share capital of the Company and 13.86% of votes at the General Meeting.

In the period from the date of submitting the previous periodic report, i.e. the annual report for 2018 published on 10 April 2019, there were no changes in the shareholdings of the above mentioned persons managing and supervising the Company.

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 Artur Chabowski - the right to subscribe for up to 8,465 A warrants,
- 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 2017, the Management Board of the Company adopted a resolution on the development plan for medicinal products. The plan was drawn up following the completion of an internal analytical project, which accounted for nearly 50 potential candidates for development in the Company, taking into account, among others, expiry dates of reference drug patents, the current and forecast size of the reference drug market, the Company's medicine production technology, team competences, experience with MabionCD20 and competition in the field of biosimilar drugs.

The Company annually updates the development plan for medicinal products, and may change it from time to time.

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 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.

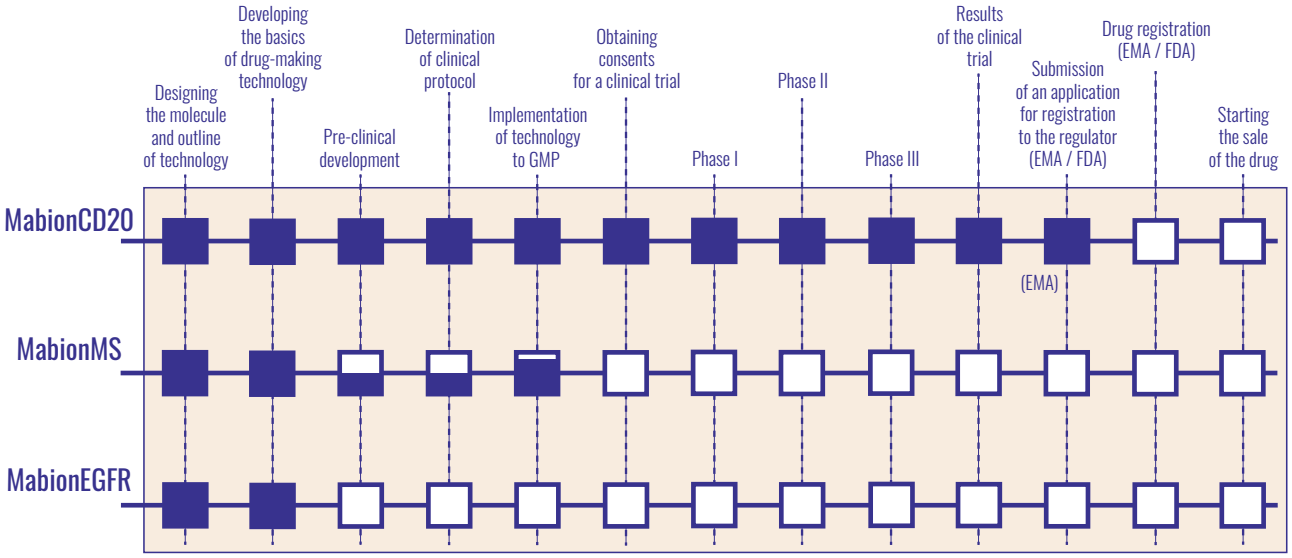
New projects planned for 2019

Projects for which the Company plans to start research and development work in the second half of 2019. They will include projects concerning three biosimilar medicines in the areas of autoimmunology, metabolic diseases and oncology.

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.

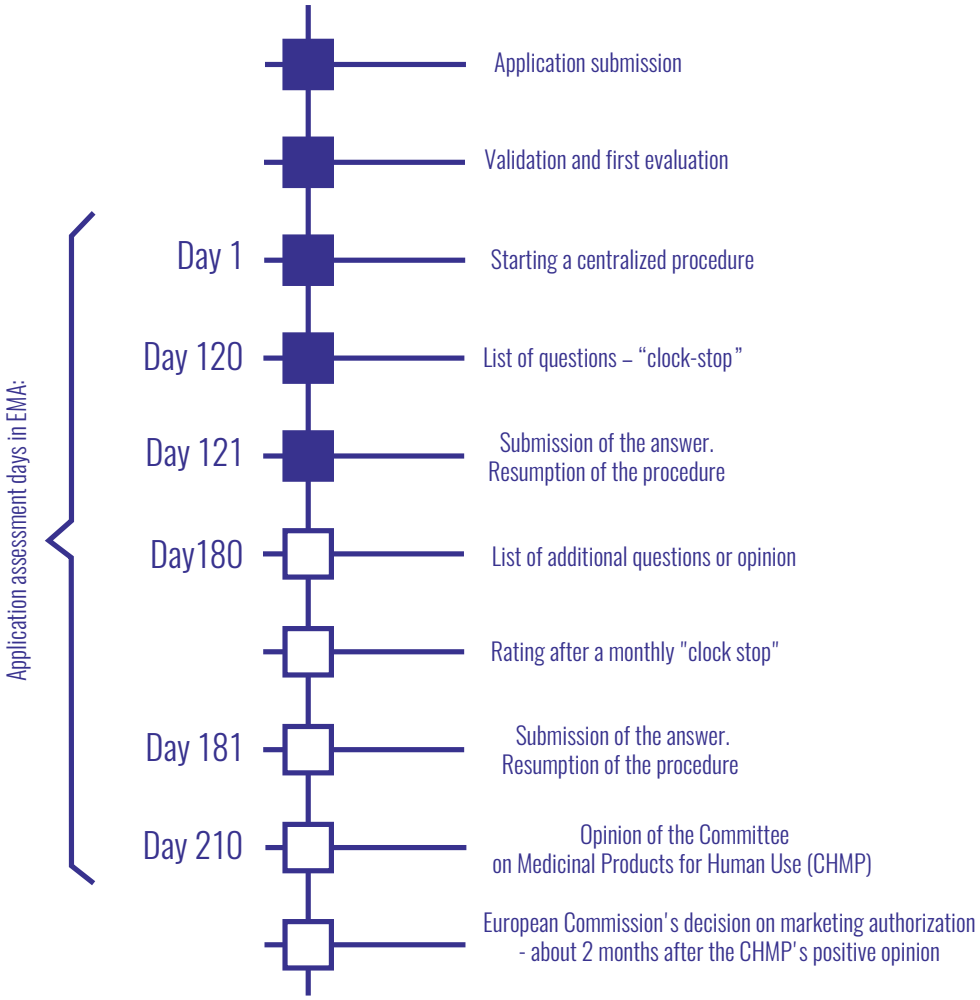
The graphs below show in detail the already completed stages of development of projects underway.



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.

In accordance with the EMA regulations, the application assessment procedure is divided into the following stages:



Mabion is currently at stage of Day 121. 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.

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[1]).

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.

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

It has been agreed that a Type 3 BPD meeting is required, for which a complete set of clinical data for the US market is necessary, before a dossier can be submitted. This requires a bridging test and additional analytical tests. The Company has been admitted to parallel stages of the consultation process, the aim of which is to specify the requirements of the FDA, also in non-clinical areas, e.g. analytical area. 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.

As at the date of publication of this report, the Company is in the process of developing a bridge clinical trial protocol based on the existing arrangements with the FDA. The protocol is drawn up in cooperation with Parexel – a company conducting clinical trials on behalf of the CRO (Contract Research Organization), having extensive experience in clinical trials of biosimilar drugs, including rituximab. This is a necessary task for further communication and proceedings with the FDA (Type 3 BPD meeting). The aim of the study is to compare European MabThera with the American Rituxan (a bridging study), while using MabionCD20 as a bridging arm. The research will enable to obtain some kind of "bridge" to the results of the comparative study of MabionCD20 and MabThera carried out by the Company.

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 and from EU funds. As far as US partners are concerned, Mabion's priority is Mylan, and depending on the Mylan's decision, Mabion will only be able to consider other partners who may co-finance research and activities leading to the commercialisation of the drug on the US market. Until Mylan has made a decision on this (which should take place 30 days after the final minutes of the FDA type 3 meeting are issued), the Company may not make any commitments to other partners. The Company is also considering the possibility of obtaining financial resources for research from European Union funds; however, as at the date of publication of this report, the potential scope of financing or the date of conclusion of a potential co-financing agreement are not known.

In August 2018, the Company received permission from the European Medicines Agency to submit a second registration application ("duplicate application") for a medicine under the working name of MabionCD20. The duplicate application is for the Company to 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 could accelerate the commercialisation of the medicine under the working name of MabionCD20 in markets where RA is still protected by the patent for MabThera.

On 6 May 2019, the Company received from the partner a confirmation of correct submission of the duplicate registration application in consideration with the EMA. Currently, the Company is awaiting information on the results of validation of the application.

The positive results of the study, about which the Company has informed in current and periodic reports so far and the EMA's consent to submit a duplicate registration application do not guarantee the approval of the product by the European Medicines Agency.

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

- work related to the determination of the process space for the manufacturing process was completed;
- the sensitivity of biological analytical methods has been confirmed;
- the scope of the bioequivalence and biosimilarity study has been extended;
- MabionCD20 was continuously tested for stability;
- the range of MabionCD20 and reference drug degradation studies has been extended;
- responses were developed and submitted as part of the ongoing registration process with the European Medicines Agency,
- work related to the extension of manufacturing process scale for MabionCD20 was conducted.

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 quarter of 2019 the Company conducted preparations for the pre-clinical trial, including, among others, toxicological examination on animals.

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. In 2018,as a result of the project's work, the analytical and experimental critical functions of the technology were confirmed.

Within the scope of the above project, in the first quarter of 2019 the Company conducted activities related to:

- analysis of the critical attributes of protein;
- verification of the genetic construct;
- development of analytical methods for characterising the protein obtained;
- optimisation of the conditions for introducing the vector into host cells.

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 of detail, 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 partially cover the estimated demand from customers in the European Union (the supply of the medicine will cover the first sale). A necessary stage in the Company's development is to retrofit 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, the Company undertook to incur investment expenditures within the Zone 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 the amount of at least PLN 20 million by 31 December 2019. An application for extending the deadline for disbursement of these funds is planned to be submitted. The investment is scheduled to be completed by 31 December 2021.

As at 31 March 2019, on account of permit No. 301, the Company incurred expenditures 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. In 2018, the Company also received a decision of the Pabianice District Governor to approve the construction design and grant a building permit for the above mentioned investment "Centrum Naukowo - Technologiczne zaawansowanej biotechnologii medycznych Mabion S.A." along 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 (implementation 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.), as well as formal opportunities to enter non-European markets (signed distribution agreements, formal consent of regulatory authorities, 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 20 March 2019, an audit was carried out on the implementation by the Company of the condition of permit No. 203 of 12 April 2012 to operate in the Łódź Special Economic Zone (ŁSEZ) concerning the completion, by 31 December 2018, of the construction of a new manufacturing plant for technologically innovative biotechnological drugs used in targeted therapies for cancer, immune system disorders and metabolic diseases within the Łódź Special Economic Zone - Łódź Subzone, Complex 1. On the basis of the audit activities, it was concluded that the condition was met. The Company incurred investment expenditures in the total amount of approximately PLN 74.6 million, of which PLN 45 million are eligible investment costs. The Company informed about the event in current report no. 5/2019 of 20 March 2019. About obtaining the abovementioned permit the Company informed the current report no. 10/2012 of 16 April 2012, and about the fulfilment of previous conditions of the permit – in current report no. 5/2017 of 11 January 2017.

On 1 April 2019, the Company received a letter from the Turkish Ministry of Health concerning the issue of compliance of the Scientific-Industrial Complex for Medical Biotechnology of the Company in Konstantynów Łódzki with the requirements of Good Manufacturing Practice (GMP) recognised in the territory of Turkey. The letter was issued as a result of an inspection carried out in the Complex in February 2019. According to the letter, no critical non-conformities were found during the inspection. The remaining identified deficiencies are few and, in the Company's opinion, easy to correct, and the Company has therefore positively assessed the completed inspection and the nature of the received comments. A positive verification of the GMP system with regard to Turkish requirements is necessary for the submission of a dossier in that country, and forms the first milestone in this respect. Turkey has its own independent regulatory system, so European certification does not ensure GMP status in that country. The Company is in contact with the Turkish regulator in order to continue the proceedings aimed at submitting registration documentation for the drug MabionCD20 in the territory of Turkey. The Company informed about the event in current report no. 6/2019 of 1 April 2019.

On 3 April 2019, the Management Board of Mabion S.A., as a result of the annual update of the development strategy for medicinal products, adopted a resolution approving the changes in this 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 planned for 2019, and partnership projects. Detailed information on the strategy update is presented in point 3.1. of this report. The Company informed about the event in current report no. 8/2019 of 3 April 2019.

On 24 April 2019, the Company submitted answers to questions from the European Medicines Agency (EMA) received as part of the Day 120 stage of the registration procedure for MabionCD20 in the EMA. The submission of the answers to the EMA questions (Day 121) allows the Agency to continue the assessment of the application. However, it does not guarantee that the product will be approved by the European Medicines Agency. The Company informed about the event in its current report no. 10/2019 of 24 April 2019.

On 6 May 2019, the Company received confirmation from a partner that the second registration application ("duplicate application") for the medicine under the working name of MabionCD20, had been correctly submitted to the EMA. If the registration procedure is completed successfully, the duplicate application will enable the Company to obtain an additional trade name for the medicine for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). In the Company's opinion, this measure may accelerate the commercialization of the drug under the working name of MabionCD20 on markets where RA is still protected by the patent for MabThera. The Company informed about the event in current report no. 13/2019 of 6 May 2019.

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

In the first 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

- 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);
- personnel costs including the increase in the number of employees and general administrative costs of the Company;
- debt service costs;
- foreign exchange differences resulting from changes in foreign exchange rates;
- 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 be affected by possible delays in talks or unforeseen deviations from the schedules of contracts already signed.

3.5 Transactions with related parties

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

In the first 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 first 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 Q1 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 first quarter of 2019, the Company's activity was comparable to the previous periods.

In 2018, the Company made a declaration on termination of the lease agreement for the office, service and warehouse space at ul. Fabryczna 17 in Łódź to the company from which it leases the aforementioned premises. The declaration on termination of the lease agreement was made with effect as of 1 November 2018 with 6 months' notice effective as of the end of a calendar month. At the same time, Mabion S.A. expressed its willingness to extend the notice period so that the lease agreement would be terminated on 31 December 2019. On 20 February 2019, the parties reached an agreement under which they extended the aforementioned period of notice for the lease agreement until 31 December 2019. The premises house a research and development laboratory for biotechnological medicinal products.

On 28 March 2019, the Company obtained information from the Polish Agency for Enterprise Development (PARP) on the adoption of the Company's report on the dissemination of industrial research results in the project entitled " An innovative double cutting technology for obtaining modern analogues of the human insulin hormone". The report has been accepted, thus meeting the condition for granting a bonus for broad dissemination of results, in accordance with the provisions of the agreement on co-financing of the project in question (agreement of 2 February 2012). The project was implemented by the Company in the years 2011-2016. In 2015, the Company submitted an application to PARP for early completion of the project. The technology developed as part of the project was used to obtain an exemplary prototype of an insulin analogue, but it was not possible to develop an appropriate formulation, i.e. a solution in which the drug would be stable over a longer period of time, long enough for a pharmaceutical product. In 2016, the Company received from PARP a letter informing about the acceptance of the report on the implementation of industrial research and development work together with economic analysis and market research concerning the implementation of the project. At the same time, it was stated that it was not advisable to implement the results obtained under the co-financing agreement. In connection with the above, the Company was exempted from the necessity to implement the results of industrial research or development work in the form, scope and time specified in the

application for co-financing. During the project duration period (3 years from the project completion date – i.e. until 7 March 2019), the Company was obliged to disseminate the results of the related industrial research. The said work (dissemination of results by means of open source software) was carried out by the Company and reported to PARP. The letter received on 28 March 2019 confirms the correctness of the work and the final settlement of the project with regard to its merit.

There is no other information available that would be significant for the assessment of the personnel, property, financial and financial standing, financial result and their changes as well as information that would be significant for the assessment of the ability of Mabion S.A. to meet its obligations.

5 Contact details

Name (business name):	Mabion Spółka Akcyjna
Headquarters:	Konstantynów Łódzki
Address:	ul. gen. Mariana Langiewicza 60 95-050 Konstantynów Łódzki
Telephone numbers:	tel. +48 42 207 78 90
E-mail address:	info@mabion.eu
Website address:	www.mabion.eu

Management Board of the Company

Artur Chabowski	Sławomir Jaros	Grzegorz Grabowicz	Jarosław Walczak
President of the Management Board	Member of the Management Board	Member of the Management Board	Member of the Management Board

Konstantynów Łódzki, 16 May 2019