

Other information to the quarterly report of Mabion S.A. for 2018 Q3

Konstantynów Łódzki, 15 November 2018

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Other information to the quarterly report of Mabion S.A. for 2018 Q3

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1 Selected financial data

The selected balance-sheet items presented in EUR have been translated at the average EUR exchange rate announced by the National Bank of Poland for 30 September 2018 (PLN/EUR 4.2714) and 31 December 2017 (PLN/EUR 4.1709). The selected items of the profit and loss account and the cash flow statement have been translated into EUR at the exchange rate being the arithmetical mean of average EUR exchange rates announced by the National Bank of Poland and applicable as at the last day of each month in the period of the last 9 months ending 30 September 2018 and 9 months ending 30 September 2017 (respectively: PLN/EUR 4.2566 and PLN/EUR 4.2535).).

SELECTED FINANCIAL DATA	in thousands of PLN		in thousands of EUR	
	from 01.01.2018 to 30.09.2018	from 01.01.2017 to 30.09.2017	from 01.01.2018 to 30.09.2018	from 01.01.2017 to 30.09.2017
Net revenues from sales of products, commodities and materials	0	0	0	0
Profit (loss) on operating activities	-48,693	-42,209	-11,448	-9,916
Gross profit (loss)	-52,286	-38,600	-12,293	-9,068
Net profit (loss)	-52,286	-38,600	-12,293	-9,068
Net cash flows from operating activities	-32,726	-44,517	-7,694	-10,458
Net cash flows from investing activities	-3,608	-5,371	-848	-1,262
Net cash flows from financing activities	103,286	37,418	24,283	8,790
Net cash flows in total	66,952	-12,471	15,741	-2,930
	30.09.2018	31.12.2017	30.09.2018	31.12.2017
Assets, in total	154,261	82,445	36,115	19,767
Liabilities and provisions for liabilities	96,252	136,603	22,534	32,751
Long-term liabilities	32,881	16,233	7,698	3,892
Short-term liabilities	63,371	120,370	14,836	28,859
Equity	58,009	-54,158	13,581	-12,985
Share capital	1,372	1,180	321	283
Number of shares (in pcs)	13,720,772	11,800,000	13,720,772	11,800,000
Profit (loss) on one ordinary share (in PLN/EUR)	-3.81	-3.27	-0.90	-0.77

2 About Mabion S.A.

2.1 Company's bodies

2.1.1 Management Board

In the reporting period and until the day of submission of this report, the composition of the Company's Management Board did not change and as at 15 November 2018 the Company's Management Board is comprised of 3 members:

- » Artur Chabowski - President of the Management Board,
- » Sławomir Jaros - Member of the Management Board,
- » Jarosław Walczak - Member of the Management Board.

2.1.2 Supervisory Board

In the reporting period and until the day of submission of this report, the composition of the Company's Supervisory Board did not change and as at 15 November 2018 the Company's Supervisory Board is comprised 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 Share capital structure

As at 30 September 2018 and as at the day of submission of this report, the share capital of the Company totals PLN 1,372,077.20 and is divided into 13,720,772 shares, each having a par value of PLN 0.10, 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,
- » 1,405,999 ordinary bearer and 514,773 ordinary registered P shares.

Registered A, B, C, E, F, and G shares are preference shares, as each of them carries the right to cast two votes at the General Meeting. The total number of votes resulting from all issued shares is 15,290,772.

2.3 Shareholders' structure

To the best knowledge of the Management Board, as at the day of submission of the report for 2018 Q3 (15 November 2018), the following shareholders hold at least 5% in the general number of votes at the Company's General Meeting:

No.	Shareholder	Number of shares	Number of votes	Share 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*:	1,624,876	2,117,726	11.84%	13.85%
	Glatton Sp. z o.o.	1,004,526	1,004,526	7.32%	6.57%
	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.	Other	4,781,258	4,781,258	34.85%	31.27%
	In total	13,720,772	15,290,772	100%	100%

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

** In accordance with the list of shareholders presented at the General Meeting of Mabion S.A. on 28.06.2018.

In the period from the submission of the previous interim report, i.e. from 13 September 2018 until the day of publication of this report, no changes occurred in the ownership structure of qualified holdings of the Issuer.

2.4 Shareholdings of managing and supervising persons

	Shares held as at the day of submission of the report for 2018 Q3 (15 November 2018)
Management Board	
Artur Chabowski	indirectly, through FL Real Investments Holding Limited with its registered office in Nicosia (Cyprus), in which Artur Chabowski holds a 100% share in the share capital, he holds 24,034 shares of the Company in total, each having a par value of PLN 0.10, constituting together 0.18% of the Company's share capital and representing 0.16% of votes at the General Meeting.
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds a 100% share in the share capital) and Celon Pharma S.A. (in which he holds a 66.67% share in the share capital), he holds 1,624,876 shares of the Company in total, each having a par value of PLN 0.10, constituting together 11.84% of the Company's share capital and representing 13.85% of votes at the General Meeting.

In the period from the day of submission of the previous interim report, i.e. report for 2018 H1, published on 13 September 2018, no changes occurred in the shareholding structure of the Company’s managing and supervising persons listed above.

Other managing and supervising persons of the Company did not hold shares in the period from the day of submission of the Company’s report for 2018 H1 to the submission of the present report. Members of the Management Board and the Supervisory Board of Mabion S.A. do not have any rights to the Company’s shares.

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 Activities of Mabion S.A.

3.1 Implementation of the Company’s development strategy

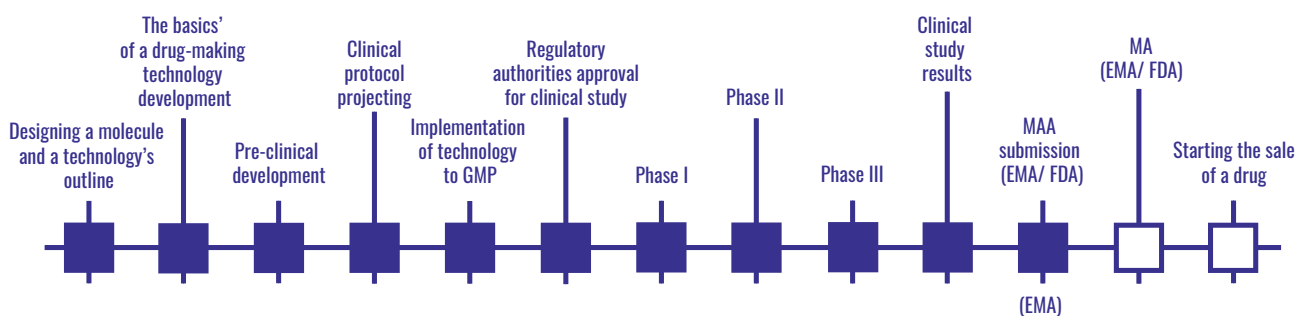
The basic goal of Mabion’s activity is development, production, and marketing of medicines which are biosimilar to original biotechnological medicines (so-called reference medicines) present on the market, as well as innovative medicines.

On 30 March 2017, the Company’s Management Board adopted a resolution on the development plan for medicinal products. The plan was developed as a result of completion of an internal analytical project which took account of nearly 50 possible medicines – candidates for development in the Company, with account taken, among other things, of expiry dates of the patents for reference medicines, the existing and projected size of the reference medicine market, medicine production technology of the Company, competences of the team, experience related to MabionCD20 and competition in the field of biosimilar medicines.

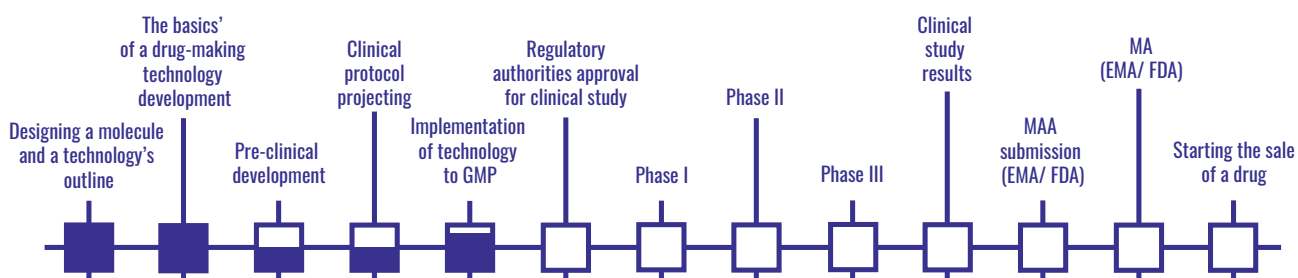
Each year, the Company updates the development plan for medicinal products, with a view to possible adjustments. In 2018, no significant changes were made in the development plan as part of the review. Another such update will take place in 2019.

The table below presents in detail the already completed development stages of ongoing projects.

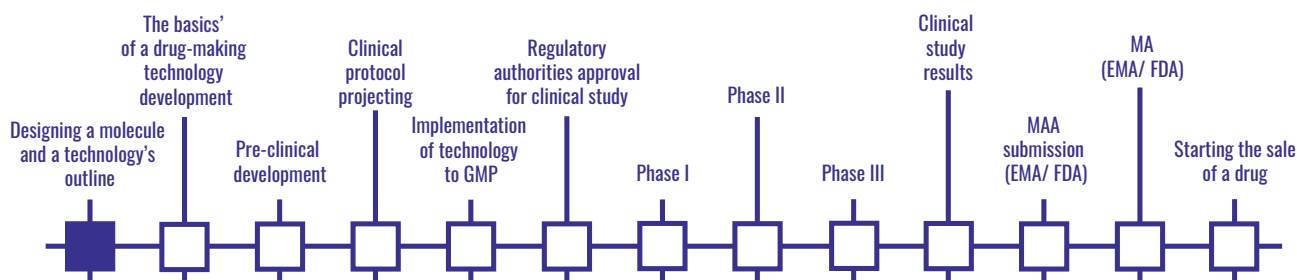
MabionCD20



MabionMS



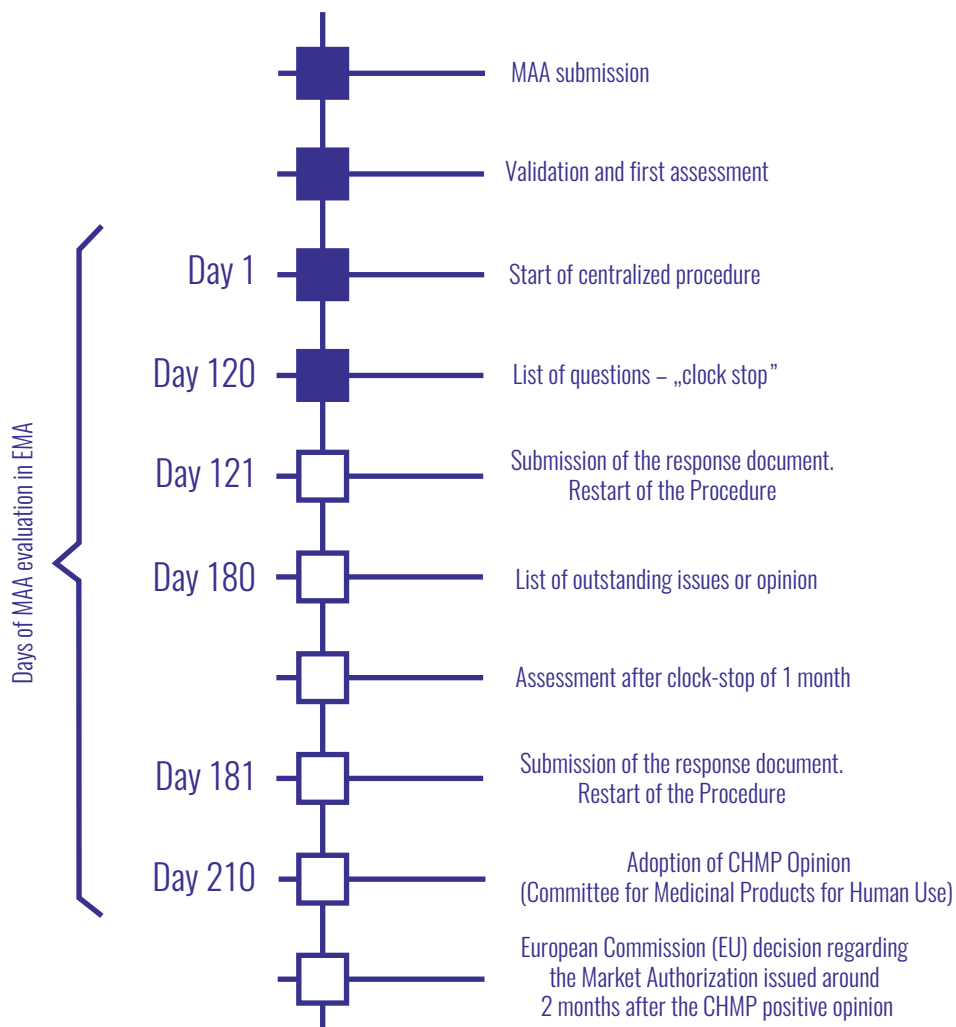
MabionEGFR



In the scope of the MabionVEGF project, the Company completed the agreed tasks and the project is currently transferred to the ordering party.

The priority and most advanced project of the Company is introduction of MabionCD20 on the highest possible number of regional markets. On 1 June 2018, the Company submitted a marketing authorisation application (MAA) to the European Medicines Agency with regard to the market regulated by EMA for the medicine code-named “MabionCD20” (Current Report no. 36/2018 of 1 June 2018). On 21 June 2018, the Company’s Management Board received information on the positive completion of validation of the said application and on referring it as a result to the evaluation procedure (Current Report no. 46/2018 of 21 June 2018).

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



Currently, Mabion is at the stage of Day 120 and work related to development of replies to questions is ongoing.

On 27 June 2018, the Company received a summary from the American Food and Drug Administration (FDA) after the BPD meeting (Biosimilar Biological Product Development) of Type 2 (Current Report no. 50/2018 of 28 June 2018). The meeting was aimed at a preliminary, general presentation of data gathered by the Company in the course of development of MabionCD20 in relation to the reference medicine, MabThera, as well as at determining basic issues related to the possible establishment of cooperation with the Agency on the basis of these data in order to obtain registration of MabionCD20 in the USA. In accordance with the received summary, the Agency provided for the possibility of using the data owned by the Company to support the application process. At the same time, the Agency proposed a general strategy of linking the product registered in the European Union (Mabthera) with a market-authorized product in the USA (Rituxan). The Agency did not indicate the necessity for an entirely separate development process for MabionCD20 for the American market. The Company has been qualified to further stages of the consultation process aimed at specification of the FDA's requirements. The process of registration and marketing authorisation of MabionCD20 in the territory of the USA is a multi-stage process and one cannot exclude that additional requirements connected with the product approval by the FDA will occur in the future.

As at the day of publication of this report, the Company maintains ongoing relations with the FDA, conducting working consultations with the regulatory authority in the scope of the bridge clinical trial.

As regards the project of innovative therapy MabionMS, up to date the Company has reported submitting two patent applications in this therapeutic area. On 5 December 2017, Mabion submitted to the Patent Office of the Republic of Poland an European patent application with a possibility of extension under the PCT procedure, based on which the Company applies for legal protection for its invention "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand". The subject matter of the submitted patent application is an innovative therapy for multiple sclerosis sufferers using MabionCD20 antibody combined with other substances (Current Report no. 56/2017 of 5 December 2017).

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On 26 October 2018, the Company submitted another patent application to the Patent Office of the Republic of Poland, with a possibility of extension under the PCT procedure, concerning the area of application of MabionCD20 in treatment of patients with MS, "Low aggregate anti CD20 ligand formulation". It is the second patent application related to the use of MabionCD20 in treatment of multiple sclerosis, constituting an innovative indication for the molecule. The application in consideration concerns application of MabionCD20 as a monotherapy (Current Report no. 59/2017 of 26 October 2018). Currently the Company conducts substantive work connected with the development of the above mentioned therapy.

In the reporting period, the Company continued cooperation with Plexus Ventures LLC – an experienced adviser supporting the Company in the scope of business development. Plexus pursues activities aimed at prospecting partners able to effectively sell medicines from the above mentioned Mabion's pipeline. This is a complex and lengthy process – it consists in consulting with companies, entering into confidentiality agreements and presenting data of different levels of detail, depending on the advancement of the process. Concurrently, the companies update their offers.

In 2017, the Company launched preparatory work connected with the extension of the existing plant (MABION II), aimed at increasing the production and research and development capacity of the Company. An extension concept for the Scientific and Industrial Complex of Medical Biotechnology was developed, and work was launched to select the architectural studio, together with administrative activities aimed at obtaining necessary official authorisations.

In February 2018, the Company's Management Board selected an international consortium of architectural and technology companies, to which it entrusted development of the technological and construction design. When selecting the contractor, apart from commercial issues, the offers were assessed in terms of technological knowledge potential of the offeror, experience in administrative procedures and knowledge and references in the scope of architectural and construction projects. It is one of the first elements in the implementation of the complex MABION II project, which as a target will be carried out as part of project or projects co-financed by EU funds and own resources. In addition, the project will be covered by another zonal permit.

In July 2018, the first stage of the extension project related to the existing plant was completed – namely the conceptual and technological design. Since July 2018, work has been ongoing on the construction design and working designs for all industries related to the investment.

In September 2018, an application was submitted for the construction permit with the planned date for obtaining a legally binding document in November 2018. On 14 November 2018, the Company received a decision on the approval of the construction project and the award of the construction permit for the building and necessary infrastructure (Current Report no. 60/2018 of 15 November 2018). The investment plans of the Company may be extended in the future in relation to the investment covered by the existing permit, and therefore it is possible that the Company will apply for another permit.

Planned extension of the existing Mabion's plant – a visualisation.



3.2 Description of achievements and failures of the Company in 2018 Q3 and after the balance-sheet date

On 17 July 2018, the Company entered into an agreement with Bank Zachodni WBK S.A. (currently: Santander Bank Polska S.A.) on revolving loan to finance the operating activities of the Company, for a period of two years as of the execution of the agreement. The amount of awarded Loan is PLN 30 million, whereas disbursement of the Loan in an amount of PLN 15 million is possible as of 18 October 2018, i.e. from the moment when formal and legal conditions are met and collaterals are established. Disbursement of the Loan in an amount exceeding PLN 15 million may take place after the Company obtains a positive decision of the European Medicines Agency as regards the registration of MabionCD20. Until the day of publication of this report, the Issuer did not use the awarded Loan. The Loan bears interest based on a floating interest rate and WIBOR 1M increased by the Bank's arm's length margin. The Loan is secured with the following collaterals: contractual mortgage entered as item one on the land and mortgage register, up to the highest amount of PLN 45 million, established on the ownership right of the Company to the real property in Konstancin-Jeziorna, and assignment of receivables in favour of the Bank under the insurance agreement related to buildings/structures located on that real property, a statement of submission to enforcement in the form of a notary deed, in line with the procedure provided for in Article 777 § 1 (5) of the Code of Civil Procedure, each time up to the amount constituting 150% of the Loan amount, as well as sureties and other collaterals provided by related entities of the Company (main shareholders of the Company). The Agreement provides for numerous obligations of the Company towards the Bank as well as events constituting a breach of the agreement, resulting, inter alia, in its possible termination by the Bank. This information was published in Current Report no. 55/2018 of 17 July 2018.

10 In 6 August 2018, the Company received from the European Medicines Agency (EMA) a consent for submission of the second registration application ("Duplicate Application") for a medicine code-named MabionCD20. The Duplicate Application is aimed at obtaining an additional trade name, for which the list of indications for the product will be limited and will exclude rheumatoid arthritis (RA). This action may accelerate the commercialisation of the medicine code-named MabionCD20 on the markets where RA is still covered by patent protection for Mabthera. At the same time, the Company informed that the above mentioned consent of EMA is only a preliminary confirmation of the possibility of registering the medicine and does not guarantee a success of this process. The Company also reserved the possibility of resigning from the submission of the second registration application depending on the final assessment of possible business benefits for the Company. Until the day of publication of this report, the Company did not take the final decision as regards the submission of the second registration application. This information was published in Current Report no. 56/2018 of 6 July 2018.

On 27 August 2018, the Company took notice of the payment of USD 5 million made by Mylan Ireland for achieving the milestone defined in the agreement of mutual cooperation, consisting in the acceptance of registration documents for MabionCD20 by EMA. In accordance with the cooperation agreement, apart from the above mentioned payment, the Company, after reaching further milestones, shall receive further payments of USD 30 million in total. The milestones currently pending, conditioning future payments are: approval of the market authorisation for MabionCD20 and progress in its commercialisation. This information was published in Current Report no. 58/2018 of 27 August 2018.

On 26 October 2018 (an event after the balance-sheet date), the Company submitted a patent application to the Patent Office of the Republic of Poland, with a possibility of extension under the PCT procedure, from the area of application of MabionCD20 in treatment of multiple sclerosis sufferers, "Low aggregate anti CD20 ligand formulation". It is the second patent application related to the use of MabionCD20 in treatment of multiple sclerosis, constituting an innovative indication for the molecule. The application in consideration concerns application of MabionCD20 as a monotherapy. This information was published in Current Report no. 59/2018 of 26 October 2018. The first patent application in this therapeutic area was submitted by Mabion on 5 December 2017 (Current Report no. 56/2017). Submitting the application does not mean a guarantee that patent protection will be granted.

On 14 November 2018 (an event after the balance-sheet date), the Company received a decision of the District Head of Pabianice on the approval of the construction design and the award of the construction permit for the building as part of the investment "Scientific and Technological Centre for Advanced Medical Biotechnology of Mabion S.A." along with necessary infrastructure in Konstancin-Jeziorna. The award of the construction permit makes it possible to commence work on the extension of the existing plant of the Scientific and Industrial Complex of Medical Biotechnology of the Issuer, which will result in a significant

increase of production and research and development capacity of the Company. The Scientific and Technological Centre will develop and prepare for commercialisation latest-generation biotechnological medicines: monoclonal antibodies. The investment plans of the Company may be extended in the future in relation to the investment covered by the existing permit, and therefore it is possible that the Company will apply for another permit in the future. This information was published in Current Report no. 60/2018 of 14 October 2018.

3.3 Indication of factors and events, including those of extraordinary nature, having significant impact on the condensed financial statements

In 2018 Q3, no factors and events occurred other than those indicated in other items of the report, including factors and events of extraordinary nature, which would have a significant impact on the condensed financial statements of the Company.

3.4 Factors which will influence results achieved in a horizon of at least the next quarter

Main factors which will influence the Company's results in the next quarter include:

- » costs of conducted research and development work related to MabionCD20 and other medicines in the Company's pipeline;
- » Company's general management costs;
- » debt servicing costs;
- » exchange rate differences resulting from fluctuations in exchange rates of foreign currencies;
- » revenues from aid granted from EU funds;
- » revenues from expected fees from distribution partners for MabionCD20.

Possible delays in talks conducted or unexpected divergences from schedules of implementation of already executed agreements may influence the amount of revenues.

3.5 Transactions with related entities

In 2018 Q3, the Company did not enter into transactions with any related entities on conditions other than arm's length.

3.6 Granted sureties and guarantees

In 2018 Q3 the Company did not grant any sureties for loans or borrowings, or guarantees to a single entity or a subsidiary of that entity, where the total amount of existing sureties and guarantees would be significant for the Company.

3.7 Proceedings pending before court, authority competent for arbitration, or public administration body

In 2018 Q3, there were no significant court, administrative, or arbitration proceedings pending before court, authority competent for arbitration, or public administration body, related to the liabilities and receivables of the Company.

3.8 Management Board's position as regards the possibility of attaining previously published forecast results

The Company's Management Board took a decision on revoking the financial forecasts published in 2010 (drawn up in relation to applying for floating I Shares in an alternative trading system) and on abandoning the practice consisting in providing forecast financial results.

4 Other information significant for the assessment of the Company's situation

In 2018 Q3, the activities of the Company were comparable to previous periods.

On 31 October 2018, the Company submitted a statement of termination of the agreement on the lease of office, service, and warehouse space at ul. Fabryczna 17 in Łódź of 17 August 2015 to Fabryczna 17 SPP Sp. z o.o. S.K.A. – the company being the

lessor of the said premises. The statement of termination of the lease agreement was submitted effective as at 1 November 2018 with a 6-month period of notice effective as at the end of the calendar month. At the same time, Mabion expressed its intent to extend the period of notice in such a way so that the lease agreement would terminate on 31 December 2019. The premises housed a research and development laboratory for biotechnological medicinal products. The lease agreement was terminated due to the fact of extension of the scientific and industrial complex of biotechnology in Konstantynów Łódzki at ul. Langiewicza 60. Considering the above, the Company decided that lease of the space at ul. Fabrycznej 17 in Łódź until the end of October 2020, in accordance with the applicable lease agreement, would not be economically justified.

No other information occur which would be significant for the assessment of the situation in the area of human resources, property, or financial situation, financial results and changes thereof, or information important for the assessment of the possibility of fulfilling liabilities by Mabion.

5 Contact data

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Website www.mabion.eu

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Management Board of the Company

Konstantynów Łódzki, 15 November 2018



Artur Chabowski

President of the Management Board



Sławomir Jaros

Member of the Management Board



Jarosław Walczak

Member of the Management Board

