

Mabion S.A. Directors' Report for H1 year 2018

Konstantynów Łódzki, 13th September 2018

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MABION S.A. Directors' Report for H1 year 2018

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1 Selected financial data

	PLN thousands		EURO thousands	
	January 1, 2018 – June 30, 2018	January 1, 2017 – June 30, 2017	January 1, 2018 – June 30, 2018	January 1, 2017 – June 30, 2017
Net sales of finished goods, goods for resale and materials	0	0	0	0
Operating profit/(loss)	-36 889	-29 026	-8 701	-6 834
Profit/(Loss) before tax	-41 182	-25 369	-9 714	-5 973
Net profit/(loss)	-41 182	-25 369	-9 714	-5 973
Weighted average number of shares (not in thousands)	12 447 332	11 800 000	12 447 332	11 800 000
Earnings (loss) per one ordinary share (in PLN/EUR)	-3,31	-2,15	-0,78	-0,51
Diluted earnings (loss) per one ordinary share (in PLN/EUR)	-3,31	-2,15	-0,78	-0,51
Net cash from operating activities	-34 214	-26 703	-8 070	-6 287
Net cash from investing activities	-2 362	-1 728	-557	-407
Net cash from financing activities	103 635	38 624	24 445	9 094
Net increase/(decrease) in cash and cash equivalents	67 059	10 193	15 818	2 400
	June 30, 2018	December 31, 2017	June 30, 2018	December 31, 2017
Total assets	171 073	82 445	39 223	19 767
Liabilities and provisions for liabilities	101 960	136 603	23 377	32 751
Long-term liabilities	33 562	16 233	7 695	3 892
Short-term liabilities	68 398	120 370	15 682	28 859
Equity	69 113	-54 158	15 846	-12 985
Share capital	1 372	1 180	315	283
Number of shares (not in thousands)	13 720 772	11 800 000	13 720 772	11 800 000
Book value per share (in PLN/EUR)*	13.93	6.99	3.19	1.68
Diluted book value per share (in PLN/EUR)	13.93	6.99	3.19	1.68
Declared or paid dividend per share (in PLN/EUR)	0,00	0,00	0,00	0,00

The selected balance sheet items presented in EUR were converted at the average EUR exchange rate published by the National Bank of Poland as of June 30, 2018 (4.3616 PLN/EUR) and as of December 31, 2017 (PLN 4.1709/EUR). The selected of the income statement and the cash flow statement were converted into EUR at the arithmetical average of the EUR exchange rates published by the National Bank of Poland prevailing as at the last day of each month during the six months ended June 30, 2018 and the six months ended June 30, 2017 (4.2395 PLN/EUR and 4.2474 PLN/EUR, respectively).

2. INFORMATION ABOUT MABION S.A.

2.1 Composition of the Management Board and the Supervisory Board

In the financial year and until the date of submitting this report, the Management Board of the Company comprised:

- » Artur Chabowski – Chairman of the Board,
- » Sławomir Jaros – Board Member,
- » Jarosław Walczak – Board Member.

In the reporting period, the composition of the Company's Supervisory Board changed.

On January 1, 2018 the Board consisted of the following members:

- » Robert Aleksandrowicz – Chairman of the Supervisory Board,
- » Maciej Wieczorek – Deputy Chairman of the Supervisory Board,
- » Grzegorz Stefański – 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,
- » Artur Olech – Independent Member of the Supervisory Board.

On June 27, 2018 the Company received a resignation from Robert Aleksandrowicz and Grzegorz Stefański - Members of the Supervisory Board and on June 28, 2018 from Artur Olech (document dated June 27, 2018)

On June 28, 2018 the Annual General Meeting passed a resolution on appointing the following members of the Supervisory Board:

- » Krzysztof Kaczmarczyk,
- » Dirk Kreder,
- » Józef Banach.

After the changes referred to above, from June 28, 2018 to the date of submission of this report, the composition of the Supervisory Board was as follows:

- » Maciej Wieczorek – Chairman of the Supervisory Board,
- » Józef Banach - Deputy Chairman 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 Entities covered by consolidation

Mabion S.A. does not hold any shares in any other entities. There are no circumstances which could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1. 4 of the Commercial Companies Code. In the first half of 2018 Mabion was not part of a Group and did not prepare consolidated financial statements.

3. OPERATIONS OF MABION S.A.

3.1 The Company's business

Mabion concentrates on conducting research and development projects enabling the introduction of the newest generation of biotechnological drugs, including biosimilar drugs, which can be developed thanks to the achievements of the contemporary genetic engineering. The strategic goal of the Company is development, production and sale of the drugs that will be used in cancer therapies as well as autoimmune and metabolic treatments.

Mabion's most developed product is a drug biosimilar to MabThera/ Rituxan (Roche), called MabionCD20. On June 1, 2018 the Company filed the marketing authorization application (MAA) with the European Medicines Agency (EMA); on June 21, 2018 the information about the positive result of the drug validation was received and, therefore, the drug was taken to assessment. In accordance with the strategy of the development for medicinal products adopted in 2017, the Company is conducting currently research on the following drugs:

PROJECT	REFERENCE DRUG	REGULATORY CATEGORY
CLINICAL AREA		
PROJECTS in PRE-REGISTRATION PHASE		
MabionCD20		mAB biosimilar
PROJECTS CURRENTLY CONDUCTED		
MabionEGFR		mAB biosimilar
MabionMS		mAB
MabionVEGF_Fab*		Fab biosimilar
PLANNED PROJECTS		
MabionHER2_ADC		mAB biosimilar
MabionAI2		mAB biosimilar
MabionAI3		mAB biosimilar
MabionTR		mAB biosimilar
MabionON4		mAB biosimilar
MabionON5		mAB biosimilar
MabionInAI4		mAB biosimilar
CONTINGENT PROJECTS		
MabionHER2		mAB biosimilar



Immunology



Oncology



Ophthalmology



Tissue metabolism



Neurology

* Stage of joint development with partner.

3.2 Summary of Mabion S.A.'s activities in the first half of 2018 and until the date of publication of the report

On January 5, 2018, the Company's Management Board received information on the initial results of the assessment of the results of the clinical trial conducted in patients treated with MabionCD20 in the indication of non-Hodgkin's lymphomas (NHL) in respect of two primary pharmacokinetic endpoints, from the external company contracted to perform the assessment. The initial results indicated that the assumed bioequivalence criteria were met. This information was published in Current Report No. 2/2018 on January 5, 2018.

On January 10, 2018, the Management Board received initially processed data on the effectiveness of the treatment and the overall safety profile of MabionCD20 in the indication of non-Hodgkin's lymphomas (NHL) from an external company (secondary endpoints). Based on the data relating to the efficacy of the therapy, the Management Board assessed the patients' response to the treatment in both groups (treated with MabionCD20 and with MabThera) as comparable. In the Company's opinion, MabionCD20 met the requirements of the overall safety profile. The Management Board emphasized that due to the relatively small population of patients participating in the trial compared with the MabionCD20 RA trial, the assessment had not been based on statistical inference. The assessment was based on descriptive statistics. This means that the final assessment of the reported results will be made by the European Medicines Agency (EMA) and may differ from the Company's assessment. Research reports in their final versions were used in the marketing authorization application (MAA) which the Company filed with the EMA in June 2018. This information was published in Current Report No. 3/2018 on January 10, 2018.

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On January 11, 2018, the Company's Management Board obtained information that the last visit of the last patient in the follow-up extension study (the so-called long-term follow-up) of patients included in the MabionCD20 NHL trial had taken place. In conclusion, all the patients who participated in the MabionCD20 NHL trial ended a 46-week treatment and follow-up cycle consisting of the basic treatment and the follow-up period which lasted 26 weeks and additional 20 weeks of long-term follow-up. Therefore, the data collection for all endpoints of the research ended. Based on the collected data the Company is to obtain results in respect of the secondary endpoints related to long-term follow-up. This information was published in Current Report No. 4/2018 on January 11, 2018.

On January 15, 2018, the Management Board received initially processed data in respect of the pharmacokinetic secondary endpoints and pharmacodynamics of MabionCD20 in the indication of non-Hodgkin's lymphomas (NHL) from an external company (secondary endpoints). The Management Board assessed the obtained pharmacokinetic parameters in the groups treated with MabionCD20 and MabThera as equivalent. In respect of the pharmacodynamics, in both groups a depletion (removal) of B-cells was noted, the degree of repletion (recreation) of lymphocytes in both groups was similar. The Management Board emphasized that due to the relatively small population of patients participating in the trial compared with the MabionCD20 RA trial, the assessment had not been based on a simplified statistical approach. This means that the final assessment of the reported results will be made by the European Medicines Agency (EMA) and may differ from the Company's assessment. Trial reports in their final versions will be used in the marketing authorization application (MAA) which the Company is planning to file with the EMA. This information was published in Current Report No. 6/2018 on January 15, 2018.

On March 22, 2018, the Company obtained financing in the amount of PLN 174.8 million, in the form of a borrowing agreement, from the Company's shareholder, Twiti Investments Ltd. (the Shareholder). The funds for the borrowing were obtained by the Shareholder from the sale of the Company's 1,920,772 ordinary bearer shares under the private offering referred to below. Originally, the borrowing from the Shareholder was to be repaid by June 30, 2018 by way of a set-off between reciprocal claims: the Company's receivables from the Shareholder's payment for the same number of the Company's newly issued ordinary bearer shares as the number shares sold under private offering that were to be issued by the Company at the same price as the price obtained from the sale of shares under private offering, and the Shareholder's receivables from the repayment of the borrowing from the Shareholder. The borrowing was eventually repaid by the Company in cash on April 23, 2018. This information was published in Current Report No. 26/2018 on April 23, 2018.

On March 22, 2018, Twiti Investments Ltd. concluded the agreement concerning the sale of the Company's 1,920,772 ordinary bearer shares in its possession under private offering to a limited number of selected institutional investors, including from the U.S., pursuant to the exception concerning private placements provided for in Section 4)a)(2) of the U.S. Securities Act of 1933, as amended, and non-U.S. investors based on the exclusion provided for in Regulation S of the U.S. Securities Act. The private offering was carried out in a manner which does not constitute a public offering in the meaning of Article 3 par. 1 of the Act of 29 July 2005 on Public Offering (...) and does not require the preparation or approval of the issue prospectus or information memorandum. The sale of shares took place as block trade transactions at the GPW carried out on March 23, 2018 and settled on March 27, 2018. The price of one share sold by the Shareholder was PLN 91.00. The private offering was addressed mainly at the U.S. institutional investors specializing in healthcare and biotechnology sectors who strengthened and diversified the Company's shareholding structure. The investors who purchased shares from the Shareholder and joined the Company's shareholding structure included, among others, the European Bank for Reconstruction and Development (EBRD) which purchased shares for PLN 61.4 million, and PFR Life Science sp. z o.o. (PFR Life Science), which purchased shares for PLN 38.3 million. Pursuant to framework agreements concluded with PFR Life Science and the EBRD, as long as PFR Life Science or the EBRD hold shares representing more than 1% of the Company's share capital, the EBRD, following consultations with PFR Life Science, will have the right to nominate a candidate to the Company's Supervisory Board, who shall meet the independence criteria stipulated in Annex II to the Commission Recommendation of 15 February 2005 on the role of non-executive or supervisory directors of listed companies and on the committees of the (supervisory) board. Pursuant to the framework agreement concluded with the EBRD, the Company undertook to follow good practices adopted by the EBRD in the scope of environmental and social policy and to comply with the policy for combating fraud. This information was published in Current Report No. 12/2018 on March 23, 2018.

On March 22, 2018, the Company received from the company contracted to analyse the results of the clinical trial with MabionCD20 in RA patients the confirmation that the status of the clinical trial results reported previously by the Company as "initial", following thorough data verification, was changed to "final". Thus the positive assessment of the clinical trial result did not change. The final versions of the report were attached to the marketing authorization application (MAA). The positive trial results do not warrant the approval by the European Medicines Agency (EMA). This information was published in Current Report No. 13/2018 on March 23, 2018.

On April 4, 2018, the Company received information that the Company's application for co-funding of a project entitled "Expansion of the Research and Development Centre of Mabion S.A. – research on a new generation of medicines" submitted in the course of competition 2.1/2/2017 to Measure 2.1: Support for investments in R&D infrastructure of enterprises of the Smart Growth Operational Programme 2014-2020 has been selected for co-financing. The subject of the project is development of the company's R&D facilities by preparing the necessary infrastructure: the Research and Development Centre building and the purchase of research equipment for the purpose of research on innovative medicines. The designated Research and Development Centre will be used to develop the most cutting-edge generation of biotechnological medicines, – monoclonal antibodies – and prepare them for commercialization. The total cost of the Project is estimated at PLN 172.88 million and the recommended value of co-financing is equal to the amount specified in the application, i.e. PLN 63.25 million. This information was published in Current Report No. 22/2018 on April 4, 2018.

On April 18, 2018, the Company's Extraordinary General Meeting (EGM) adopted the resolution on an increase in the Company's share capital from PLN 1,180,000 to the amount of PLN 1,372,077.20 by means of issuing 1,920,772 P-series ordinary bearer shares with a nominal value PLN 0.10 each in the private placement according to Article 431 par. 2 point 1 of the KSH, addressed to Twiti Investments Ltd. The EGM decided to exclude the pre-emptive rights of the existing shareholders with respect to all P-series shares. The issue price of one P-series share was PLN 91.00 per share (total value of the issue: PLN 174.8 million). The Company's Management Board was authorized to apply for admission and introduction of the P-series shares and the rights to P-series shares into trading on the regulated market operated by Giełda Papierów Wartościowych S.A. and to conclude with Krajowy Depozyt Papierów Wartościowych S.A. (Central Securities Depository of Poland) the agreement on the registration in the securities depository of P-series shares as well as to take all and any further necessary measures for their dematerialisation. This information was published in Current Report No. 23/2018 on April 18, 2018.

On April 23, 2018 the Company addressed to Twiti Investments Ltd. an offer to subscribe to the Company's 1,920,772 P-series ordinary bearer shares in the private placement according to Article 431 par. 2 point 1 of the KSH. The Shareholder accepted the offer to subscribe to P-series shares and on April 23, 2018 the P-series Share Subscription Agreement was concluded, under which the Shareholder subscribed to the Company's 1,920,772 P-series ordinary bearer shares with a nominal value of PLN 0.10 per share at the issue price of PLN 91.00 per share (total sale price of P-series shares equaled PLN 174.8 million). The total issue price for P-series shares was paid by the Shareholder in cash on April 23, 2018. The Company intends to use funds obtained from the P-series share issue among others for the expansion of the Research and Development Centre in Konstancin Łódzki, covering the costs and expenses in connection with the development and commercialization of MabionCD20, and repayment of loans from and other liabilities towards financial institutions. Information on the Shareholder's subscribing to P-series shares was published in Current Report No. 26/2018 on April 23, 2018.

On May 25, 2018 the Company received from the company contracted to analyses the results in the scope of patients' response to treatment of non-Hodgkin's lymphomas (NHL) the confirmation that the status of the clinical trial results reported in the previous announcements as "initial", following thorough data verification, was changed to "final". Thus the positive assessment of the clinical trial result remains unchanged. The final versions of the reports will be enclosed to the marketing authorization application (MAA). The positive trial results do not warrant the product approval by the European Medicines Agency (EMA). This information was published in Current Report No. 35/2018 on May 25, 2018.

On June 1, 2018 the Company filed with the EMA the marketing authorization application (MAA) for the markets regulated by EMA for the drug called "MabionCD20". The drug was developed as biosimilar to MabThera and its indications are in line with the MabThera list of indications. This information was published in Current Report No. 36/2018 on June 1, 2018.

On June 11, 2018 the Company signed an agreement with the Minister of Investment and Development for co-funding of a project entitled "Expansion of the Research and Development Centre of Mabion S.A. – research on a new generation of medicines" as part of the Measure 2.1: Support for investments in R&D infrastructure of enterprises of the Smart Growth Operational Programme 2014-2020 co-financed by the European Regional Development Fund. The total cost of the Project was estimated at PLN 172.88 million and the value of co-financing is PLN 63.25 million. This information was published in Current Report No. 42/2018 on June 11, 2018.

On June 21, 2018 the Company's Management Board received the information about the positive result of the validation of the marketing authorization application (MAA) by the European Medicines Agency (EMA) for the drug called "MabionCD20" and, therefore, the drug was taken to assessment. The acceptance of the application does not warrant the approval by the European Medicines Agency (EMA). This information was published in Current Report No. 46/2018 on June 21, 2018.

On June 27, 2018 the Company received the summary from the US Food and Drug Administration (FDA) after the BPD (Biosimilar Biological Product development) meeting Type 2. The objective of the meeting was to present the basic data gathered by the Company on the development of MabionCD20 in relation to the reference drug MabThera. What is more, aim of the meeting was to identify the basic issues connected with the cooperation with FDA in order to register the drug MabionCD20 in the USA. In accordance with the summary, FDA agreed to allow using the data to support the application. It also suggested the general strategy of linking the product registered in the EU (Mabthera) with the product allowed to be marketed in the USA (Rituxan). FDA did not find a completely separate research process for the US market necessary. The Company was admitted to the next stages of consulting process whose aim is to specify the FDA requirements. The company informs that the registration process as well as the marketing authorization process of MabionCD20 in the USA is a multi-stage process and the situation when some additional authorization requirements of FDA in the future will be introduced cannot be precluded. This information was published in Current Report No. 50/2018 on June 28, 2018.

On July 17, 2018 (event after the balance sheet date), the Company concluded a revolving loan agreement with Bank Zachodni WBK S.A. to finance operating activities of the Company in the period of 2 years from the day of signing the agreement. The amount of the loan granted equals PLN 30 million. Disbursement of up to PLN 15 million PLN will be possible after fulfilment of certain formal and legal requirements, as well as establishment of collateral. Disbursement of further PLN 15 million will be possible after the Company received a positive decision of the European Medicines Agency concerning marketing authorization

for MabionCD20 drug. The loan bears interest at a variable, based on the WIBOR 1M reference rate increased by the Bank's margin, which is set at market terms. The Loan requires collateral, including a contractual mortgage (entered as item one in the land and mortgage register) up to PLN 45 million on the title to the real property in Konstancin-Jezierna Łódzki along with assignment of the amounts due under the insurance policy, the Company's declaration of submission to enforcement by a notarial deed pursuant to art. 777 § 1 point 5 of the Civil Procedure Code each time up to 150% of the Loan amount, as well as surety and other forms of protection provided by related parties of the Company _major shareholders of the Company_. The agreement contains numerous obligations of the Company towards the Bank and covenants, which may result in termination of the agreement by the Bank, if not satisfied. This information was published in Current Report No. 55/2018 on July 17, 2018. On August 6, 2018 (event after the balance sheet date), the Company received permission from the European Medicines Agency (EMA) to submit a second registration application ("Duplicate application") for the drug called MabionCD20. The assumption of the second application is the acquisition by the Company of an additional trade name for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). This activity may accelerate the commercialization of the drug MabionCD20 on the markets where RA is still covered by the patent protection for MabThera. At the same time, the Company announced that the above-mentioned EMA's consent is only a preliminary confirmation of the possibility of registering the drug and does not warrant success in the present process. The company also reserved the possibility to withdraw from submitting the second registration application depending on the final assessment of potential business benefits for the Company. This information was published in Current Report No. 56/2018 on August 6, 2018.

On August 27, 2018 (event after the balance sheet date), the Company was notified of Mylan Ireland's payment of USD 5 million for the achievement of the milestone specified in the mutual cooperation agreement in the form of the acceptance of the registration documents of MabionCD20 by EMA. According to the concluded cooperation agreement, apart from the above-mentioned payment, the Company, after the implementation of the subsequent milestones, will receive further payments in the total amount of up to USD 30 million. The remaining milestones, which future payments depend on, are: the approval of the marketing authorization application for MabionCD20 and progress in its commercialization. This information was published in the Current Report No. 58/2018 on August 27, 2018.

3.3 Related party transactions

In the first half of 2018, the Company did not enter into transactions with related entities on terms other than an arm's length basis. More information about transactions with related entities can be found in Note 24 to the interim condensed financial statements of the Company as at and for the six months ended June 30, 2018.

3.4 Information on guarantees and warranties granted in respect of loans and advances

In the first half of 2018 the Company did not grant any warranties for loans or advances, or any guarantees jointly to one entity or subsidiary of that entity, where the total value of the existing warranties or guarantees would be significant for the Company.

3.5 Description of the basic threats and risks to which Mabion S.A. may be exposed

Risk related to the macroeconomic conditions

Potential unfavourable changes in the macroeconomic conditions on the markets where the Company is planning to sell its drugs, in particular the slow-down in the rate of economic growth or reduction in expenditure on healthcare may have a negative impact on the operations and financial results of the Company. Significant economic factors which have an impact on the results achieved by our Company include the level of GDP, average wages, unemployment level, inflation level, level of expenditure on healthcare. The Management Board monitors the situation on the target markets on a current basis, trying to adapt the Company's strategy to the changes respectively in advance.

Risk of Force Majeure

Unexpected events such as war or terrorist attacks may lead to unfavourable changes in the business conditions and on the financial market, which may have a negative impact on the Company's financial condition. Additionally, such chance events as: fires, floods and other extraordinary Acts of God may lead to break-downs or damage to material tangible assets belonging to Mabion S.A., and to disruptions in the operations in which it engages, which may have a negative impact on the Company's results.

Risks related to changes in legal regulations and their interpretation

Frequent changes in regulations may cause a potential risk for the Company which may lead to outdated the Company's business forecasts and to deterioration in the Company's financial condition, potentially up to a complete crisis.

The changes in regulations with the largest impact on the Company's operations are amendments to the Pharmaceutical Law, tax law and intellectual property law.

Amendments to the above regulations may lead to a significant change in the Company's legal environment and influence its results.

Also discrepancies in interpretation of the legal order prevailing in Poland and in the EU constitute a material factor which may have an impact on the development prospects, results achieved and financial position of the Company. Inconsistency of interpretations by local courts and public administration authorities, and by Community courts may lead to consequences which will have an indirect or a direct impact on the Company.

The Management Board monitors amendments to legal regulations which are key to the Company and the manner of their construction, trying to adapt the Company's strategy to those changes in a proactive manner.

Risk related to the tax policy

One of the main elements with an impact on the entrepreneurs' decisions is Polish tax law which is characterized by frequent changes and the lack of precision of its regulations, which often cannot be interpreted in a uniform way. Both the practices of tax authorities and court judicature relating to tax issues are based on inconsistent legal regulations which translate into increased business risk in Poland compared with the more stable tax systems in countries with more mature economies. Gradually, the process of standardization of tax regulations is taking place, allowing determining their unambiguous interpretation by entrepreneurs and tax authorities.

The Management Board monitors amendments to legal regulations which are key to the Company and the manner of their construction on a current basis, trying to adapt the Company's strategy to those changes in a proactive manner.

Risk related to administrative decisions

The Company is unable to ensure that it will obtain particular permits, licences and consents required to complete biotechnological projects, or that no current or future permits, licences and consents will be revoked. Such situations may lead to delays in completion or to the need to change original projects and have a negative impact on the operations and results of the Company.

Currency risk

The Company purchases most of its laboratory equipment and reagents for conducting research in foreign currencies, mainly in EUR and USD. Unfavourable foreign exchange fluctuations (weakening of the PLN compared to other currencies) may have a negative impact on the level of capital expenditure incurred by the Company and lead to an increase in research and

development expenses, which in turn may contribute to the deterioration in the Company's financial results. Due to the fact that Mabion intends to sell its drugs on foreign markets (mainly denominated in EUR and USD), the risk related to foreign exchange fluctuations will be limited in the future. This risk is slightly reduced due to the fact that the decided majority of costs relating to the clinical trials of MabionCD20 is incurred in EUR.

Market risk

The basic objective of the Company's operations is the development, manufacture and launch to trading of drugs biosimilar to the original biotechnological drugs (so-called reference drugs). The biotechnological drugs market is already very attractive, and its value is expected to significantly increase over the next few years. However, there is a risk that if the reference drugs are withdrawn from the market or replaced with newer generation drugs, the Company's potential revenues from the biosimilars developed will be lower than previously assumed or will not find buyers.

The Management Board monitors the reference drug market on a current basis and to mitigate this risk it is prepared to undertake work on other biosimilars.

Risk of inventing and launching other drugs used in respect of the same indications as Mabion S.A.'s drugs

Oncological conditions, on which the currently conducted research is focused, are the most intensely researched group of conditions in biomedical studies. It is estimated that approx. 30% of all capital expenditure on research and development in biotechnological companies is spent on oncology. Additionally, genetics and molecular biology are developing quickly. As a result, it is probable that over the next few years innovative medicines will be launched which will have an advantage over the drugs developed by the Company in terms of their efficacy or tolerance by the human body. Additionally, there is a risk that other treatment methods will be invented – such as vaccines – which could be used against conditions currently subjected to therapies which could use the Company's future drugs. The emergence of new drugs and therapies could have a negative impact on the amount of future sales revenues and the Company's results. The Management Board monitors scientific progress in the area of new therapies and drugs for conditions in which the Company's medicines are to be used on a current basis. Additionally, most oncological schemes use therapy sequences (a consecutive drug with a different operating mechanism is used after the potential of the first drug is exhausted), and polytherapies (several drugs with different operating mechanisms are applied at the same time), which significantly reduces the risk of erosion of the drugs applied in tumour therapies.

Competitive risk

The drugs which the Company develops are biosimilar to the original reference drugs which are protected with patents for publicly known periods. It follows from the published information that currently there are many entities on the market which develop biosimilars and work on some of them is highly advanced.

Until the date of the publication of this report, two companies - Celltrion and Sandoz, have introduced biosimilars to MabThera / Rituxan to the European market. According to the previously provided information, this did not affect the operations of Mabion, which in June this year after completing the clinical trials, started the registration procedure for MabionCD20 in the European Medicines Agency (EMA). Even if the commercialization of a biosimilar medicine to MabThera / Rituxan is successful for several entities, analysis shows that this market has potential for growth.

It should be remembered that despite the high sales of Roche's original medicine, many patients do not currently have access to this therapy. In many countries, the treatment with MabThera / Rituxan for the patients with NHL is not reimbursed by the public health system, and for the patients with RA, the access is even more limited.

The market for biosimilars is a market with high entry barriers. These include, among others, very high requirements in clinical trials, especially in the US and other developed markets, in order to prove that the drug is biosimilar to the original medicine. This is confirmed by the fact that so far no company has been able to register a biosimilar medicine on the US market for MabThera / Rituxan.

Risk related to the research and development process

The biotechnological industry, in particular manufacture of modern biosimilar drugs, is characterized by high labour-intensiveness and the need to incur large expenditure on research and development. Not only the possibility of launching the developed drugs on the market but also the efficiency of production processes and therefore also the manufacturing costs depend on the results of the conducted research and development work. To-date Mabion has expended most of the funds obtained on research and development.

There is a risk that part or all of the objectives of the Company's scientific work will not be achieved in the planned scope or time, which would lead to the inability to recover significant or all the expenditure spent on the research. That would have a material negative impact on the possibility of completion of the Company's strategic plans, and therefore also on the results achieved.

The results of the research and development work to-date attest to the Company's capability to produce proprietary biosimilars, and in the opinion of the Management Board significantly mitigate the risk of not achieving ultimate success. Additionally, the Management Board monitors the course of the research and development work on a current basis and implements operating and procedural solutions which ensure high effectiveness of the said work.

Risk of underestimating manufacturing costs and launching the MabionCD20 drug

According to assumptions very generally adopted by the biotechnological industry, the development and production of a single biosimilar which meets global standards lasts around 7–9 years and costs approximately up to several dozen million USD. Guidelines relating to biosimilars are only now being formed and each case is analysed by market regulators individually, therefore, the scope of requirements relating to the technology, documentation, analytics and clinical development is not strictly specified. Therefore, the exact scope of research and development work cannot be determined and the development costs of the drugs cannot be precisely anticipated.

In the Company's opinion, the policy for developing proprietary research and development competencies, investing in the Company's own production capacity and consulting with the EMA and FDA with reference to the clinical program of MabionCD20 allow significant cost reduction compared to industry assumptions.

It cannot be eliminated that the actual costs of production and launching the developed drugs (including MabionCD20) on the market will be much higher than currently anticipated. A material increase in the costs of production and the market launch of the developed drugs may have a negative impact on the financial results achieved by the Company.

Industry dynamics, both in respect of the regulations which are being formed and the technologies which arise and are constantly being enhanced, may lead, among other things, to the following direct reasons for underestimating the costs of drug development, which includes MabionCD20:

- » amendments to the regulations concerning the production of drugs and the need to use more expensive technological solutions or creating new ones;
- » an increase in the costs of purchase of raw materials and materials used to manufacture drugs, following from market conditions or new guidelines;
- » amendments to regulations concerning the scope of analyses necessary to characterize the product, e.g. need to perform additional costly analyses or develop new analytical methods or tools;
- » increasing the requirements concerning registration documentation, e.g. the need to perform additional trials or studies;
- » increasing the scope of the clinical trials as a result of the biological variability of patients, in response to treatment, the drug's metabolism, the patients' or doctors' non-compliance with the study protocol;
- » increasing the scope of the clinical trials as a result of the biological variability of patients higher than that given in the available clinical literature based on which the study was designed;
- » increasing the cost of the clinical trials due to strong competition on the clinical trials market and limited availability of research centres and patients.

Risk related to the work schedule

The achievement of the Company's strategic goal, which is the registration and market launch of biosimilars, is possible after the expiry of patent protection of the original drugs, and is connected with the need to develop a detailed work schedule for several years. The possibility of pursuing this schedule is conditioned by many various factors, both internal and external. Potential unexpected delays in the adopted time schedule may lead to not achieving the planned sales revenue in the expected period and have a negative impact on the Company's financial results. The Management Board monitors all works related to the development of drugs and if necessary implements the required operating solutions to minimize the impact of unexpected events on future time schedules.

In 2007 the Company initiated the research and development process of MabionCD20, which is a drug directly competitive with the currently marketed drug MabThera/Rituxan by Roche. In Europe the basic patent protection for this drug expired in the period: end of 2013 – end of 2014, and the basic patent protection in the USA expired in June 2018.

The Company's goal is to launch MabionCD20 on the market as quickly as possible after the patent protection expires, which would enable the Company to temporarily achieve a competitive advantage. Delays in conducting clinical trials and the time necessary to complete the procedure for registering the drug MabionCD20 (in Europe this as a rule lasts 210 days) may cause the market launch of the drug to be delayed compared with the Company's current assumptions.

From the beginning of work on developing MabionCD20 the Company has been cooperating with EMA on the issue of compliance with all the guidelines and procedures related to the registration process in the European Union. To-date, many scientific advice sessions took place. The sessions were aimed at eliminating doubts and to refine actions related to preparing registration documentation.

The company has also launched a consultation process with the US Food and Drug Administration (FDA), which aims to detail the requirements of the FDA in the registration of MabionCD20.

Risk related to low quality or loss of biological material

The basic material used in Mabion S.A. products is biological material. It is both manufactured by the Company and delivered by third party suppliers. Selecting optimal cell clones which form the basis for further drug production on a larger scale is very important for the process of developing and producing biotechnological drugs. The quality of the biological material and its storage in strictly determined conditions is of key importance for the success of the work. There is a risk that the biological material acquired from third party suppliers will be of a low quality or that the material produced by the Company will be damaged or destroyed, which would have a negative impact on achieving the Company's assumed revenues and financial results.

Mabion S.A. entered into cooperation with verified suppliers, it controls the quality of the supplies and stores the biological material in specialist devices, using monitoring and two independent power sources. Additionally, the original deposit of the biological material used by the Company for the production of drugs is stored in an independent storage place outside Poland so as to be able to continue its production in another external facility in the case of any unexpected events.

The Company also monitors the course of production and the quality of the manufactured products introducing necessary organizational, human resources, and technological changes following from the quality management processes.

Risk related to the manufacturing process

One of the key elements of production of biotechnological drugs is the production process which must be conducted in compliance with the previously planned parameters. The production process of such drugs comprises several stages and even the smallest change in any of them may have an impact on the drug's properties (e.g. in terms of its effectiveness or safety). Transferring from the small laboratory scale to industrial scale (up-scaling) is an extremely important element of the drug

¹ source: GlobalData

production process. Ensuring the consistency, stability and sterility of the whole production process is extremely important. Mabion laboratories were equipped with modern apparatuses which ensure the maximum accuracy and repeatability of the results obtained. The materials used in the production sphere are appropriately attested to be used in the pharmaceutical industry. The installed production line was wholly based on sterile materials. The Management of particular Departments of Mabion S.A. comprises high-class specialists, with professional education, appropriately trained and prepared for working in the scope of duties they have been assigned both by internal and external experts.

The production process is constantly monitored and verified in accordance with the procedures adopted by the Company, which enable the Company to systematically strive to reduce the level of risk in this area. The Company meets the requirements of Good Laboratory Practices (GLP) and Good Production Practices (GMP), it has the necessary attestations and permits (including a GMP Certificate for the complex in Konstancin Łódzki issued by the Chief Pharmaceutical Inspector).

Risk of achieving production capacity compliant with demand

Currently, it is difficult to assess the exact demand for MabionCD20, nevertheless, the expectations of Mabion's global partner related to the supply plans for sale on the EU and USA markets may lead to the need to increase production capacity over the level achievable in the current building in the scientific and industrial complex in Konstancin Łódzki. The Company is aware of this risk and has capabilities to add another building to the existing one in the same location and on the same plot. The building may to a larger extent be used for production purposes (part of the current building is used for office purposes). The Company's experience in investment and technological processes related to the current building will be used in the potential new project. Additionally, it will be possible to use part of the industrial plant installed in the current building in the added part, which will enable using the additional space for installing the maximum number of bioreactors. The final necessity, dates and scope of such an investment will depend on consultations with the global partner in respect of the planned deliveries of MabionCD20 to the EU and USA market.

Risk related to attestations for the laboratory and production plant

Maintaining appropriate conditions on the premises where work is conducted on the Company's products is extremely important. Currently Mabion has all the required attestations for the equipment and laboratory and production premises in both plants.

The risk of not obtaining or delay in obtaining pharmaceutical acceptance by the Chief Pharmaceutical Inspectorate of Kompleks Naukowo-Przemysłowy in Konstancin Łódzki has been eliminated. Nevertheless, due to the number of stakeholders (differentiated supply and service channels, the human factor, etc.), the Company's Management Board cannot guarantee that the attestations will be maintained in the future.

Risk related to clinical trials

One of the material stages of work on the preparation for registration and launching a drug on the market are clinical trials conducted on human beings. Conducting clinical trials is always exposed to the risk related to insufficient effectiveness or safety of application of the Tested Medicinal Product. The risk is related both to the current and the future trials which will be conducted by the Company.

In order to avoid such risk, the Company consults its clinical trials both with the regulator and the advisory entities.

Risk related to registering drugs

The basic purpose of Mabion is the introduction of the developed biosimilars to global markets, mainly to the markets of the European Union and the USA, which is related to the duty to register those drugs by relevant authorities – appropriately the European Medicines Agency (EMA) and the American Food and Drug Administration (FDA). The work conducted by Mabion S.A. on the development and implementation of drugs are compliant with the EMA guidelines. The FDA issued several regulations regarding biosimilar drugs, nevertheless, instances of registering such drugs in the USA have been few to-date and it is impossible to widely verify the regulations in practice.

There is a risk that in the event of e.g. procedural changes or errors in documentation the process of registering the drug in the area of the European Union may be delayed or impossible to finalize. Additionally, there is a risk that further regulations adopted by the FDA will be more restrictive than the EMA. In such cases the Company would be exposed to the need to incur additional costs or to fully discontinue activities on the American market, which would have a negative impact on the level of financial results achieved by the Company.

From the beginning of work on developing biosimilars, Mabion S.A. has been cooperating with the EMA on the issue of compliance with all the guidelines and procedures related to the registration process in the European Union. In June 2018 the Company presented the data on the development of MabionCD20 in relation to the drug MabThera to the American Food and Drug Administration (FDA). The Agency accepted the possibility of using the data held by the Company as supporting the application process. At the same time, FDA proposed a general strategy for linking the product registered in the EU (Mabthera) with the product admitted for sale in the USA (Rituxan). A completely separate development process of MabionCD20 on the American market has not been indicated.

However, the risk cannot be ruled out that the methodology adopted by the Company, its scope and nature, as well as the form of data collection and its details, can be assessed by EMA or FDA as insufficient to register the drug.

Risk related to launching and maintaining the drugs on the market

After registering the drugs, Mabion is planning to launch them on the market as quickly as possible, which is related to preparing the drug as a market product (production, marketing, distribution and sales) and requires significant financial expenditure and good organizational preparation. Due to the very specific product and differentiated specificity of the markets on which Mabion S.A. intends to operate, the Management Board expects diversified promotion and distribution strategy for the drugs produced.

In accordance with the adopted assumptions, marketing and distribution of the drugs in Poland and in selected Central and Eastern European countries will be conducted independently by the Company. In other European countries and other countries globally, marketing and distribution activities will be conducted by global and local partners.

There is a risk that launching the Company's drugs on particular global markets will not be compliant with the current assumptions or that as a result of negligence or error in sales, logistics or distribution the drugs will be found unsellable on a given market which could have a negative impact on the sales revenue earned by Mabion and on its financial results.

Mabion S.A. acquired a distribution partner for the EU and Balkan region and currently is actively looking for an experienced and strong partner to effectively sell Mabion S.A. drugs in the USA. This is being done via Plexus Ventures LLC (the Company informed about this in its current report no. 16/2014). The process is complex and long – it consists of contacting companies, signing confidentiality agreements and presenting data at various levels of detail depending on the stage of development of the process. At the same time, the companies are updating their offers.

Members of the Management Board, of the Supervisory Board, and current shareholders with a significant interest in the Company and those who actively support it have significant legal and technical insight in organizing hospital sales and large experience in launching and maintaining pharmaceuticals on the market.

Risk related to refunding drugs

The costs of developing and producing the newest generation of biosimilar drugs are very high, which is related to their relatively high market price later. There are drugs whose sales are refunded by state budgets or other non-budgetary payers on the market. The Management Board's intention is to cover the drugs produced by Mabion with refunds in the largest possible number of countries in which they will be admitted to sale. There is a risk that in the event that the goal is not achieved or is only partly achieved, and the reference drugs or biosimilars produced by competitors are refunded, demand for Mabion S.A.'s medicines will be lower than planned. As a result, this may have a negative impact on the level of revenues earned by the Company and its financial results.

Risk of withdrawing the permit for admitting the Company's products to trading and product liability risk

In the cases stipulated by law, the permit for admitting the drugs to trading (or the production permit) in the area in which the drugs had previously been admitted to trading may be withdrawn.

For example, pursuant to Polish law the Minister of Health withdraws permits for the admission of medicinal products to trading, among other things, in the case of determining an unexpected, serious undesirable effects of the product which are a threat to human life or health, lack of declared therapeutic effectiveness of the product, determining a risk of use disproportionate to the therapeutic effect or determining that the medicinal product is launched on the market in a manner which is non-compliant with the permit or legal regulations. The withdrawal of a permit for admitting Mabion S.A.'s medicinal products to trading would have a significant unfavourable impact on the Company's development perspectives and on the financial results achieved.

Irrespective of the above, in some circumstances (e.g. in the event of a justified suspicion that the medicinal products do not meet the respective requirements) the provincial pharmaceutical inspector uses decisions on suspending trading in certain series of the product in the area of operations of the said inspector.

In the indicated circumstances and in other cases where the use of the Company's products may cause damage to individual entities, Mabion may be liable for damages which is related to the risk of claims being filed in respect of the Company under civil law proceedings. The Company may also incur liability if the product is found to be dangerous. For example, pursuant to Polish law, a dangerous product is a product which does not ensure the safety that may be expected during normal use of the product. Whether the product is safe is decided in circumstances when it is introduced to trading, in particular the manner in which it is presented on the market and the information provided to the consumer about the product's properties. Also the need to satisfy potential claims for damages addressed to the Company may have a material negative impact on the operations and financial position of the Company.

Risk of loss of key personnel

Mabion S.A. conducts its operations based on the knowledge and experience of highly qualified managers and scientific and research personnel.

There is a risk of the Company's key personnel leaving the Company in the future, which could have a negative impact on the quality of the products offered. This could also cause loss of reputation and difficulties in acquiring new orders, and lead to a deterioration in the financial results. The Company's Management Board pursues an active personnel policy aimed at retaining the most valuable specialists in the Company.

The Company's employees may count on the possibility of developing professionally in a comprehensive manner, which includes participation in training (internal and external), support in starting doctoral studies, and inclusion in the promotion procedure – the principles for obtaining these benefits are formalized, open and unbiased (e.g. the promotion procedure, implementing bonus programs for employees with long work service, implementing loyalty programs and bonus programs).

Risk related to disclosure of trade secrets

The pursuit of Mabion's plans may depend on keeping the Company's confidential information in secrecy, in particular information relating to the trials conducted and the technological processes. Disclosure of this information and its use by persons cooperating with the Company, in particular its employees, cannot be eliminated, and the effect of such disclosure may be its use by entities conducting competitive business operations. In such instance, the Company's legal defence rights, in particular the claims it may lodge, may prove insufficient to protect it from the negative effects of such events.

The Company has undertaken several legal steps to eliminate this risk.

Risk related to disputes concerning industrial and intellectual property rights

Mabion operates in an area where industrial and intellectual property rights regulations and their protection are of great importance. There is no litigation pending in respect of any violations of industrial or intellectual property rights. The Company intends to engage in business so as not to violate any third party rights in this respect. However, potential claims lodged by third parties against the Company in respect of industrial and intellectual property rights violations cannot be eliminated, in particular at the stage of research work and at the stage of obtaining permits for admitting the Company's medicinal products to trading. If such claims are lodged, even if they are unjustified, it could have an unfavourable impact on the time needed to obtain the said permit, and defence against such claims may involve the need to incur significant costs which in effect may have a negative impact on the Company's financial results.

Risk related to the funding granted

In the reporting period in connection with the research and development and implementation projects carried out by Mabion S.A. the company was a party to the following agreements on co-financing:

- » "Development and scaling of an innovative therapeutic production process, a recombinant monoclonal antibody, to enable the industrial implementation of the first Polish biotechnology drug for oncological and autoimmune therapies"
 - The project value is PLN 54 188 035.17
 - The value of co-financing (contribution from European Funds) is: 27 094 017.84 PLN
 - Years of project implementation: November 1, 2016 - December 31, 2019
- » "The development of a biotechnology drug through the development of an innovative monoclonal IgG1 subclass with reduced content of unfavorable glycoforms against the reference drug - directed against EGFR"
 - The project value is PLN 39,965,267.64
 - The value of co-financing (contribution from European Funds) is: 28 354 422,06 PLN
 - Years of project implementation: August 1, 2017 – July 30, 2021.
- » "Clinical development and registration of a humanized HER2 receptor-binding monoclonal antibody used in the treatment of breast cancer".
 - The project value is PLN 23,949,430
 - The value of co-financing (contribution from European Funds) is: PLN 10,000,000
 - Years of the project implementation: June 1, 2014 – May 31, 2019.
- » Expansion of the Research and Development Center Mabion S.A. - research on the new generation of medicines "
 - Project value: PLN 172,876,340.70
 - The value of eligible costs: PLN 140,594,870.60
 - The value of co-financing from ERDF: PLN 63 247 441.60
 - Years of project implementation: January 20, 2018 – December 31, 2021.

The concluded contracts provide in detail the dates and scope of tasks that may be co-financed. There is a risk that if the Company uses all or part of the co-financing not in accordance with the intended purpose or fails to comply with the applicable procedures, it will collect all or part of the co-financing in an undue or excessive manner, it will be obliged to return some or all of the co-financing plus interest. Therefore, if the conditions giving rise to a liability come true, the financial situation of the Company may deteriorate significantly, which may in the long-term jeopardize the achievement of the Company's strategic goals.

Liquidity risk

The Company does not generate on-going revenue from sales of market products, and its operations to-date have been financed with funds from the issuance of shares, co-financing from public funds and – to some extent – sales of research and development services. The Management Board is planning to acquire funds for financing the Company's further operations from a distribution contract signed with Mylan Ireland, from new EU projects and from the issuance of shares.

In accordance with the provisions of the agreement with Mylan, Mabion S.A. will receive payments for completing the milestones specified in the agreement depending on the filing for and obtaining the trading admittance and launching the MabionCD20 in the EU countries. Potential delays in meeting the planned time schedule may lead to a delay in receiving the assumed tranches from the distributor.

If the application for additional aid funding from the EU is unsuccessful Mabion S.A. may be exposed to serious liquidity problems and to the need to obtain an alternative source of funding.

Risk related to operations in the Łódź Special Economic Zone

Mabion S.A. conducts research and development, and production operations, and has built a fully-equipped scientific and industrial complex in the Łódź Special Economic Zone. In accordance with the Act on Special Economic Zones the income earned on business activities in the special economic zone, under a permit received, is exempt from Corporate Income Tax. Mabion S.A. is exempt from the tax until December 31, 2026.

There is a risk that due to an amendment to the legal regulations on the operation of the zones and principles relating to the tax exemptions, as well as the Company's potential non-compliance with the ratios specified in the permits, which entitle to the tax exemptions, the conditions for the Company's further operations in the ŁSEZ may become unattractive in terms of taxes or the Company may lose its rights to use the said tax reliefs.

4. ANALYSIS OF THE COMPANY'S FINANCIAL POSITION

4.1 Principles for preparing the semi-annual condensed financial statements

The interim condensed financial statements of Mabion for the period from January 1, 2018 to June 30, 2018 have been prepared in accordance with the accounting policies of the International Financial Reporting Standards (IFRS), covering International Accounting Standards (IAS) and the Standing Interpretation Committee (SIC) and interpretations of the International Financial Reporting Interpretations Committee (IFRIC), endorsed by the European Union (EU) and effective as at the end of 2017. The financial statements have been prepared on the historical cost basis. The interim condensed financial statements, with the exception of the cash flow statement, have been prepared according to the accruals principle.

The interim condensed financial statements of Mabion for the period from January 1, 2018 to June 2018 have been prepared according to International Accounting Standard 34 "Interim financial reporting", as endorsed by the European Union ("IAS34"). The accounting policies used in the preparation for these interim condensed financial statements were unchanged in scope compared with the policies used in the preparation of the annual financial statements for 2017, with the exception of income tax which was calculated using the expected annual average effective tax rate.

In the first half of 2018 there were no changes in the policies for determining the value of assets and liabilities, or measuring the financial results.

The interim condensed financial statements of the Company for six-month periods are not subject to auditing, but are reviewed by the Company's auditor, PricewaterhouseCoopers Sp. z o.o.

4.2 Financial position of Mabion S.A. after the first half of 2018

Revenues, expenses and results

An analysis of the results achieved by the Company in the first half of 2018 (in PLN thousands) is shown in the table below:

	January 1, 2018 – June 30, 2018	January 1, 2017 – June 30, 2017	Change (%)
Net sales and sales equivalents	0	0	N/A
Cost of sales of finished goods, goods for resale and materials	0	0	N/A
Gross profit/(loss) from sales	0	0	N/A
General administrative expenses	-11 360	-8 695	31%
Research and development costs	-26 730	-21 398	25%
Other operating income and expenses, net	1 201	1 067	13%
Operating profit/(loss)	-36 889	-29 026	27%
Profit/(Loss) before tax	-41 182	-25 369	62%
Income tax	0	0	N/A
Net profit/(loss)	-41 182	-25 369	62%

In 2018 in connection with the concentration of work on the final stage of development of MabionCD20 the Company did not earn any sales revenues.

In the reporting period, the Company generated a tax profit of PLN 4,690 thousand. The profit is the result of recognizing part of the advances for future MabionCD20 distribution rights received from Mylan as tax revenue. At the same time, the Company incurred the costs of research and general management costs which are not directly related to the development works carried out by the Company, in particular costs of remuneration and derivatives and depreciation, media supplies and property tax connected with the plant in Konstantynów Łódzki.

The Company's assets and their funding

Assets	June 30, 2018		June 30, 2017		Change (%)
	Value (PLN'000)	Structure	Value (PLN'000)	Structure	
Non-current assets	71 142	41.6%	72 470	96.9%	-2%
Property, plant and equipment and intangible assets	70 945	41.5%	72 276	34.1%	-2%
Long-term receivables	197	0.1%	194	0.1%	2%
Long-term investments	0	0.0%	0	0.0%	N/A
Long-term prepayments and deferred costs	0	0.0%	0	62.7%	N/A
Current assets	99 931	58.4%	9 975	3.1%	902%
Inventories	9 590	5.6%	7 159	1.5%	34%
Short-term receivables	21 974	12.8%	1 649	0.9%	1233%
Prepayments	270	0.2%	129	0.4%	109%
Cash and cash equivalents	68 097	39.8%	1 038	0.3%	6460%
Total assets	171 073	100.0%	82 445	100.0%	107%

As of June 30, 2018 the value of Mabion S.A.'s assets is PLN 171,073 thousand; this constitutes 207% of the value of assets as of December 31, 2017.

The increase in the cash balance related to raising funds from the issue of series P shares in April 2018 had the greatest impact on the asset growth in the last half year, the increase in receivables due to issuing an invoice regarding the next installment of payments for exclusive distribution rights MabionCD20 from Mylan Ireland and increase inventories related to the launch of MabionCD20 production for technical purposes and for the purpose of validation of the production line.

In 2018 the Company financed its operations mainly with the issue of series P shares, the bank loan with BZ WBK as well as and borrowings from related entities and other financial institutions, and short-term liabilities and accruals. The increase in liabilities and provisions for liabilities is related to the the issue of series P shares and currency rate fluctuations which had an impact on the value of liabilities denominated in foreign currency.

The increase in the value of accruals results from the reclassification of a part of the amounts received from Mylan Ireland from the item of short-term liabilities and prepayments.

Equity and liabilities	June 30, 2018		June 30, 2017		Change (%)
	Value (PLN'000)	Structure	Value (PLN'000)	Structure	
Equity	69 113	40.4%	-54 158	-65.7%	-228%
Liabilities and provisions for liabilities	101 960	59.6%	136 603	165.7%	-25%
Bank loans and borrowings	2 454	1.4%	62 768	76.1%	-96%
Long-term liabilities	2 181	1.3%	2 308	2.8%	-6%
Short-term liabilities	63 988	37.4%	55 885	67.8%	14%
Accruals and deferred income	33 337	19.5%	15 642	19.0%	113%
Total equity and liabilities	171 073	100.0%	82 445	100.0%	107%

Cash flow statement

The Company's cash flow statement is shown in the table below (in PLN'000):

	January 1, 2018 – June 30, 2018	January 1, 2017 – June 30, 2017	Change (%)
Net cash from operating activities	-34 214	-26 703	28.1%
Net cash from investing activities	-2 362	-1 728	36.7%
Net cash from financing activities	103 635	38 624	168.3%
Net increase/(decrease) in cash and cash equivalents	67 059	10 193	557.9%

In the first half of 2018 the Company generated negative cash flows from operating activities. Costs of research and development work incurred by the Company had the largest impact on the cash flows from operating activities.

The Company's cash flows from investing activities were higher than in the comparable period of the previous year due to the decisions on purchasing additional lab equipment taken by the Company, to reduce third-party service expenses as well as the

investment in the IT systems supporting different departments of the Company. The capital expenditure on property, plant and equipment was to a large extent financed with finance leases and borrowing from financial institutions.

The Company generated significant positive cash flows from financing activities in effect of the issue of series P shares.

Selected financial ratios

Liquidity ratios	Measure	June 30, 2018	December 31, 2017	Formula
Current	multiple	1.46	0.08	current assets / short-term liabilities
Quick	multiple	1.32	0.02	(current assets – inventories – short-term prepayments) / short-term liabilities
Cash	multiple	1.00	0.01	cash and cash equivalents / short-term liabilities

Profitability ratios	Measure	January 1, 2018 – June 30, 2018	January 1, 2017 – June 30, 2017	Formula
Operating margin	%	N/A	N/A	profit on sales / sales revenue
Gross margin	%	N/A	N/A	operating profit / sales revenue
Net profitability	%	N/A	N/A	net profit / sales revenue
Return on assets (ROA)	%	-24.07%	-30.77%	net profit / total assets
Return on equity (ROE)	%	-59.59%	46.84%	net profit / equity

Liability ratios	Measure	June 30, 2018	December 31, 2017	Formula
Gearing	%	59.60%	165.69%	short- and long-term liabilities / total assets
Debt to equity	%	147.53%	-252.23%	Liabilities and provisions for liabilities / equity
Long-term gearing	%	19.62%	19.69%	long-term liabilities / total assets

4.3 Description of factors and events with a significant impact on the condensed financial statements

In the first half of 2018 there were no one-off events with the exception of the event described below. The Company's activity in the first half of 2018 was comparable to that in earlier periods.

As of June 30, 2018, thanks to the proceeds from the issue of series P shares, the Company possesses positive equity. In the opinion of the Management Board of the Company, support from shareholders (both strategic and participants of the exchange market) and a long-term cooperation agreement with Mylan Ireland Limited will provide the Company with financing necessary to complete development related to MabionCD20 and its commercialization and justify further activity of the Company in accordance with adopted development strategy.

4.4 Factors which will have an impact on the achieved financial results in the perspective of at least the following six months

In future reporting periods revenues will be strictly related to contracts already signed or work in progress related to the registration and distribution of MabionCD20. Potential delays of negotiations or unexpected departures from time schedules of contracts already signed may have an impact on the amount of revenues.

4.5 Position of the Management Board concerning the possibility of meeting the previously published forecasts concerning the results for the year

The Company's Management Board took a decision to cancel the financial forecasts published in 2010 (prepared in connection with applying for admitting I-Series shares to trading in an alternative trading system) and for resigning from publishing forecast financial results.

5. SHARES AND SHAREHOLDINGS

5.1. Structure of share capital

As of June 30, 2018 and as at the date of the report, the Company's share capital amounted to PLN 1,372,077,20 and consisted of 13,720,772 shares with a nominal value of PLN 0.10 each, including:

- » 450,000 registered A-series preferred shares;
- » 450,000 registered B-series preferred shares;
- » 450,000 registered C-series preferred shares;
- » 450,000 ordinary D-series bearer shares;
- » 100,000 registered E-series preferred shares;
- » 100,000 registered F-series preferred shares;
- » 20,000 registered G-series preferred shares;
- » 2,980,000 ordinary H-series bearer shares;
- » 1,900,000 ordinary I-series bearer shares;
- » 2,600,000 ordinary J-series bearer shares;
- » 790,000 ordinary K-series bearer shares;
- » 510,000 ordinary L-series bearer shares;
- » 360,000 ordinary M-series bearer shares;
- » 340,000 ordinary N-series bearer shares;
- » 300,000 ordinary O-series bearer shares.
- » 1.405.999 ordinary bearer shares and 514.773 ordinary P-series registered share

A, B, C, E, F and G-series registered shares are preferred as to votes – each share gives the right to two votes at the General Meeting. The total number of votes resulting from all the issued shares is 15,290,772.

On March 13, 2018, the National Depository for Securities S.A. ("KDPW") made conditional registration in the deposit of securities under the ISIN code PLMBION00016 340,000 ordinary bearer shares of the N series of the Company and 300,000 ordinary bearer shares of the O series of the Company, with a nominal value of PLN 0.10 each. The condition for registration of the above shares were their introduction to trading on the regulated market, which, in accordance with the resolution of March 14, 2018, of the Warsaw Stock Exchange Management Board, S.A. (WSE) regarding the admission and introduction of the abovementioned shares for stock exchange trading on the WSE Main Market took place on March 19, 2018. In accordance with the KDPW operational communication of 15 March 2018, the registration of the above-mentioned shares in the depository of securities took place on March 19, 2018.

On 30 April 2018, the District Court for Łódź-Śródmieście in Łódź, 20th Division of the National Court Register registered the

increase in the share capital of the Company. The share capital of the Company was increased from PLN 1,180,000.00 to PLN 1,372,077.20 as a result of the issue of 1,920,772 ordinary bearer series P shares with a nominal value of PLN 0.10 each. After registering the share capital increase, the total number of votes resulting from all issued shares is 15,290,772.

On May 18, 2018, the Management Board of the Company in connection with the motion of the shareholder of Twiti Investments Limited, issued on the basis of art. 334 par. 2 of the Commercial Companies Code, adopted a resolution to change, in accordance with the submitted application, 514,773 ordinary bearer shares of the P series into ordinary registered shares of the P series and issue a collective section of shares representing 514,773 ordinary registered shares and depositing a collective share in the Company. The shares to be converted account for 3.75% of the share capital and 3.37% of the total number of votes in the Company. The remaining 1,405,999 series P shares remain ordinary bearer shares.

On June 8, 2018, KDPW made conditional registration in the securities depository of 1,405,999 ordinary series P bearer shares, with a nominal value of PLN 0.10 each. The condition for registration of the above shares was their introduction to trading on the regulated market, which, in accordance with the resolution of June 8, 2018, the WSE Management Board regarding the admission and introduction of the abovementioned shares for stock exchange trading on the WSE Main Market took place on June 12, 2018. According to the KDPW operational communication of June 11, 2018, the registration of the abovementioned shares in the securities depository took place on June 12, 2018.

5.2. Shareholders with at least 5% of the total number of votes

According to the Company's Management Board's knowledge, as at the publication date of this half-year report for the, i.e. as of September 13, 2018, the following shareholders have at least 5% voting rights at the Company's General Meeting:

No.	Shareholder	Number of shares	Number of votes	% share in share capital	Share in 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.	Others	4 781 258	4 781 258	34.85%	31.27%
	TOTAL	13 720 772	15 290 772	100%	100%

* Mr Maciej Wieczorek has 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 75% in the total number of votes in Celon Pharma S.A.

** Pursuant to the list of shareholders at the Extraordinary General Meeting of the Company held on June 28, 2018

Struktura akcjonariatu Spółki na dzień przekazania raportu za I kwartał 2018 roku (30 maja 2018 r.) według wiedzy Zarządu przedstawiała się następująco:

Lp.	Akcjonariusz	Liczba akcji	Liczba głosów	Udział w kapitale zakładowego	Udział w ogólnej liczbie głosów										
1.	Twiti Investments Limited*	2 520 072	3 114 372	18.37%	20.37%										
2.	Maciej Wieczorek indirectly, including through **: <table border="0" style="margin-left: 20px;"> <tr> <td>Glatton Sp. z o.o.</td> <td>1 004 526</td> <td>1 004 526</td> <td>7.32%</td> <td>6.57%</td> </tr> <tr> <td>Celon Pharma S.A.</td> <td>620 350</td> <td>1 113 200</td> <td>4.52%</td> <td>7.28%</td> </tr> </table>	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%	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 Nationale Nederlanden PTE S.A.	912 390	912 390	6.65%	5.97%										
6.	Funds managed by Investors TFI S.A.	794 566	794 566	5.79%	5.20%										
8.	Others	4 940 340	4 940 340	36.01%	32.31%										
	TOTAL	13 720 772	15 290 772	100.00%	100.00%										

* Mr Maciej Wieczorek has 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 75% in the total number of votes in Celon Pharma S.A.

5.3. Schedule of shares held by management and supervisory board members

Shares held as at the date of filing the report for the first half of 2018 (September 13, 2018)	
Management Board	
Artur Chabowski	indirectly, through FL Real Investments Holding Limited with its registered office in Nicosia (Cyprus), in which Artur Chabowski holds 100% interest in the share capital, holds jointly 24,034 of the Company's shares with a nominal value of PLN 0.10 each, which constitutes 0.18% of the Company's share capital and gives 0.16% voting rights at the General Meeting;
Supervisory Board	
Maciej Wieczorek	indirectly, through Glatton Sp. z o.o. (in which he holds 100% interest in the share capital) and Celon Pharma S.A. (in which, through Glatton Sp. z o.o., he holds 66.67% of interest in the share capital) he holds jointly 1,624,876 of the Company's shares with a nominal value of PLN 0.10 each, which constitute 11.84% of the Company's share capital and give 13.85% voting rights at the General Meeting;

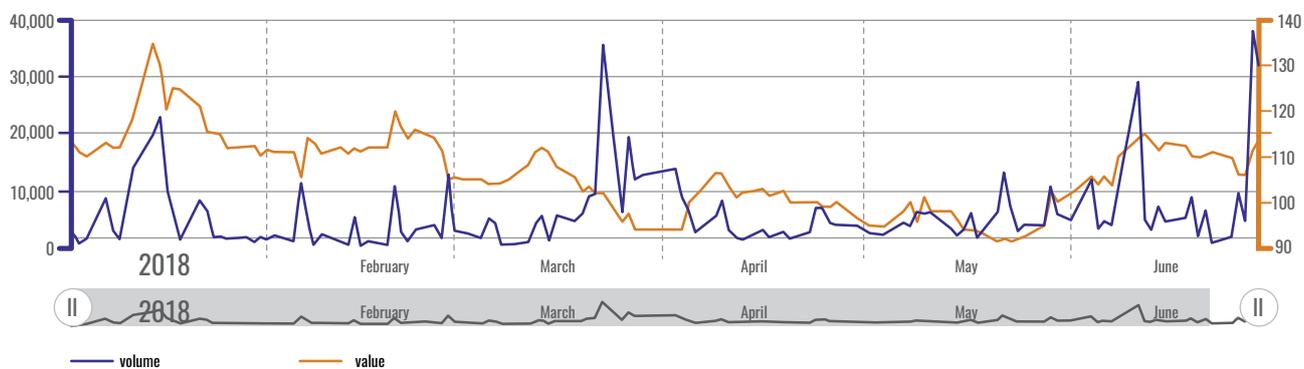
In the period from the date of publication of the previous periodic report, i.e. the report for the first quarter of 2018 published on May 30, 2018, there were no changes in the possession of the abovementioned persons managing and supervising the Company.

Other Members of the Management and Supervisory Boards did not hold any of the Company's shares in the period from the submission of the report for the first quarter of 2018 to the date of submission of this report. Members of the Management Board and Supervisory Board of Mabion S.A. have no rights to the Company's shares.

5.4. Share quotations on the Warsaw Stock Exchange

Data for the first half of 2018:

Reference price:	PLN 112.80 (December 17, 2017)
Start date:	January 3, 2018
End date:	June 29, 2018
Change:	1.06%
Change:	PLN 1.20
Minimum:	PLN 90.20 (May 22, 2018)
Maximum:	PLN 139.00 (January 15, 2018)
Average:	PLN 106,48
Trading volume:	729,421 shares
Average volume:	5,930 shares
Turnover:	78.242 million
Average turnover:	0.636 million



Source: www.gpw.pl

6. OTHER SIGNIFICANT INFORMATION AND EVENTS

6.1. Litigation pending before the court, the competent arbitration body or the public administration body

In the first half of 2018 and until the date of submitting this report, no litigation was in progress before a court, a body competent for arbitration or a public administration body regarding the liabilities and receivables of the Company.

6.2. Other information which is material to the assessment of the human resources, asset and financial position of Mabion S.A., its results and respective changes, and information material to assessing its ability to discharge its liabilities

There is no other information which is material to the assessment of the human resources, asset and financial position of Mabion S.A., its results and respective changes, and information material to assessing its ability to discharge its liabilities.

The Company's Management Board

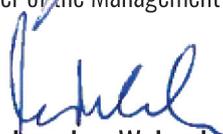
Konstantynów Łódzki, September 13, 2018



Artur Chabowski
President of the Management Board



Sławomir Jaros
Member of the Management Board



Jarosław Walczak
Member of the Management Board

