Mabion S.A.
Management Report for H1 2016

Konstantynów Łódzki, 31 August 2016

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Contents:

1. Selected financials

	in PLN ' 000		in EUR ' 000	
	from 01.01.2016 to 30.06.2016	from 01.01.2015 to 30.06.2015	from 01.01.2016 to 30.06.2016	from 01.01.2015 to 30.06.2015
Net sales of products, goods and materials	0.0	2.727.3	0.0	659.7
Profit (loss) on operating activities	-4 356.8	-1.964.3	-994.6	-475.1
Gross profit (loss)	-4 556.0	-2.084.1	-1 040.1	-504.1
Net profit (loss)	-4 630.3	-1.987.6	-1 057.0	-480.8
Net cash flows from operating activities	-19 499.2	-7.117.6	-4 451.4	-1.721.7
Net cash flows from investing activities	-738.2	-7.794.4	-168.5	-1.885.4
Net cash flows from financing activities	15 078.9	8.010.8	3 442.3	1.937.7
Total net cash flows	-5 158.5	-6.901.2	-1 177.6	-1.669.3
	30.06.2016	31.12.2015	30.06.2016	31.12.2015
Total assets	203 714.9	193 546.9	46 032.1	45 417.5
Liabilities and provisions for liabilities	66 609.5	65 911.2	15 051.3	15 466.7
Long-term liabilities	138.2	155.4	31.2	36.5
Short-term liabilities	16 181.7	12 219.5	3 656.5	2 867.4
Equity	137 105.4	127 635.7	30 980.8	29 950.9
Share capital	1 150.0	1 116.0	259.9	261.9
Number of shares	11 500 000	10 800 000	11 500 000	10 800 000
Earnings (loss) per ordinary share (in PLN/EUR)	-0.65	-0.44	-0.15	-0.10
Diluted earnings (loss) per ordinary share (in PLN/EUR)	-0.65	-0.44	-0.15	-0.10
Book value per share (in PLN/EUR) *	11.93	11.44	2.70	2.59
Diluted book value per share (in PLN/EUR)	11.93	11.44	2.70	2.59
Declared or paid dividend per share (in PLN/EUR)	0	0	0	0

Selected items of the balance sheet presented in EUR were converted according to the average exchange rate of EUR, as announced by the National Bank of Poland (NBP) on 30 June 2016 (4.4255 PLN/EUR) and on 31 December 2015 (4.2615 PLN/EUR). Selected items of the income statement and the statement of cash flows were converted into EUR according to the arithmetic mean of the average exchange rates for EUR, as announced by the National Bank of Poland (NBP) on the last day of each month during the period of 6 months ended on 30 June 2016 and the period of 6 months ended on 30 June 2015 (respectively: 4.3805 PLN/EUR and 4.1341 PLN/EUR).

2. About Mabion S.A.

2.1. Composition of the Management Board and Supervisory Board

In the reporting period and by the date of this report, the composition of the Management Board has not changed, and so as at 31 August 2016, the Board was composed of 4 members:

Maciej Wieczorek	President of the Management Board
Sławomir Jaros	Member of the Management Board
Jarosław Walczak	Member of the Management Board
Artur Chabowski	Member of the Management Board.

In the reporting period, the composition of the Supervisory Board has changed. On 7 June 2016, the Ordinary General Meeting, acting pursuant to Article 385 § 1 of the Code of Commercial Companies and § 21 section 3 of the Articles of Association, appointed Ms Małgorzata Badowska to be a Member of the Supervisory Board as of 7 June 2016. As at 31 August 2016, the Supervisory Board was composed of 7 members:

Robert Aleksandrowicz	Chairman of the Supervisory Board;
Bogdan Manowski	Deputy Chairman of the Supervisory Board;
Grzegorz Stefański	Member of the Supervisory Board;
Jacek Nowak	Member of the Supervisory Board;
Tadeusz Pietrucha	Independent Member of the Supervisory Board;
Tomasz Jasny	Independent Member of the Supervisory Board;
Małgorzata Badowska	Independent Member of the Supervisory Board.

2.2. Consolidated entities

Mabion does not own any shares or stock in other entities. No other circumstances apply either that could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1 item 4) of the Code of Commercial Companies. In H1 2016 Mabion was not involved in a capital group and did not prepare consolidated financial statements.

3. Mabion S.A. business

3.1. Scope of activity

The activity of Mabion is focused on conducting research and development activities which enable the implementation of new biotechnological and biosimilar drugs developed thanks to the achievements of modern genetic engineering. The Company's strategic goal is to develop, manufacture and market drugs used in treatment of cancer, autoimmune and metabolic diseases. The Company is currently developing several drugs which are biosimilar to original medicinal products (so–called reference drugs) available on the market, which are used in the treatment of cancer, autoimmune and metabolic diseases. These include:

- Monoclonal antibody Mabion CD20 – an oncology drug biosimilar to MabTher/Rituxan (where the active substance is rituximab) manufactured by Roche. MabThera/Rituxan is widely used in the treatment of blood cancers (lymphomas, leukaemia) and rheumatoid arthritis;
- Monoclonal antibody MabionHER2 – an oncology drug biosimilar to Herceptin (where the active substance is trastuzumab) manufactured by Roche. Herceptin is used in breast cancer treatment;
- Monoclonal antibody MabionVEGF_Fab – a drug biosimilar to Lucentis (where the active substance is Ranimizumab). Lucentis (Roche) is used in adults in several diseases resulting in vision impairment;
- Monoclonal antibody MabionEGFR – an oncology drug biosimilar to Erbitux (where the active substance is Cetuximab). Erbitux (by Imcolne) is indicated in metastatic colorectal cancer treatment;

» Monoclonal antibody MabionVEGF – an oncology drug biosimilar to Avastin (where the active substance is Bevacizumab). Avastin (Genetech/Roche) is used in adults in cancer treatment (colon or rectal cancer, metastatic breast cancer, metastatic or recurrent lung cancer) along with other anticancer drugs.

Mabion CD20 is the top priority drug which is currently also at the most advanced stage of development among all drugs produced by the Company.

3.2. Summary of the activities conducted by Mabion S.A. in the 1st half of 2016 and until the report publishing date

On 8 January 2016 the Company familiarised itself with the Chief Pharmaceutical Inspector's decision dated 31 December 2015 on granting the permission to Mabion S.A. to "The production of the Investigational Medicinal Product" at the Scientific-Industrial Complex of Medical Biotechnology in Konstantynów Łódzki. The permission granted by the Chief Pharmaceutical Inspector enables the launching of the production of said drug by the Konstantynów Łódzki Complex. The Company announced the receipt of the permission in its current report No. 1/2016.

On 5 February 2016 Mabion received the report on the inspection conducted on 3 February 2016, concerning the fulfilment of the conditions stipulated in the permission to conduct activity in the Łódź Special Economic Zone, in the Research and Development Centre of Biotechnological Medicinal Products at 17, Fabryczna Street. Based on the inspection conducted, it was found that the condition set in the permission, imposing the obligation to incur eligible investment outlays within the Zone, in the minimum amount of PLN 20,000,000, had been fulfilled. As part of its activities conducted within the Zone, the Company is entitled to tax relief in respect of the costs of the investment, provided that the maximum amount of eligible expenses is PLN 30,000,000. The Company has incurred eligible investment outlays in the total amount of approximately PLN 30,000,000 (all covered.). At the same time, the maximum intensity of the regional investment aid in respect of the relief equals 70%, which forms the basis for the Company's enjoying its right to tax relief until 2026, to the amount of 70% of the total maximum eligible costs. The condition which is yet to be fulfilled by the Company refers to maintaining employment of at least 25 workers until the end of 2016. Currently the Company hires over 50 employees in its Centre at 17, Fabryczna Street in Łódź. This condition can therefore be reasonably expected to be fulfilled. The Company announced this fact it its current report No. 4/2016.

On 21 June 2016 the Company's Management Board released information on the current status of clinical trials, indicating an increase, as of 20 June 2016, in the number of patients who already had been administered the drug in both trials:

Trial status as of 11 May 2016	Trial status as of 20 June 2016
NHL » 17 patients covered by the clinical trial procedures, including » 9 patients already administered the drug	**NHL** » 38 patients covered by the clinical trial procedures, including » 28 patients already administered the drug
Rheumatoid arthritis (RA) » 801 patients covered by the clinical trial procedures, including » 583 patients already administered the drug, including 105 patients already administered the drug as part of the PK/PD sub-trial	**Rheumatoid arthritis (RA)** » 887 patients covered by the clinical trial procedures, including » 622 patients already administered the drug, including 141 patients already administered the drug as part of the PK/PD sub-trial, due to recruiting PK/PD patients[1] both in Poland and Ukraine. An extension of cooperation with Ukrainian facilities by including the PK/PD option was aimed at accelerating the recruitment of patients for the purpose of the PK/PD sub-trial.

The above information was published in the current report No. 18/2016.

[1] The PK/PD patients are subjected to additional procedures as part of the clinical trial. They form a group of patients in whom the following parameters are examined:
» PK- plasma drug concentration at different time points;
» PD- lymphocyte level at different time points.

As of the report publishing date (31.08.2016), the status of the clinical trial is as follows:

Trial status as of 31 August 2016
NHL » 91 patients covered by the clinical trial procedures, including » 61 patients already administered the drug
Rheumatoid arthritis (RA) » 965 patients covered by the clinical trial procedures, including » 679 patients already administered the drug, including 203 patients already administered the drug as part of the PK/PD sub-trial.

Considering the above and assuming that the recruitment to the RA trial will continue, it is very likely that the last RA patient will be recruited at the turn of the 3rd and 4th quarter 2016. The NHL trial proceeds smoothly. The recruitment process is regular and proceeds nearly as expected. Ukraine is definitely the most important country in the trial and the access to patients from that country currently determines the recruitment speed. Taking into account the current variables, the last patient should be recruited by the end of the 4th quarter of 2016. Recruitment of the last patient as part of the clinical trial, however, does not mean the trial completion, given that all recruited patients must undergo the entire clinical trial procedure (i.a. drug administration, analysis, and six-month observation period).

On 15 July 2016 (i.e. after the balance sheet day) the Company decided to restrict the inclusion of new patients from the PK/PD sub-group to the MabionCD20 clinical trial in respect of the Rheumatoid Arthritis (RA). This decision resulted from the fact that the number of patients included had exceeded the level indispensable to conducting statistical analyses by the number close to the historic level of "drop outs". The Company's Management Board launched the procedures to verify the completeness of clinical data which is necessary to take a decision on the final closing of the RA recruitment. The Company's decision was published in its current report No. 21/2016.

On 29 July 2016 the Company announced that the talks conducted with three entities having global experience in the marketing, distribution and evaluation of biosimilar drugs, aimed at selecting the exclusive distributor for the sales and marketing of MabionCD20 within the European Union, continued to be at an advanced level. Each of these entities expressed keen interest in Mabion CD20. The Company's aim was to procure the conclusion of a contract with the selected partner within a couple of weeks. The above information was published in the current report No. 22/2016.

On 8 August 2016 the Company's Management Board, having analysed the report on "The analysis of the number of patients who could qualify for the PK analyses as part of the MABRA PK/PD trial" ("the Report"), resolved to close the recruitment of patients for the purpose of the MabionCD20 RZS - PK/PD sub-trial. The decision on closing patients' recruitment for the MabionCD20 RA - PK/PD trial results from the fact that the required number was exceeded by 27%, based on comparing the number of patients required for the PK statistical analysis with the number of patients covered by the MabionCD20 RZS - PK/PD trial, who could be subjected to the statistical analysis as of 8 August 2016. This percentage is higher than the drop-out indicator recorded for the trial (21.2%). This means that the statistical analysis will not be mitigated even if the drop-out indicator exceeds the level recorded as of 8 August 2016.

The Company considered this information significant, given that recruitment for the PK/PD trial is more difficult than in the case of other RA patients and some of the most basic endpoints of the trial are achieved on the basis of the analyses concerning this trial group. The Company's decision was published in its current report No. 24/2016.

In the reporting period Mabion held the consents issued by the competent Regulatory Offices regarding the conduction of the Mabion CD20 - 002 NHL clinical trial, in compliance with the approved protocol, in Poland, Serbia, Moldova, Croatia, Bosnia, Georgia and Ukraine, and it conducted patients' recruitment for the purpose of said trial.

3.3. Transactions with related parties other than arm's length transactions

In H1 2016, the Company and its related parties did not conclude any transactions other than arm's length transactions.

3.4. Information on guarantees, loan sureties and borrowings granted

In H1 2016, the Company did not grant any loan or borrowing sureties or guarantees jointly to a single entity or a subsidiary thereof with the aggregate value of at least 10% of the Company's equity.

3.5. Basic risks and threats for Mabion S.A.

Macroeconomic risk

Adverse changes (if any) in the macroeconomic environment on the markets where the Company plans to sell its medicines, in particular a slowdown in economic growth or reduced expenditure on health may have a negative impact on the Company business and financial performance. Important factors of an economic nature that affect the Company profit include: GDP, average wage, unemployment, inflation and expenditure on health. The Management Board constantly monitors the situation on target markets in an effort to proactively adapt the Company strategy to the changes.

Legal risk (volatility of regulations and legal interpretations)

Frequent regulatory changes that are typical of the Polish legal system may expose the Company to a risk that its business forecasts will become obsolete and its financial condition will deteriorate or even totally collapse. Regulatory changes that have the greatest impact on the Company operations are those related to pharmaceutical, tax and intellectual property law, as they may significantly reshape the Company's legal environment and thus alter its financial results. Another important factor that can affect the Company's prospects for development, actual results and financial condition are the discrepancies in the interpretation of Polish and EU laws. Disparity in legal interpretations by national courts and public agencies and Community courts can have both direct and indirect consequences for the Company.

The Management Board constantly monitors changes in laws and interpretations that are of key importance for the Company in an effort to proactively adapt the Company strategy to such developments.

Risk related to the tax policy

One of the main elements that influence the entrepreneurs' decisions is Polish tax law: frequently changed, imprecise and more often than not suffering from the lack of uniform interpretations. Indeed, practices of fiscal authorities and court decisions on tax issues are all based on vague legal regulations, which translates into an increased business risk in Poland compared to the more stable tax systems in the countries with mature economies. However, tax regulations are gradually harmonised so as to ensure their unequivocal interpretation by enterprises and tax authorities alike.

On 1 January 2016, the Tax Code amendment came into force, which introduced the in dubio pro tributario principle, under which in case of an irremovable doubt as to the meaning of tax regulations, a decision should always be made in favour of the party liable to pay tax. The application of the new clause will allow taxpayers to better protect their rights and interests. This is important for the Company in the context of its activity in the Łódź Special Economic Zone and future tax exemptions on investment expenditure.

On the other hand, the Company's future financial performance may be adversely affected by corporate and personal tax increases. Apart from the fiscal burden, an important element of the tax system is the period after which a tax liability becomes time-barred. It determines how long is the time when tax liability calculations for the period may still be corrected and, in case of infringements, it affects a possibility of declaring that the tax authorities' decision is immediately enforceable. Currently, the tax authorities can audit tax returns for five years after the end of the year in which the time limit for payment expired.

Changes in tax law may also affect a short-term financial liquidity – when the Company operating revenue related to VAT refunds become irregular, as such refunds make a permanent source of the Company's budgetary proceeds.

Risk related to administrative decisions

The Company is not able to warrant that individual authorisations, permits and approvals as may be required for the implementation of biotechnology projects will be obtained nor that any of its current or future authorisations, permits or approvals will remain untouched. A negative development of the state of affairs may either delay the original projects or necessitate their change and so have an adverse impact on the Company business and financial performance.

Foreign exchange risk

The Company purchases laboratory equipment and reagents for its research work mainly in foreign currencies (predominantly EUR and USD). Unfavourable changes in exchange rates (weakening of PLN in relation to foreign currencies) may adversely affect the Company's investment expenditure and increase its R&D spending, which in turn may result in a poorer financial performance. Given that Mabion S.A. intends to sell its medicines in foreign markets (with sales transactions denominated mainly in EUR and USD), the future risk associated with exchange rate fluctuations will be limited. This risk has been reduced to some extent due to a successful completion of an investment project in Konstantynów Łódzki, where some of the suppliers involved were entities from abroad. Nevertheless, it must be borne in mind that costs of Mabion CD20 clinical trials are mainly incurred in EUR. Therefore, there is a risk that the Company's financial performance will deteriorate if the expenditure on MabionCD20 development is incurred at the time when EUR and USD exchange rates are higher, and the future sales of the medicine will take place at the time when these two currencies are weaker.

Market risk

The Company's primary objective is the development, manufacturing and marketing of biosimilars, i.e. biological medicines that are developed to be similar to the original biotech drugs (known as reference medicines). The biotech drug market is very attractive these days, and in the coming years its value should increase even more significantly. However, there is a risk that if reference medicines are withdrawn from the market or replaced with newer generation drugs, the Company's potential revenue on its in-house developed biosimilars will be lower than originally assumed, or that its products will not find buyers at all.

The Management Board constantly monitors the market of reference medicines so as to limit that risk and is ready to start work on other biosimilars.

According to the latest report published by the IMS Institute for Healthcare Informatics, Delivering on the Potential of Biosimilar Medicines, the global biologic medicines market, calculated in net producer prices, is projected to reach 390 billion USD by 2020, by which time biologics will account for 28% by value of the global market for pharmaceuticals. It is believed that this increase will be the result of greater penetration of biosimilars in developed and emerging markets, through a clearly defined regulatory pathways. By 2020, biosimilars have the potential to enter markets for a number of biologics that have current sales of more than 40 billion EUR. The potential savings to health systems in the five major European Union markets and the U.S., as a result of the introduction of biosimilars, could exceed 50 billion EUR in aggregate over the next five years and reach as much as 100 billion EUR[2]. Within the next four years, due to the expiry of patent protection in Europe and U.S., we will witness the emergence of more than 10 blockbuster biologics (i.e. medicines generating the revenue of more than 1 billion USD/year), with annual sales of 60 billion USD.

Reference medicines for biosimilars that Mabion is currently working on rank very high on the lists of drugs with the highest global sales (Cf. PharmaCompass compilation: MabThera/Rituxan – 5th place with the revenue in 2015 amounting to 7.1 billion USD, accounting for an increase by 1.4 billion USD compared to 2014; Herceptin – 8th place, with the revenue in 2015 amounting to 6.6 billion USD, accounting for an increase by 265 million USD compared to 2014).[3]

[2] Ibid.

[3] http://www.pharmacompass.com/pharma-news/top-drugs-by-sales-revenue-in-2015-who-sold-the-biggest-blockbuster-drugs

Risk of inventing and introducing other medicines used for the same indications as Mabion S.A. medicines

Oncological diseases on which the ongoing R&D efforts are focused are the most intensively studied group of diseases in biomedical sciences. It is estimated that approx. 30% of investment on research and development in biomedical companies is in the oncology domain. In addition, we witness a rapid development in the field of genetics and molecular biology. Therefore, it is likely that within a few years the market will see some innovative medicines with better efficacy or tolerability parameters compared to drugs that are currently developed by the Company. In addition, there is a risk that other treatments will be invented, such as vaccines that would be used against the same diseases that are now treated with reference medicines for the Company's future drugs. The emergence of new medicines and therapies could adversely affect the Company future sales revenue and profit.

The Management Board constantly monitors the progress of scientific research on new therapies and medicines for the diseases at which the Company drugs are to be targeted. Furthermore, most of the oncological regimens use the sequencing of treatment (in which a new medicine with a different mechanism of action is only introduced when the potential of the first drug is depleted) and polytherapies (a concomitant use of several drugs with different mechanisms of action), which significantly reduces the risk of erosion of medicines in the fight against cancer.

Competition risk

Medicines that the Company is developing are biosimilars of the original reference medicines that are protected by patents with a commonly known validity periods. From publicly available information it may be easily inferred that at the moment there are many entities that develop biosimilars related to the same original drugs, and works on some of them are already at a very advanced stage. Consequently, there is a risk that when Mabion is ready to market its biosimilar, some of its competitors will be all set to launch their own biosimilar products. This will increase competition (competitive companies may, for instance, be able to market their products at a shorter notice or at lower prices, etc.). Thus, it may be necessary for the Company to review its original assumptions as to the market share or potential revenues. The Management Board constantly monitors the biotech drug market and manufacturers' announcements of new market launches.

According to market reports, the R&D laboratories around the world are now working on 80 monoclonal antibodies, some of which will be on the market within the next decade. In the Company's opinion, most of the work on MabThera biosimilars, especially the medicines that would comply with the EU and U.S. quality requirements either failed or has been withheld. Currently, two entities conduct sufficiently large clinical trials to ensure a relatively low regulatory risk. Their programmes seem to be closer to the regulators' expectations and already are at an advanced stage. These companies are Sandoz[4] and Mabion S.A.

On 12 November 2015, Celltrion filed an application with the European Medicines Agency (EMA) for the registration of CT-P10, a drug developed by the pharmaceutical company as a biosimilar to MabThera/Rituxan. On 24 May 2016, a similar application was filed with the EMA by Sandoz, this time for registration of Rituximab GP2013. These actions, however, were no surprise for Mabion S.A. and had no impact on the Company clinical trial schedule or its strategy for marketing of MabionCD20.

According to its earlier announcements, Mabion S.A. is going to commence the registration procedure for MabionCD20 as soon as clinical trials are completed.

It should be borne in mind that the market of biosimilars is a market with high entry barriers. These include very high requirements for clinical research, especially in the markets of developed countries, in order to prove that the drug is actually biosimilar to the original one. Even if the commercialisation of a biosimilar to MabThera/Rituxan is successful for several entities, the analyses show that the market will still have the growth potential. Although current sales figures for the original drug by Roche are very high, it should be remembered that numerous patients do not have access to that therapy these days. In many countries, treatment with MabThera/Rituxan for patients with NHL is not reimbursed by the public health care system, whereas for patients with RA the access is even more limited.

[4] Clinicaltrials.gov

R&D risk

The biotechnology industry, especially the production of modern biosimilars, is characterised by high labour intensity and the need to incur significant expenditure on research and development. R&D results condition not only a mere possibility of marketing the newly developed drugs but also the efficiency of production processes and, consequently, production costs. Mabion S.A. uses most of its funds for research and development.

There is a risk that some of or all of the Company's research objectives will not be achieved to the full extent planned or within the scheduled time, and so it will be unable to recover some or all of the research outlays. This can have a significant negative impact on the feasibility of the Company's strategic plans and thus its financial performance.

Outcomes of R&D to date confirm that Mabion S.A. is able to manufacture its own biosimilars and, in the Management Board's opinion, significantly reduce the risk of failure. In addition, the Management Board constantly monitors the progress of research and development, and implements some operational and procedural solutions to ensure a high efficiency of the process.

Risk related to underestimating the cost of production and marketing of Mabion CD20

It is generally assumed in the biotechnology industry that it takes about 7-9 years and may cost dozens of millions USD to develop and manufacture a single biosimilar that will comply with global standards. It should be stressed that so far only one second generation biosimilar has been registered: (Inflectra™ monoclonal antibody – a biosimilar to Infliximab). Nevertheless, relevant guidelines are still at a very early stage, with each case reviewed separately by market regulators. Therefore, the requirements for technology, documentation, laboratory analysis and clinical development are not strictly defined. Consequently, it is impossible to accurately predict the scope of the R&D process or the actual cost of the medicine development.

In the opinion of the Company, its policy to develop own R&D competency, invest in own capacities and consult with the European Medicines Agency (EMA) on the clinical programme for Mabion CD20 do allow for a significant reduction in the cost of the development compared to the industry assumptions.

It cannot be ruled out, however, that the actual cost of production and marketing of medicines that are being developed now (including Mabion CD20) will be much higher than currently assumed. A significant increase in the costs of production and marketing of such medicines may negatively influence the Company's financial results.

The industry dynamics with regulations that are still taking shape, or emerging, on the one hand and updated technologies on the other, can be the source of the following situations, which actually may be direct causes for underestimating the cost of production and marketing of the medicines developed by the Company, including Mabion CD20:

- changing regulations on the production of drugs and the necessity to use more expensive technological solutions, or create completely new ones;
- increased costs of raw and other materials used for the production of medicines, necessitated by market conditions or new guidelines;
- changing regulations on the scope of laboratory analysis required for the product characteristics, such as the need to perform additional costly analyses or create new analytical methods or tools;
- increased requirements for registration dossiers, such as the need to conduct additional tests and studies;
- the need to extend the scope of a clinical trial resulting from the biological variability of subjects, response to treatment, drug metabolism, and subjects' or doctors' failure to follow the trial protocol;
- the need to extend the scope of a clinical trial resulting from the biological variability of subjects that turns out to be higher than that stated in the available clinical literature that was a starting point for the clinical trial design;
- increased costs of a clinical trial due to strong competition in the clinical research market and limited availability of research centres and subjects.

Risk related to the work schedule

If the Company wants to achieve its strategic objective, which is the registration and marketing of biosimilars as soon as possible after the expiry of patent protection for original drugs, it must follow a detailed work schedule for several years. The actual feasibility of that schedule is affected by many different factors, of both internal and external nature. If there are any unforeseen delays in the implementation of the adopted schedule, the Company may fail to achieve the sales revenue planned

for a specific time horizon, which will negatively translate into its financial performance. The Management Board oversees all the work associated with the development of new medicines and, if necessary, implements some essential operational solutions to mitigate the impact of unforeseen events on the approved schedules.

Risk of non-completion of research on Mabion CD20 before the expiry of patent protection for the reference drug in the U.S.

In 2007 the Company launched the R&D process for Mabion CD20, which is a drug directly competing with MabThera/Rituxan from Roche that is currently available on the market. The basic patent protection for the drug in Europe expired between the end of 2013 and the end of 2014, whereas in the United States it will expire in 2018.[5]

The Company's objective is to market Mabion CD20 as soon as possible after the expiry of patent protection, which would allow the Company to temporarily achieve a competitive advantage. Delays in recruiting subjects for clinical trials coupled with delays in conducting clinical trials and the time required for the registration of Mabion CD20 (with the procedure typically lasting 210 days in Europe) may all postpone the actual marketing date compared to the Company's current assumptions. This can have a negative impact on the Company's competitive position and thus its financial performance.

The Company used to take and is still taking active steps to reduce the risk related to the registration itself and its extended time: it carried out the Scientific Advice procedure with the European Medicines Agency (EMA) three times already (in December 2011, in November 2012 and in October 2015).

As a result of these consultations, the Company received written responses in which the scope of clinical trials and dossier requirements were agreed. It should be noted that owing to an unusual clinical trial design (focusing on the use of Mabion CD20 for the RA treatment, which significantly distinguishes the trial from those proposed by the majority of competitors) as agreed with the EMA during the scientific advice process, the Company enjoys an advantage both in terms of the basic trial duration and the rate of subject recruitment. The target group in the Mabion CD20 trial is large and widely available, and consequently, the subjects can be recruited quickly. What is more, given the published status of the competitors' research, the Company concludes that even in the event of delays, the scope and scale of its clinical trial are still advantageous.

Risk associated with low quality or loss of biological material

A basic material used in Mabion S.A. products is a biological material. It is either produced independently by the Company or provided by external suppliers. In the development and production of biotech drugs, it is the selection of optimal cell clones that form the basis for further large-scale production that is a factor of paramount importance. A key determinant for the success of scientific work is the quality of biological material and its storage under strict conditions. There is a risk that biological material obtained from external suppliers will be of low quality or that the Company own material will be damaged or destroyed, which in turn could adversely affect the Company's planned revenues and profits.

Mabion S.A. has teamed with reliable market suppliers, controls the quality of supplies and stores biological material in dedicated and monitored equipment with two independent power sources. In addition, the Company keeps the initial deposit of biological material that is used for the production of drugs at an independent location outside Poland, so that if any unexpected event occurs, the production could be resumed at a third-party manufacturer. The Company also monitors the production process and the final product quality by introducing necessary organisational, personnel and technological changes as part of the quality management process improvement. In the reporting period, the Company managed to launch a microbiology lab in Konstantynów Łódzki to work in accordance with the GMP (Good Manufacturing Practice) with the focus on the analyses of microbiological purity of the environment and the product, and the product sterility.

Risk related to the production process

One of the key elements in the production of biotech drugs is that the process must be conducted in compliance with predetermined parameters. The drug manufacturing process comprises several stages and so even the smallest change in any step can affect the product properties (e.g. in terms of efficacy or safety). A very important part of the drug manufacturing process was the transition from a small laboratory scale to industrial scale production (known as up-scaling). It is also essential

[5] www.fiercepharma.com

to ensure the continuity, stability and sterility of the entire production process. Mabion laboratories are equipped with the state-of-the-art apparatus, which ensures the utmost accuracy and repeatability of results. The materials that are used in the manufacturing area have appropriate certificates that confirm their suitability for the use in the pharmaceutical industry. The production line installed is entirely based on sterile materials. The management personnel responsible for individual departments of Mabion S.A. comprises high-level specialists with relevant education and training and appropriately prepared to perform their official duties by both internal and external experts.

In line with the growing needs of the organisation, the Company is constantly strengthening its HR base. At the moment the Company employs nearly 120 people and due to organisational changes implemented in 2015, it is easier for the Company now to closely supervise the work of each team member. The employee performance is monitored on an on-going basis and evaluated in accordance with the established in-house procedures that have proven effective for other departments. In this way, the Company systematically seeks to reduce the level of risk associated with the manufacturing personnel. The team responsible for the manufacturing process management is composed of two persons with divided competences and separate reporting lines. In this way, the processing time for key tasks is optimised, the decision-making process more objective, the information workflow improved and the managers' qualifications used to the maximum.

The Company complies with the requirements of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) and has all the necessary approvals and permits (including the licence of the Chief Pharmaceutical Inspector to manufacture the medicinal products concerned).

Risk related to the capacity/demand balance

Currently, it is difficult to estimate the precise demand for Mabion CD20. Nevertheless, the expectations of Mabion's global partner related to the supply plans to and the sale in the EU and the U.S. may force the Company to increase its current capacity beyond the level that may be achieved in the current facility, located in the Scientific and Industrial Complex in Konstantynów Łódzki. The Company is aware of this risk factor and is able to erect another building in the same location (on the same plot). Such a new building could house predominantly the production process (the current facility also has the office section). If a new construction project is undertaken, the Company will be able to use its investment and technological experience from the previous project. In addition, some industrial systems in the current building could be used in the extension and so extra space will be gained for the installation of the maximum number of bioreactors. Ultimately, the necessity, timing and scope of the investment project will depend on the arrangements with the global partner as to the planned supplies of Mabion CD20 to the EU and the U.S. market.

Risk related to the approvals for the laboratory and the manufacturing plant

A very important factor in the Company operations is the maintenance of appropriate conditions in the areas where the personnel works on the product development. Currently, Mabion is in possession of all required approvals for equipment and for laboratory and manufacturing areas that are used in the R&D Centre in Łódź, at Fabryczna St. However, the Management Board cannot guarantee that the validity of such approvals will be maintained in the future.

Fortunately, the Company has managed to eliminate the risk of non-acceptance or delayed acceptance by the Chief Financial Inspectorate of the Scientific and Industrial Complex in Konstantynów Łódzki. Nevertheless, given the number of stakeholders (diversified supply channels for products and services, human factor etc.), the Management Board cannot guarantee that the validity of such approvals will be maintained in the future.

Risk related to clinical trials

One important preparation stage related to the registration and marketing of medicines are clinical trials involving human subjects.

The Company started the clinical development of Mabion CD20 in 2012, when it submitted its first applications to conduct clinical trials. After obtaining relevant permissions from regulatory agencies, in June 2013 the Company commenced an active recruitment followed by administration of the drug to subjects with rheumatoid arthritis at trial sites in Poland, Lithuania and Georgia. Currently, the Company is authorised to conduct the trials in Poland, Georgia, Serbia, Bosnia, Lithuania and Ukraine.

Clinical trials are always exposed to the risk related to insufficient efficacy or safety of the Investigational Medicinal Product. At the current stage of research, the Company's knowledge suffices to state that the risk for MabionCD20 is moderate.

Mabion regularly submits efficacy and safety data for Mabion CD20 to the Data and Safety Monitoring Board (DSMB). It is an independent body involving rheumatology, pharmacology and statistics professionals. So far the Board held five meetings on the matter (with the last one in December 2015) and every time the trial was positively evaluated and its continuation recommended without having to amend the protocol or procedures. The Board also confirmed a great benefit for the subjects involved. In the event of failure to obtain a favourable opinion from the DSMB, the risk of the trial interruption would apply. Currently, the Company also recruits subjects with lymphoma in the context of the bridging study (MabionCD20-002NHL).

Risk related to drug registration

The primary objective of Mabion is to develop biosimilars and subsequently introduce them to global markets, primarily the EU and U.S. markets, which involves the obligation to register such drugs with the European Medicines Agency (EMA) and Food and Drug Administration (FDA) respectively. It should be noted that drug development and implementation efforts of Mabion S.A. are consistent with the EMA guidelines only, since there are no corresponding FDA guidelines on biosimilars available to date. There is a risk that if some procedural changes are introduced or errors occur in the medicine dossier, the registration process in the European Union may be delayed beyond the planned date or prevented altogether. In addition, there is a risk that future regulations of the FDA prove more strict than the current EMA guidelines. Then Mabion's successfully completed clinical trials will be challenged by the FDA and will have to repeated for drug registration in the United States. If this is the case the Company would have to either incur additional costs or withdraw from the U.S. market, which could have a negative impact on the Company profit.

From the very start of its biosimilar development activities, Mabion S.A. has been cooperating with the EMA to ensure compliance with all guidelines and procedures related to the registration process within the European Union (the third scientific advice process is pending). What is more, it monitors the development of the FDA guidelines for the registration of biosimilars in the United States.

Risk related to marketing and keeping the medicines on the market

Mabion's intention is to market the drugs concerned as soon as they are registered, which requires their preparation to the market product status (production, marketing, distribution and sales) and involves some substantial outlays and organisational preparedness. As the product is unique and the target markets of Mabion S.A. are diverse, the Management Board plans to implement a multi-faceted strategy for the promotion and distribution of its medicine products.

It is assumed that the marketing and distribution efforts in Poland and selected CEE countries will be carried by the Company on its own. In the remaining European countries and other countries in the world, such marketing and distribution activities will be handled by local partners.

There is a risk that the launch of the Company medicines on individual world markets will not take place as planned or that certain oversights and errors in sales, logistics or distribution will make it impossible for the products to remain afloat, which may have a negative impact on Mabion S.A.'s sales revenue and financial performance.

Members of the Management Board and current major shareholders that actively support the Company have a good legal and substantial understanding of the hospital sales process and its organisation, as well as extensive experience in the introduction and maintenance of pharmaceutical preparations on the market. Mabion S.A. is actively seeking experienced partners with a strong marketing and distribution background that could effectively sell Mabion S.A. drugs on local markets worldwide.

At the moment, the Company focuses on looking for distribution partners for its biggest markets (Europe, USA, Canada, Japan and Australia). The activities are outsourced to Plexus Ventures LLC (the Company communicated the arrangement in its Current Report No. 16/2014). The process is complex and lengthy: it involves networking with business partners, signing NDAs and presenting data at different levels of detail, all depending on the process advancement. At the same time, business partners update their own proposals.

In the reporting period, the Company was involved in advanced talks with three entities having global experience in sales, distribution and evaluation of biosimilars – potential partners for the sale and distribution of Mabion CD20 in the European Union. Actually, all these entities expressed great interest in MabionCD20.

Risk related to drug reimbursement

Costs associated with the development and production of the latest generation biosimilars are very high, which translates into a correspondingly high selling price afterwards. On the pharmaceutical market we have drugs the sale of which is reimbursed from the state budget or by other non-budgetary payers. It is the intention of the Management Board to ensure the reimbursement for Mabion S.A.'s products in as many countries as possible – wherever its medicines will obtain marketing authorisations. There is a risk that if this objective is not achieved or is only partially achieved and at the same time the reference drugs or their biosimilars manufactured by the competitors are covered by the reimbursement mechanism, the demand for Mabion S.A. preparations will be smaller than expected and so the Company's sales revenue and financial performance may be negatively affected.

Risk of withdrawal of marketing authorisations for the Company products and the product liability risk in certain situations that are provided for by law, an existing marketing (or manufacturing) authorisation for the product may be withdrawn in the territory.

For example, under Polish law, the Minister of Health withdraws a marketing authorisation for a medicinal product in case of a sudden, severe and adverse reaction to the product that is threatening to human life or health, the lack of a declared therapeutic efficacy, an inadequate therapeutic effect compared to the risk involved, or finding that the medicinal product is marketed in violation of the authorisation or law. If the authorisation for Mabion S.A. medicinal products was withdrawn, this would have a significant negative impact on the Company's development prospects and profit.

Notwithstanding the foregoing, in certain circumstances (for instance, whenever a justified suspicion occurs that the medicinal products do not comply with the applicable requirements), the voivodeship pharmaceutical inspector issues a decision to cease the marketing of certain batches of the product within the area of the inspector's authority.

If this is the case, as well as in other situations where the use of the Company's medicinal products could be harmful to specific entities, Mabion may be liable for damages, which is associated with the risk that relevant claims will be lodged in civil proceedings. The Company may also be held liable if its medicinal products turn out to be hazardous. For example, according to Polish law, a hazardous product is any product that does not offer the safety which can be reasonably expected during its normal use. Whether the product is considered safe depends on the circumstances at the time of its marketing, especially the way in which it is presented on the market, as well as consumer information on the product characteristics. If any claims for damages are lodged against the Company in connection with the above, this could also have a material adverse effect on its business and financial condition.

Risk of losing key employees

Mabion's business is based on the knowledge and experience of its highly skilled managers and scientific and research personnel. However, there is a risk that key employees may leave the Company in the future, which could adversely affect the quality of its products. This in turn could result in the loss of reputation, problems with sourcing new contracts and deterioration of financial results. The Management Board pursues an active HR policy to retain the Company's most valuable talents.
The Company employees are offered comprehensive professional development opportunities, including in-house and external training, support in doctoral studies, promotion paths and benefits – all available via formal, transparent and objective procedures. Specific examples include the promotion schemes, bonus schemes for long serving employees, loyalty programmes and bonus schemes for managers).

Risk related to disclosure of trade secrets

The actual implementation of Mabion's plans may depend on the confidentiality of the Company's confidential information, in particular on research and technological processes. It cannot be ruled out that such information will be disclosed and used by the Company business partners or, in particular, its employees, and so it will become available to and used by competitors. If this is the case, the remedies, defences and claims of the Company may prove to be inadequate to protect it against negative consequences of the disclosure.

Risk related to industrial and intellectual property disputes

Mabion operates in the area where industrial and intellectual property rights and their protection are issues of key importance. There are no pending proceedings regarding infringement of intellectual and industrial property. Also, the Company intends to operate in such a way as to avoid any infringements of such third party rights. It cannot be ruled out that third party claims for infringement of the industrial and intellectual property rights are brought against the Company, especially at the research stage and when the Company is trying to obtain marketing authorisations for its medicinal products. Such claims, even if they prove unfounded, may adversely affect the time required to obtain the said authorisation, and the defence against such claims may require considerable spending, which in turn could negatively affect the Company's financial performance.

Risk related to the funding obtained

The Company is now implementing the project known as "The clinical development and registration of a humanised monoclonal antibody that binds to the HER2 receptor for the treatment of breast cancer." As there are some delays in the project, in November 2015 the Company applied to the National Centre for Research and Development (NCBiR) for an extension of the implementation schedule. This will enable the Company to adapt to the current situation and continue the implementation with full intensity. If the original schedule was adhered to, this would entail the risk of an inefficient use of both third-party and own funds. In the reporting period, the Company negotiated with the NCBiR on a possibility to extend the project implementation period. Until the date of this report, no addendum has been signed to the funding agreement.

As with any project that uses the aid funds, there is a risk that if the Company uses the funding amount, in whole or in part, contrary to the intended purpose or the applicable procedures, or accepts the funding amount, in whole or in part, when it is not due, or accepts funding in an excessive amount, it will be obliged to return the principal amount (in whole or in part) plus interest. Therefore, if any of the liability criteria specified above is fulfilled, the financial standing of the Company may significantly deteriorate, which could in the long run jeopardise the implementation of its corporate strategic objectives.

Liquidity risk

At the moment, the Company does not earn any revenue from sales of market products, and its activities to date have been financed with the share issue money, public funding and, to some extent, with the sale of R&D services. The Board plans to finance the Company's further operations with the proceeds from selling Mabion CD20 distribution rights. If the negotiations linger on, the actual receipt of funds from the distribution partner may be postponed, which in turn could adversely affect the Company's financial results.

Risk related to the operation in the Łódź Special Economic Zone

Mabion S.A. is involved in research, development and manufacturing activities and has built a fully equipped scientific and industrial complex within the area of the Łódź Special Economic Zone. Pursuant to the Act on Special Economic Zones, income derived from an economic activity in special economic zones, as part of the business permit held by the operator, is exempt from corporate income tax. Mabion S.A. remains eligible for the exemption until 31 December 2026. There is a risk that due to the changes in legal regulations on the SEZ operation and exemption criteria, coupled with the Company's failure to achieve the targets specified in the permits (on which tax exemptions are conditional), the ŁSEZ environment may cease to be attractive for the Company business in tax terms or that the Company will lose its entitlement to tax reliefs altogether.

On 5 February 2016 Mabion received a report from the audit that took place on 3 February 2016 and checked whether the Company fulfils the requirements of its permit to operate in the Łódź Special Economic Zone in the Research and Development Centre of Biotech Medicinal Products at 17 Fabryczna St. Since the audit report was positive, it can be stated that the Company's approach to the implementation of the ŁSEZ permit is correct, and so the risk that Mabion will lose its entitlement to future tax reliefs for the facility in Konstantynów is mitigated.

4. Assets and financial position of Mabion S.A.: Overview

4.1. Rules for the preparation of the condensed half-yearly financial statements

The condensed interim financial statements of Mabion S.A. cover the period between 1 January 2016 and 30 June 2016. Comparative information for the income statement and the statement of cash flows covers the period between 1 January 2015 and 30 June 2015, whereas in the case of the statement of changes in equity, also for the period between 1 January 2015 and 31 December 2015. As regards the balance sheet, comparative information consists of figures as at 31 December 2015.

The accounting principles that have guided the preparation of the condensed interim financial statements for the period between 1 January 2016 and 30 June 2016 are in line with the Polish Accounting Act of 29 September 1994 (consolidated text: J. of Laws of 2013, item 330, as amended). As of 1 January 2016, the Company updated its accounting policy. In the opinion of the Management Board, the updated document presents the Company financial and accounting activities in more detail, whereas the accounting principles are now adjusted to the entity's needs and allow for a separate presentation of all events that are important for the assessment of Mabion's assets and financial position. The accounting principles (policy) applied to the preparation of the interim condensed financial statements are consistent with those applied to the preparation of the annual financial statements of Mabion S.A. for 2015.

In view of its organisational changes, starting from January 2016 the Company has been using a new, updated chart for its nominal accounts, which better reflects a unique nature of its business.

Individual items of assets, equity and liabilities are measured at cost (of acquisition), in line with the prudence principle.
In the reporting period, there were no significant changes in estimates.

4.2. Financial position of Mabion S.A. after H1 2016

Sales, costs and profit/loss

The table below shows the breakdown of the Company performance figures for H1 2016 (in PLN):

	01.01 -30.06.2016	01.01 -30.06.2015	Change (in%)
Net sales and equivalent revenue	0.0	2 727 300.5	-100%
Costs of products, goods and materials sold	0.0	2 802 857.8	-100%
Gross profit (loss) on sales	0.0	-75 557.3	-100%
General administrative expenses	5 362 750.8	1 979 822.4	171%
Profit (loss) on sales	-5 362 750.8	-2 055 379.6	161%
Other operating income	1 092 652.4	92 865.7	1077%
Other operating costs	86 708.7	1 802.9	4709%
Profit (loss) on operating activities	-4 356 807.1	-1 964 316.8	122%
Gross profit (loss)	-4 556 037.0	-2 084 117.6	119%
Income tax	74 218.8	-96 496.0	-177%
Net profit (loss)	-4 630 255.8	-1 987 621.6	133%

In 2016 the Company focused on finalisation of MabionCD20 development, therefore, it did not earn any sales revenue.

In the reporting period, the Company recorded the net loss of 4,630,300 PLN. The loss is attributable to increased general administrative expenses, which are not directly related to the Company's development efforts, especially amortisation/depreciation, costs of utility supplies and the property tax for the newly commissioned facility in Konstantynów Łódzki (ŁSEZ).

Costs of the operating activities over the first six months of 2016, by type, were as follows (in PLN):

Costs of operating activities	01.01 -30.06.2016	01.01 -30.06.2015	Change (in%)
Amortisation/Depreciation	3 263 182.9	1 046 838.3	212%
Consumption of materials and energy	6 788 827.3	4 277 442.3	59%
Third party services	10 386 313.8	9 499 941.3	9%
Taxes and charges	256 013.6	70 744.9	262%
Wages and salaries	3 522 793.1	1 546 378.7	128%
Social insurance and other benefits	607 423.0	279 373.7	117%
Other costs by type	96 700.2	138 394.6	-30%
Value of goods and materials sold	0.0	0.0	N/A
TOTAL	**24 921 253.8**	**16 859 113.6**	**48%**
Movements in inventories, products, prepayments and accruals	-19 558 503.0	-12 076 433.4	62%
Own work capitalised (negative figure)	0.0	0.0	N/A
Selling costs (negative figure)	0.0	0.0	N/A
General administrative expenses (negative figure)	-5 362 750.8	-1 979 822.4	171%
Cost of products sold	0.0	2 802 857.8	-100%

Company assets and their financing

Assets	30.06.2016		31.12.2015		Change (in%)
	value	structure	value	structure	
Non-current assets	**197 313 798.74**	**96.86%**	**181 142 038.17**	**93.59%**	**8.93%**
Intangible assets	13 049.99	0.01%	0.00	0.00%	N/A
Property, plant and equipment	69 516 690.00	34.12%	72 054 749.85	37.23%	-3.52%
Long-term receivables	110 138.44	0.05%	110 138.44	0.06%	0.00%
Long-term investments	0.00	0.00%	0.00	0.00%	N/A
Long-term prepayments	127 673 920.31	62.67%	108 977 149.88	56.31%	17.16%

Assets	30.06.2016		31.12.2015		Change (in%)
	value	structure	value	structure	
Current assets	**6 401 093.97**	**3.14%**	**12 404 849.80**	**6.41%**	**-48.40%**
Inventories	3 119 279.60	1.53%	3 119 279.60	1.61%	0.00%
Short-term receivables	1 796 964.23	0.88%	2 693 074.09	1.39%	-33.27%
Short-term investments	915 079.43	0.45%	6 073 559.57	3.14%	-84.93%
Short-term prepayments	569 770.71	0.28%	518 936.54	0.27%	9.80%
Total assets	**203 714 892.71**	**100.00%**	**193 546 887.97**	**100.00%**	**5.25%**

As at 30 June 2016 the assets of Mabion S.A. amounted to 203,714,900 PLN, which accounts for 105.25% of its assets as at 31 December 2015.
The factor that most contributed to the asset increase over the last six months was an increase in long-term prepayments related to the recognition of the development costs thereunder.
Sources of the Company financing include equity, short-term liabilities and accruals. In H1 2016, the equity increase was attributable to the new issue of shares (which was not offset by the need to cover the loss for 2015). Higher liabilities and provisions for liabilities stem from an increase in short-term trade liabilities and borrowings. A decrease in long-term accruals is related to amortisation of earlier subsidies for investment expenditure (debiting to costs of the current period).

Equity and liabilities	30.06.2016		31.12.2015		Change (in%)
	value	structure	value	structure	
Equity	**137 105 435.95**	**67.30%**	**127 635 691.78**	**65.95%**	**7.42%**
Liabilities and provisions for liabilities	**66 609 456.76**	**32.70%**	**65 911 196.19**	**34.05%**	**1.06%**
Provisions for liabilities	2 138 506.81	1.05%	1 271 795.21	0.66%	68.15%
Long-term liabilities	138 212.64	0.07%	155 371.13	0.08%	-11.04%
Short-term liabilities	16 181 659.56	7.94%	12 219 466.51	6.31%	32.43%
Accruals	48 151 077.75	23.64%	52 264 563.34	27.00%	-7.87%
Total equity and liabilities	**203 714 892.71**	**100.00%**	**193 546 887.97**	**100.00%**	**5.25%**

Statement of cash flows

The Company cash flows are summarised in the table below:

	01.01.2016 30.06.2016	01.01.2015 30.06.2015	Change (in%)
Net cash flows from operating activities	-19 499 232.2	-7 117 562.2	174%
Net cash flows from investing activities	-738 173.1	-7 794 380.8	-91%
Net cash flows from financing activities	15 078 925.1	8 010 766.9	88%
Total net cash flows	**-5 158 480.1**	**-6 901 176.1**	**-25%**

In H1 2016 the Company recorded the loss on its operating activities. The most important factor behind the operating flow figure was an increased balance of prepayments (related to capitalisation of development costs).

Owing to the completion of the investment project in Konstantynów Łódzki, cash flows from investing activities were much lower than in the corresponding period last year.

The Company's considerable positive cash flows from financing activities result from the acquisition of shareholder borrowings, with the money converted into new shares.

Selected measures for the assessment of the Company's financial position

Liquidity ratios	Measure	30.06.2016	31.12.2015	Calculation algorithm
current	multiplication factor	0.40	1.02	current assets/short-term liabilities
quick	multiplication factor	0.17	0.72	(current assets – inventories – short-term prepayments)/short-term liabilities
cash	multiplication factor	0.06	0.50	cash/short-term liabilities

Profitability ratios	Measure	01.01.2016 -30.06.2016	01.01.2015 -30.06.2015	Calculation algorithm
Return on sales (ROS)	%	N/A	-75.36%	profit on sales/sales revenue
Operating profit margin	%	N/A	-72.0%	operating profit/sales revenue
Net profit margin	%	N/A	-72.9%	net profit/sales revenue
Return on assets (ROA)	%	-2.3%	-1.2%	net profit/total assets
Return on equity (ROE)	%	-3.4%	-2.0%	net profit/equity

Debt ratios	Measure	30.06.2016	31.12.2015	Calculation algorithm
total debt ratio	%	8.0%	6.4%	short- and long-term liabilities/total assets
debt to equity ratio	%	48.6%	51.6%	liabilities and provisions for liabilities/equity
long-term debt ratio	%	0.1%	0.1%	long-term liabilities/total assets

4.3. Description of factors and events with material effect on the condensed financial statements

In the reporting period, there were no events of an untypical nature that could have a significant influence on the Company's condensed financial statements.

4.4. Factors which will influence the financial performance for at least the upcoming six months

Revenues in the upcoming settlement periods will be closely correlated with the contracts on the registration or distribution of Mabion CD20 (just signed or already performed). The revenue figure may also be influenced by delays (if any) in the talks with prospective partners or by unexpected deviations from schedules to the existing contracts.

4.5. Position of the Management Board on the feasibility of the previously published performance forecasts for the year

The Management Board has decided to revoke its financial forecasts (prepared on the introduction of I-series shares to the alternative trading system and published in 2010). The Board also resigned from announcing any financial forecasts.

5. Shares and shareholders

5.1. Ownership of the share capital

As at 30 June 2016, the Company share capital amounted to 1,150,000 PLN and was divided into 11,500,000 shares with a par value of 0.10 PLN each, including:

- 450,000 A-series registered preference shares;
- 450,000 B-series registered preference shares;
- 450,000 C-series registered preference shares;
- 450,000 D-series ordinary bearer shares;
- 100,000 E-series registered preference shares;
- 100,000 F-series registered preference shares;
- 20,000 G-series registered preference shares;
- 2,980,000 H-series ordinary bearer shares;
- 1,900,000 I-series ordinary bearer shares;
- 2,600,000 J-series ordinary bearer shares;
- 790,000 K-series ordinary bearer shares;
- 510,000 L-series ordinary bearer shares;
- 360,000 M-series ordinary bearer shares;
- 340,000 N-series ordinary bearer shares.

A-, B-, C-, E-, F- and G-series shares are multiple-vote shares, giving the holder two votes at the General Meeting. The total number of votes resulting from all issues amounts to 13,070,000 votes.

On 18 May 2016 the Company, Twiti Investments Ltd. and Glatton Sp. z o.o. signed preliminary agreements for the acquisition of not more than 200,000 and 100,000, respectively, O-series ordinary bearer shares at the issue price of 47 PLN per share. In accordance with the agreements, O-series shares were to be acquired by investors, provided that the Management Board adopted a resolution on an increase in the Company share capital within the authorised share capital, pursuant to the authorisation granted to the Board by the Extraordinary General Meeting on 30 September 2015. On 23 May 2016, the Management Board, acting pursuant to § 9a section 1 of the Articles of Association, adopted the resolution on an increase in the Company share capital within the authorised share capital by offering O-series shares with the pre-emptive right excluded. The issue price of O-series shares was determined with the approval of the Supervisory Board and amounted to 47 PLN per share. On 24 May 2016, the Company concluded the following agreements concerning the acquisition of O-series ordinary bearer shares for the unit issue price of 47 PLN:

- an acquisition agreement with Twiti Investments Ltd., under which Twiti Investments Ltd. acquired 200,000 O-series shares;
- an acquisition agreement with Glatton Sp. z o.o., under which Glatton Sp. z o.o. acquired 100,000 O-series shares.

All shares were fully paid up. The actual payment was effected by contractual offsetting of claims under the acquisition agreements with the Company's liabilities under borrowing agreements with the above-mentioned entities, whereas the remaining amount was paid in cash. The agreements were concluded in the implementation of the preliminary agreements referred to above.

On 4 July 2016, the District Court for Łódź-Śródmieście (Łódź City Centre) in Łódź, XX Division of the National Court Register (KRS) registered an increase in the Company share capital from 1,150,000 PLN to 1,180,000 PLN following the issue of 300,000 O-series ordinary bearer shares.

As at the date of this report, the Company share capital amounts to 1,180,000 PLN and is divided into 11,800,000 shares with a par value of 0.10 PLN each, including:

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

A-, B-, C-, E-, F- and G-series shares are multiple-vote shares, giving the holder two votes at the General Meeting. As at the date of this report, the total number of votes resulting from all issues amounts to 13,370,000 votes.

5.2. Shareholders holding at least 5% of the total votes

Shareholders as at the date of the report for H1 2016

To the knowledge of the Management Board, as at the date of the report for H1 2016 (31 August 2016), the shareholders holding at least 5% of the total votes at the Company's General Meeting of Shareholders are:

Shareholders with a stake of more than 5%	Number of shares	% of share capital	Number of votes	% of votes held
1. Twiti Investments Limited	2 499 457	21.18%	3 078 757	23.03%
2. Maciej Wieczorek, indirectly, including via:	1 624 876	13.77%	2 117 726	15.84%
- Glatton Spółka z o.o.*	1 004 526	8.51%	1 004 526	7.51%
- Celon Pharma S.A.*	620 350	5.26%	1 113 200	8.33%
3. Polfarmex S.A.	1 437 983	12.19%	1 920 333	14.36%
4. Funds managed by Amathus TFI S.A.	988 042	8.37%	988 042	7.39%
5. Generali OFE**	893 930	7.58%	893 930	6.69%
6. Other shareholders	4 355 712	36.91%	4 371 212	32.69%

* *Mr Maciej Wieczorek holds 100% in the share capital of Glatton Sp. z o.o. and indirectly, via Glatton Sp. z o.o., 100% in Celon Pharma S.A.*

** *In accordance with the list of shareholders at the Ordinary General Meeting held on 7 June 2016.*

Shareholders as at the date of the report for Q1 2016

To the knowledge of the Management Board, as at the date of the report for Q1 2016 (11 May 2016), the shareholders holding at least 5% of the total votes at the Company's General Meeting of Shareholders (before the issue of O-series shares) were:

Shareholders with a stake of more than 5%	Number of shares	% of share capital	Number of votes	% of votes held
1. Twiti Investments Limited	2.294.457	19.95%	2.868.757	21.95%
2. Maciej Wieczorek, indirectly, including via:	1.524.876	13.26%	2.017.726	15.44%
- Glatton Spółka z o.o.*	904.526	7.87%	904.526	6.92%
- Celon Pharma S.A.*	620.350	5.39%	1.113.200	8.52%
3. Polfarmex S.A.	1.437.983	12.50%	1.920.333	14.69%
4. Funds managed by Amathus TFI S.A.	988.042	8.59%	988042	7.56%
5. Generali OFE**	892.244	7.76%	892.244	6.83%
6. Other shareholders	4.362.398	37.93%	4.382.898	33.53%

** Mr Maciej Wieczorek holds 100% in the share capital of Glatton Sp. z o.o. and indirectly, via Glatton Sp. z o.o., 100% in Celon Pharma S.A.*

*** As at 31/12/2015 according to the report of Generali OFE*

5.3. Summary of shareholding by managers and supervisors

	Shareholding as at the date of the report for H1 2016 (31 August 2016)	Shareholding as at the date of the report for Q1 2016 (11 May 2016)
Management Board		
Maciej Wieczorek	indirectly, via Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds, indirectly, via Glatton Sp. z o.o. 100% of the share capital) holds the total of 1,624,876 shares in the Company with a par value of 0.10 PLN each, accounting for 13.77% of the Company share capital and 15.84% of votes at the General Meeting.	indirectly, via Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds, indirectly, via Glatton Sp. z o.o. 100% of the share capital) holds the total of 1,524,876 shares in the Company with a par value of 0.10 PLN each, accounting for 13.26% of the Company share capital and 15.44% of votes at the General Meeting.
Artur Chabowski	indirectly, via FL Real Investments Holding Limited based in Nicosia (Cyprus), in which Artur Chabowski holds 100% of the share capital, holds the total of 29,649 shares in the Company with a par value of 0.10 PLN each, accounting for 0.25% of the Company share capital and 0.22% of votes at the General Meeting.	indirectly, via FL Real Investments Holding Limited based in Nicosia (Cyprus), in which Artur Chabowski holds 100% of the share capital, holds the total of 29,649 shares in the Company with a par value of 0.10 PLN each, accounting for 0.26% of the Company share capital and 0.23% of votes at the General Meeting.
	Shareholding as at the date of the report for H1 2016 (31 August 2016)	Shareholding as at the date of the report for Q1 2016 (11 May 2016)

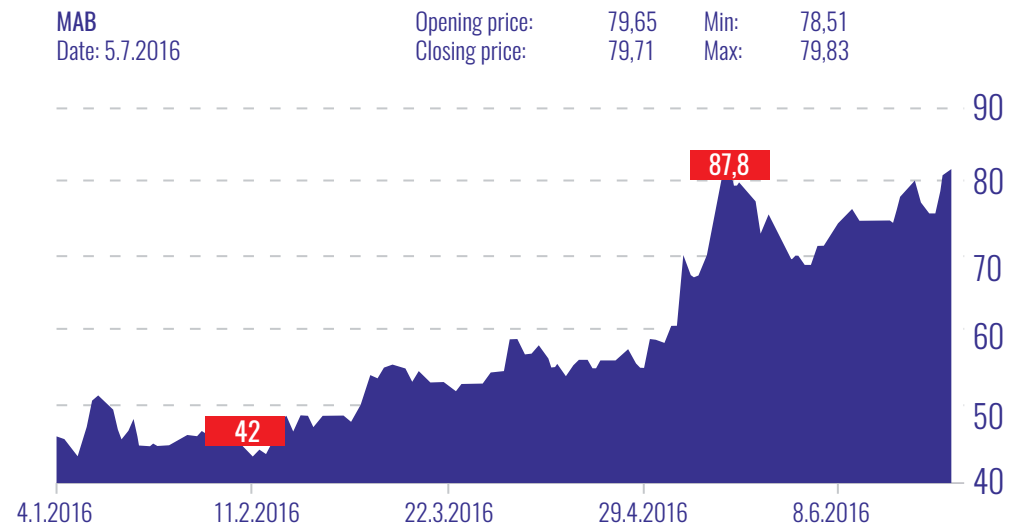
	Shareholding as at the date of the report for H1 2016 (31 August 2016)	Shareholding as at the date of the report for Q1 2016 (11 May 2016)
Supervisory Board		
	directly holds the total of 128,184 ordinary bearer shares with a par value of 0.10 PLN each, accounting for 1.09% of the Company share capital and 0.96% of votes at the General Meeting;	directly holds the total of 128,184 ordinary bearer shares with a par value of 0.10 PLN each, accounting for 1.11% of the Company share capital and 0.98% of votes at the General Meeting.
Robert Aleksandrowicz	indirectly, via Twiti Investments Limited based in Nicosia (Cyprus), in which Robert Aleksandrowicz holds 50% of the share capital and 50% of votes at the general meeting of that company, is a shareholder in Mabion and holds the total of 2,499,457 shares in the Company with a par value of 0.10 PLN each, accounting for 21.18% of the Company share capital and 23.03% votes at the General Meeting.	indirectly, via Twiti Investments Limited based in Nicosia (Cyprus), in which Robert Aleksandrowicz holds 50% of the share capital and 50% of votes at the general meeting of that company, is a shareholder in Mabion and holds the total of 2,294,457 shares in the Company with a par value of 0.10 PLN each, accounting for 19.95% of the Company share capital and 21.95% votes at the General Meeting.
Tadeusz Pietrucha	indirectly, via Bio-Tech Consulting Sp. z o.o. based in Łódź (in which Tadeusz Pietrucha holds 97% of the share capital) holds the total of 15,000 shares in the Company with a par value of 0.10 PLN each, accounting for 0.13% of the Company share capital and 0.22% of votes at the General Meeting.	indirectly, via Bio-Tech Consulting Sp. z o.o. based in Łódź (in which Tadeusz Pietrucha holds 97% of the share capital) holds the total of 20,005 shares in the Company with a par value of 0.10 PLN each, accounting for 0.17% of the Company share capital and 0.31% of votes at the General Meeting.

Other managers and supervisors did not and do not hold any shares or rights to shares in the Company in the period between the date of the report for Q1 2016 and the date of this report.

5.4. Share quotations on the Warsaw Stock Exchange

In H1 2016:

Reference exchange rate:	46.96 PLN (15-12-30)
Start date:	2016-01-04
End date:	2016-06-30
Change:	73.55%
Change:	34.54 PLN
Minimum:	42.00 PLN (16-02-11)
Maximum:	87.80 PLN (16-05-18)
Average:	58.31 PLN
Trading volume:	915,981
Average volume:	7387
Turnover:	60.3 million
Average turnover:	0.486 million



Source: www.gpw.pl

6. Other material information and events

6.1. Procedures pending before courts, competent arbitration authorities or public administration authorities

In H1 2016 and until the date of this report there were no proceedings pending before courts, competent arbitration authorities or public administration authorities whose individual or aggregate value would equal at least 10% of the Company equity.

6.2. Other information that might be important for the assessment of the Company's human resources, assets, financial position, profit/loss and changes thereof, as well as any information considered significant in order to assess Mabion S.A.'s capacity to meet its obligations.

There is no other information that might be important for the assessment of the Company's human resources, assets, financial position, profit/loss and changes thereof or information considered significant in order to assess Mabion S.A.'s capacity to meet its obligations.

6.3. Other events

On 8 January 2016, the Company returned to the National Centre for Research and Development (NCBiR) the amount of 3.1 million PLN, received earlier as an advance payment for the implementation of the project: "The clinical development and registration of a humanised monoclonal antibody that binds to the HER2 receptor for the treatment of breast cancer." within the framework of the INNOMED programme. The return was related to the settlement of phase I of the project. The advance payment covered the scope of work that the Company was unable to accomplish at that time. It includes the activities related to the recruitment of subjects with breast cancer in the clinical trial MabionHER2, which the Company has not completed yet. The Company wrote to the agency responsible for settlements of the delays in the implementation and requested for an extension of the Project, which is currently being negotiated with NCBiR.

On 1-2 February 2016 and on 23 March 2016 the Company laboratory in Łódź at 17 Fabryczna St was audited for compliance with the principles of Good Laboratory Practice (GLP) by the Bureau for Chemical Substances. The audit confirmed the laboratory's compliance with GLP, including in terms of reliability of test results (since the planning stage) and correct storing of source data and reports in such a way as to allow for a comprehensive traceability and reproducibility of tests. As a result the laboratory certification was upheld.

The GLP certificate confirms a high level of testing quality and reliability, and do it is not necessary to repeat the tests in the Member States of the Organisation for Economic Cooperation and Development (OECD).

On 22 February 2016, in Warsaw, the Company held a meeting for individual and institutional investors during which it discussed current events at Mabion S.A. and the Company plans for 2016.

By the end of March 2016, the Company had managed to launch a microbiology lab in Konstantynów Łódzki to work in accordance with the GMP (Good Manufacturing Practice) with the focus on the analyses of microbiological purity of the environment and the product, and the product sterility. This was significant progress in the planned tasks of the Quality Control Department.

On 9 and 10 May 2016, the representatives of Mabion S.A. took part in BioForum – another edition of the most important event in the Polish biotechnology industry. Later on, on 16 May, Mabion – as the leading Polish biotechnology company – presented itself during the second edition of the Polish Capital Markets Conference held in New York and organised by the Warsaw Stock Exchange, IPOPEMA Securities and Auerbach Grayson. The conference was to promote Polish companies and the Polish market among a broadly ranging group of American investment vehicles. Mabion had the opportunity to present its latest achievements, strategies and prospects during several dedicated meetings. It was also an opportunity to establish new business relationships with the best industry managers in the U.S.

In May 2016 the Company received a letter from the Polish Agency for Enterprise Development (PARP) communicating the acceptance of its report on the implementation of industrial research and development work, together with the economic analysis and market research related to the implementation of the project: "Innovative technology of double cutting for obtaining modern analogs of human insulin". The Agency also stated that the results obtained did not have to be implemented under the funding agreement. Accordingly, the Company was released from the obligation to implement the results of its industrial research or development work in the form, scope and within the time limits specified in the funding application.

On 7 June 2016 the Supervisory Board selected PricewaterhouseCoopers Sp. z o.o. with its registered office in Warsaw, Al. Armii Ludowej 14 to be a statutory auditor of the financial statements for 2016. PricewaterhouseCoopers Sp. z o.o. has been entered on the list of entities authorised to audit financial statements, kept by the National Council of Statutory Auditors (KRBR) under No. 144. The auditor was selected in line with the applicable laws and professional standards. The Company has used the entity's services before: it reviewed the interim statements for the period: 1 January 2015 – 30 June 2015 and audited the annual statements for 2015.

On 24 June 2016 the National Labour Inspectorate (PIP) in Łódź delivered a favourable opinion on Mabion's compliance with the OHS requirements as regards the facilities, rooms, workstations and work processes at the Company location in Konstantynów Łódzki at 60 gen. Mariana Langiewicza St.

Then, on 27 June 2016, the State Sanitary Inspector for the Voivodeship in Łódź issued a decision in which the authority gave a positive opinion on compliance with the work hygiene requirements in the contained use of Class 1 GMO at the Company headquarters in Łódź, at 17 Fabryczna St and the location in Konstantynów Łódzki, at 60 gen. Mariana Langiewicza St.

These decisions were necessary for the Company to apply for the status of a genetic engineering plant from the Ministry of the Environment. The Company currently expects a relevant ministerial decision.

In the period between 27 June and 18 July 2016, the Company announced public consultations on granting an integrated permit to operate a plant. This is the last phase of the approval process of the Company's application related to the facility in Konstantynów Łódzki, filed with the Marshal's Office in Łódź.

In the reporting period, the Company continued with its efforts to launch a large-scale production in Konstantynów Łódzki. From January to June 2016 the Company carried out intensive process testing of the production line for commercial manufacturing of monoclonal antibodies in Konstantynów Łódzki. In the period from April to June, a technological batch was run in a mixed system, with 2x250 l bioreactor production followed by the product purification on the commercial line. This is the first of the two-step technology transfer process, when it is assessed how the change in the place of manufacture itself influences the product. The second step will be a change in the scale of bioreactor production. The first series will be run in Q4 2016.

On 27 April 2016 a licence agreement (the Agreement) expired with Biolotus Biotech, based in Rio de Janeiro (Biolotus). The Agreement concerned the intended cooperation between Mabion S.A. and Biolotus on the registration, analysis and sales of Mabion CD20 in Brazil and, in the longer term, handling the entire medicine production process in that country – up to the final product stage.

In the reporting period, the parties have chosen not to sign new agreements.

In August 2016 Laboratorio LKM S.A. (Argentina) terminated the distribution agreement for Mabion CD20 in the territory Argentina. At the moment the Company considers the EU and U.S. to be its main target markets for Mabion CD20, which does not exclude, however, the acquisition of distributors elsewhere, including on the Argentinean market, depending on market conditions and the Company's future standing.

Management Board

Konstantynów Łódzki, on 31.08.2016

President of the Management Board
Maciej Wieczorek

Member of the Management Board
Jarosław Walczak

Member of the Management Board
Sławomir Jaros

Member of the Management Board
Artur Chabowski