# Mabion S.A.
## Directors' Report
## for the first half of 2019

Konstantynów Łódzki, 12 September 2019

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# 1. Selected financial data

| | in PLN thousand | | in EUR thousand | |
|---|---|---|---|---|
| | from 01.01.2019 to 30.06.2019 | from 01.01.2018 to 30.06.2018 | from 01.01.2019 to 30.06.2019 | from 01.01.2018 to 30.06.2018 |
| Net revenues from sales of products, goods and materials | 0 | 0 | 0 | 0 |
| Profit (loss) on operating activities | -32252 | -36 889 | -7521 | -8 701 |
| Gross profit (loss) | -31696 | -41 182 | -7392 | -9 714 |
| Net profit (loss) | -31696 | -41 182 | -7392 | -9 714 |
| Weighted average number of shares (in pcs.) | 13 720 772 | 12 447 332 | 13 720 772 | 12 447 332 |
| Profit (loss) per ordinary share (in PLN/EUR) | -2.31 | -3.31 | -0.54 | -0.78 |
| Diluted profit (loss) per ordinary share (in PLN/EUR) | -2.31 | -3.31 | -0.54 | -0.78 |
| Net cash flows from operating activities | -19324 | -34 214 | -4495 | -8 070 |
| Net cash flows from investing activities | -7041 | -2 362 | -1654 | -557 |
| Net cash flows from financial activities | -1243 | 103 635 | -290 | 24 445 |
| Total net cash flows | -27608 | 67 059 | -6438 | 15 818 |
| | 30.06.2019 | 31.12.2018 | 30.06.2019 | 31.12.2018 |
| Total assets | 117954 | 144717 | 27741 | 33655 |
| Liabilities and provisions for liabilities | 107524 | 102578 | 25288 | 23855 |
| Long-term liabilities | 42313 | 36069 | 9951 | 8388 |
| Short-term liabilities | 65211 | 66509 | 15337 | 15467 |
| Equity | 10430 | 42139 | 2453 | 9800 |
| Share capital | 1372 | 1372 | 323 | 319 |
| Number of shares (in pcs.) | 13 720 772 | 13 720 772 | 13 720 772 | 13 720 772 |
| Book value per share (in PLN/EUR)* | 8.60 | 11.06 | 2.02 | 2.57 |
| Diluted book value per share (in PLN/EUR) | 8.60 | 11.06 | 2.02 | 2.57 |
| Declared or paid dividend per share (in PLN/EUR) | 0.00 | 0.00 | 0.00 | 0.00 |

* *Assets in total/ Weighted average number of shares*

Selected balance sheet items presented in EUR were converted according to the average EUR exchange rate announced by the National Bank of Poland as at 30 June 2019 (PLN/EUR 4.2520) and 31 December 2018 (4.3000 PLN/EUR). Selected items in the profit and loss account and cash flow statement were converted into EUR at the exchange rate being the arithmetic mean of average exchange rates for EUR announced by the National Bank of Poland, in force on the last day of each month in the period of 6 months ended 30 June 2019 and 6 months ended 31 June 2018 ( PLN/EUR 4.2880 and PLN/EUR 4.2395, respectively).

# 2. Information about Mabion S.A.

## 2.1. Composition of the Management Board and Supervisory Board

From 2 January 2019 to 30 June 2019 The Management Board of the Company consisted of 4 members:
» Artur Chabowski - President of the Management Board,
» Sławomir Jaros - Member of the Management Board,
» Jarosław Walczak - Member of the Management Board,
» Grzegorz Grabowicz - Member of the Management Board.

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

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

From 1 July 2019 until the date of publication of this report, the composition of the Company's Management Board is as follows:
» Sławomir Jaros - Member of the Management Board,
» Jarosław Walczak - Member of the Management Board,
» Grzegorz Grabowicz – Member of the Management Board.



During the reporting period and until the date of submitting this report, the composition of the Company's Supervisory Board did not change and as at 12 September 2019 the Company's Supervisory Board consisted of 8 members:
» Maciej Wieczorek - Chairman of the Supervisory Board,
» Józef Banach - Deputy Chairman of the Supervisory Board, Independent Member of the Supervisory Board,
» Tadeusz Pietrucha - Independent Member of the Supervisory Board,
» Jacek Piotr Nowak - Member of the Supervisory Board,
» David John James - Independent Member of the Supervisory Board,
» Robert Koński - Independent Member of the Supervisory Board,
» Krzysztof Kaczmarczyk - Independent Member of the Supervisory Board,
» Dirk Kreder - Independent Member of the Supervisory Board.

## 2.2. Entities subject to consolidation

Mabion S.A. does not own any shares of other entities. Also, there are no other situations that could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1 point 4) of the Commercial Companies Code. In the first half of 2019, Mabion did not form a capital group and did not draw up consolidated financial statements.

# 3. Operations of Mabion S.A.

## 3.1. Scope of activities

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

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

### Active projects

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

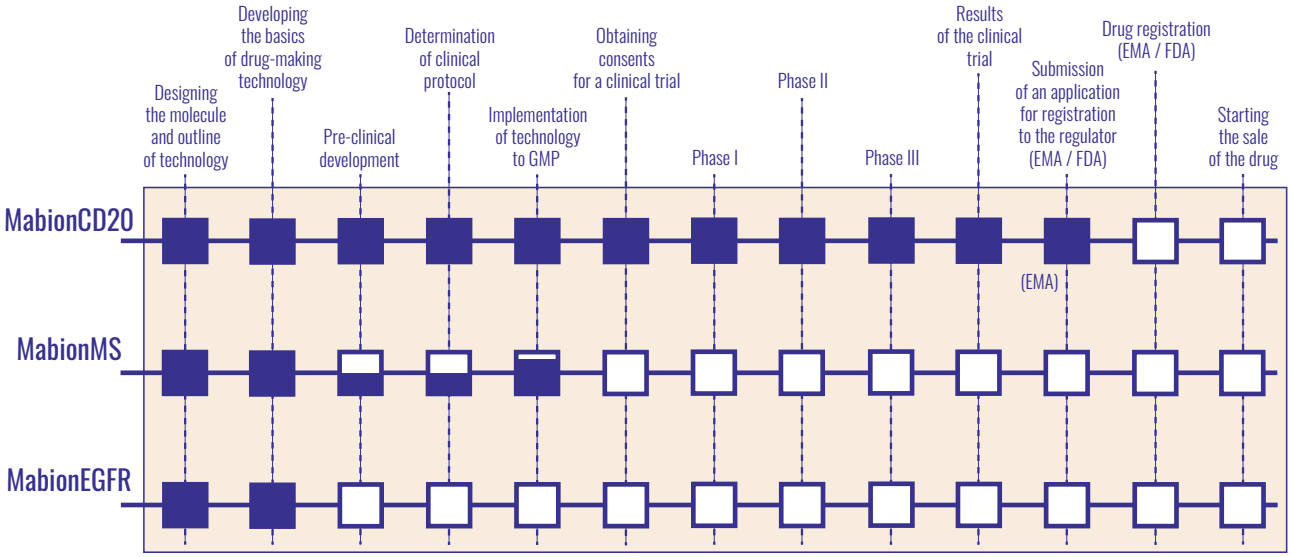
### New projects planned for 2019

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

### Partnership projects

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

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




### The MabionCD20 project

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

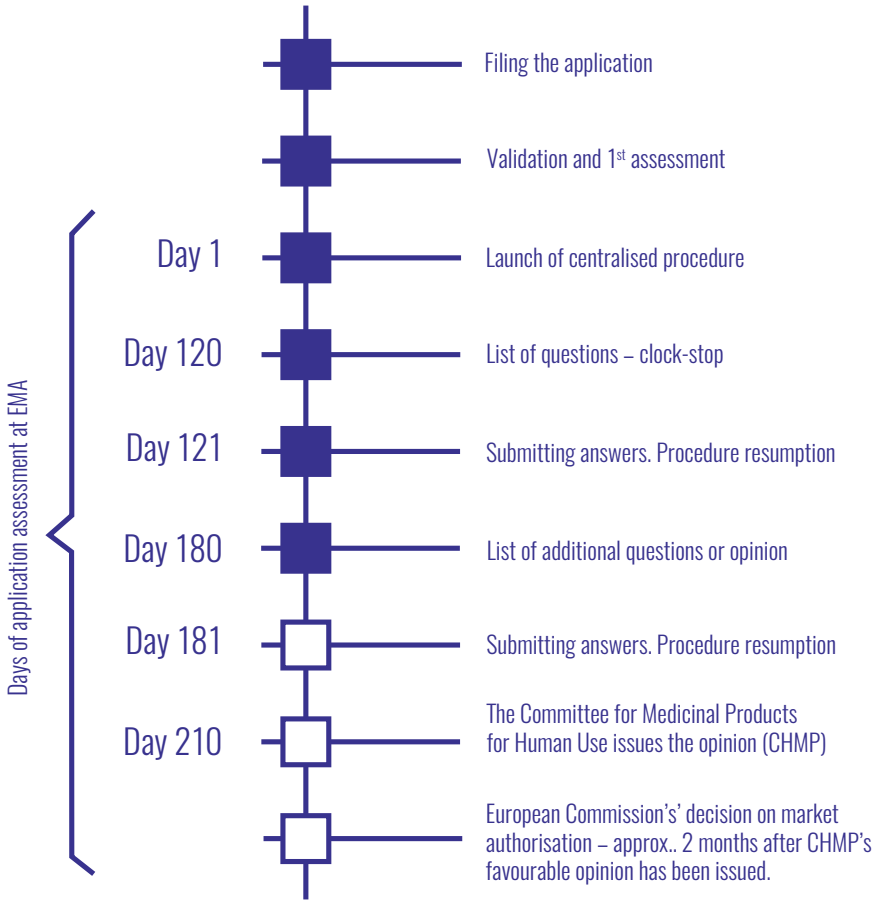
[1] Reference medicine Prolia - indications: osteoporosis, value of sales in 2018 approx. USD 2.3 billion (based on Global Data). The patent for Prolia expires in Europe in 2022 (except for France, Italy, Spain and the United Kingdom where it expires in 2025), and in the USA in 2025. Several entities are currently working on a biosimilar version of the medicine (http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab).

[2] Reference medicine Xgeva - indications: prevention of bone complications (pathological fractures, necessity to irradiate bones, spinal cord pressure or necessity to perform bone surgery) in adults with solid tumur metastases to bones. Sales value in 2018: approx. USD 1.7 billion (based on Global Data).The patent for Xgeva drug expires in Europe in 2022 (except France, Italy, Spain and the United Kingdom where it expires in 2025), and in the USA in 2025. Currently, several entities are working on a biosimilar version of the medicine (http://gabionline.net/Biosimilars/General/Biosimilars-of-denosumab).

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

On 24 April 2019, the Company filed answers to the EMA's questions received as part of Day 120 stage of the registration procedure for MabionCD20 with the EMA. The submission of answers to the EMA's questions allowed the procedure to resume and the Agency to continue its assessment of the application. On 1 July 2019, the EMA submitted to the Company the second round of questions as part of the drug registration procedure (Day 180). Answering these questions will be one of the last steps towards a final decision by the European regulator. As of the date of approval of this report for publication, the Company is at the stage of analysing the questions and preparing the answers.

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




Should a favourable decision of the European Commission on the marketing authorisation be obtained, the Company will apply for a post-registration change in the form of a dossier to increase the scale of production to 2x2500L of culture volume in a bioreactor. The application submitted to the EMA in 2018 concerned the clinical scale of bioreactor breeding, however it covered the manufacturing process already after the transfer from the plant at Fabryczna Street to the commercial manufacturing plant in Konstantynów Łódzki. Post-registration changes are a typical element of cooperation with the regulatory authority after obtaining the original registration, and may concern changes in scale, manufacturing sites, process improvements, additional manufacturing sites, etc. This is a customary practice of pharmaceutical companies (e.g. MabThera has undergone 44 post-registration reviews[4]).

In June 2018, the Company received a summary from the U.S. Food and Drug Administration (FDA) following a Type 2 BPD (Biosimilar Biological Product Development) meeting. The meeting was aimed at providing an initial, general presentation of the MabionCD20 development data collected by the Company with respect to the reference drug MabThera, as well as at identifying key issues regarding the feasibility of starting cooperation with the Administration on the basis of these data to obtain MabionCD20 registration in the United States. According to the summary, the Administration allowed for the possibility of using the data held by the Company to support the application process. At the same time, it proposed an overall strategy to link the product registered

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

in the European Union (MabThera) to the product authorised in the USA (Rituxan). On the basis of data available at that time, the Administration did not indicate the need for a completely separate process for the development of MabionCD20 for the US market. It has been agreed that a Type 3 BPD meeting is required, for which a complete set of clinical data for the US market is necessary, before a dossier can be submitted. This requires a bridging test and additional analytical tests. The Company has been admitted to parallel stages of the consultation process, the aim of which is to specify the requirements of the FDA, also in non-clinical areas, e.g. analytical area. The US registration and authorisation process for MabionCD20 is a multi-step process and it cannot be excluded that additional requirements for FDA approval may arise in the future.

The Company has completed work related to the preparation of a clinical trial protocol based on the existing arrangements with the FDA. This work was carried out in cooperation with Parexel, a contract research organisation (CRO), having extensive experience in clinical trials of biosimilar drugs, including rituximab. In addition, in the reporting period, work began on the preparation of "Briefing Package", including the study protocol and analytical characteristics of the key quality attributes of MabionCD20, MabThera and Rituxan products. The documentation is to confirm the type of meeting with the FDA (Type 3 BPD meeting), as well as allow to verify and confirm the project assumptions. For further communication and proceedings with the FDA, bridge research and additional analytical research are the necessary. The aim of the research is to compare European MabThera to American Rituxan (bridging study), while using MabionCD20 as a bridging arm. The study will enable to obtain some kind of "bridge" to the results of the comparative study of MabionCD20 and MabThera conducted by the Company.

In order to commence the bridging study, the Company, based on the study protocol, must obtain the consent of competent authorities and the consent of bioethics committees. At the same time, the Company must ensure financing for the study, which is a necessary condition for its commencement and thus determines the date of its performance. The funds for the implementation of the above assumptions may originate from a potential distribution partner, from EU funds or other sources. As far as US partners are concerned, the Company's potential partner is Mylan, and depending on the Mylan's decision, Mabion will only be able to consider other partners who may co-finance research and activities leading to the commercialisation of the drug on the US market. Until Mylan has made a decision on this (which should take place 30 days after the final minutes of the FDA Type 3 meeting are issued), the Company may not make any commitments to other partners. The Company is also considering the possibility of obtaining financial resources for research from other sources; however, as at the date of publication of this report, no decision was made in this respect, as the Company is working on several sources in parallel.



In February 2019, the Company was inspected for compliance with the requirements of Good Manufacturing Practice (GMP) recognised in Turkey. During the inspection, no critical non-conformities were found, and the Company positively assessed the completed inspection and the nature of the comments received. The positive verification of the GMP system in relation to Turkish requirements is a necessary event to submit a dossier in this country, as Turkey has its own independent regulatory system.

In May 2019, the Company underwent a GMP inspection by the Chief Pharmaceutical Inspectorate (GIF), commissioned by the EMA as part of the assessment of the Company's application for admission of MabionCD20 to trading. The inspection ended with granting the Company a GMP certificate for medicinal products (both for the active substance and the finished product), which is an important milestone for Mabion. This is the first certificate of this type confirming that the Company conducts manufacturing processes in accordance with the GMP requirements for medicinal products and after obtaining the marketing authorisation, the Company may start selling.

In 2018, the Company received permission from the European Medicines Agency to submit a duplicate application for a medicine under the working name of MabionCD20. On 6 May 2019, the Company received confirmation of the correct submission of the aforementioned duplicate application to the EMA from the partner, and on 27 May 2019, the Company was informed about the favourable completion of the validation of the aforementioned application by the EMA and thus its acceptance into the assessment procedure. The assumption of the duplicate application is that the Company will obtain an additional trade name for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). This action may accelerate the commercialisation of the medicine under the working name of MabionCD20 in markets where RA is still protected by MabThera's patent. The Company is currently awaiting a list of questions (Day 120). The positive results of the study, which have been reported by the Company in current and periodic reports so far, and the EMA's agreement to submit a duplicate application, do not guarantee the approval of the product by the European Medicines Agency.

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

- the validation/qualification of biological analytical methods has been completed (according to the latest EMA guidelines);
- the scope of the bioequivalence and biosimilarity study has been extended (MabionCD20 vs. MabThera);
- MabionCD20 and the reference drug were continuously tested for stability;
- the range of MabionCD20 and reference drug degradation studies has been extended;
- responses were developed and submitted as part of the ongoing registration process with the European Medicines Agency (Day 120); preparations are under way to answer Day 180 questions of the registration process;
- a second registration dossier for MabionCD20 has been developed and submitted to the European Medicines Agency (without indication in rheumatoid arthritis);
- work related to the determination of the process space for the manufacturing process was completed;
- technological and validation documentation was drawn up for the manufacturing process of MabionCD20 in the scale of 2x2500L;
- two technical batches of MabionCD20 were carried out on the scale of 2x2500L;
- a strategy for the control of the manufacturing process of MabionCD20 in the scale of 2x2500L was developed;
- QTPP (Quality Target Product Profile) of the reference drug Rituxan has been completed for the FDA registration process. The QTPP test characterises key attributes of a tested medicine, such as biological activity and other biological and physicochemical attributes of a medicine. The study will allow to characterise the reference drug to a sufficient extent to create its profile, which the Company will then strive to achieve by developing its biosimilar product. The trial report is part of the "Briefing Package" documentation;
- the preparation of the clinical trial protocol and the "Briefing Package" documentation was completed based on the existing arrangements with the FDA. On 12 September 2019, the "Briefing Package" documentation was handed over to an external company (the Company's project representative in the USA) for submission to the FDA. This is a continuation of the consultation process with the regulator.



### The MabionMS project

With respect to the MabionMS innovative therapy project, the Company has so far filed two patent applications in this therapeutic area.

In 2017, Mabion filed a European patent application with the Patent Office of the Republic of Poland, with the possibility of extension under the PCT procedure, based on which it applied for legal protection for its invention entitled "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand". The subject of the patent application is an innovative therapy for the treatment of patients suffering from multiple sclerosis with a combination of MabionCD20 and other substances (the MabionMS combination therapy project). In 2018, the Company filed an application with the European Patent Office in the Hague for the extension of patent protection under the PCT procedure for the aforementioned invention. In order to avoid a dangerous situation in which the Patent Office alleges an attempt at double patenting of the same scope of protection, in March 2019 the Company withdrew the originally filed European application in order to benefit from the protection granted under the international application (also covering the European area). This is a procedural solution to optimise this process.

In 2018, the Company filed another patent application with the Patent Office of the Republic of Poland, with the possibility of extension under the PCT procedure, from the area of application of MabionCD20 in the treatment of patients with MS, entitled "Low aggregate anti CD20 ligand formulation". This is a second patent application for the use of MabionCD20 to treat multiple sclerosis as an innovative indication for the molecule. The application concerns the monotherapy use of MabionCD20. Currently, the Company is looking for partners for further work related to the development of the above mentioned therapy.

In the scope of the above mentioned project, in the first half of 2019 the Company prepared both a synopsis of clinical trial as well as a "briefing package". The substantive content and regulatory assumptions of the project have been consulted with external specialists in the field of clinical trials in the treatment of multiple sclerosis. After consultations and approval of the

final version of the aforementioned documents, the Company filed them on 9 August 2019 with the EMA. On 12 September 2019, the "Briefing Package" documentation was handed over to an external company (the Company's project representative in the USA) for submitting to the FDA. Both events initiate the process of scientific consultations with regulators in order to confirm the compliance of the project assumptions with the requirements of both Agencies.

### The MabionEGFR project

As regards the MabionEGFR project, the Company is in the process of developing technological bases and analytical tools. Part of the expenditure related to the development of the drug is co-financed by EU. In 2018, as a result of the project work, the analytical and experimental critical functions of the technology were confirmed.

Within the scope of the above project, in the first half of 2019, the Company conducted activities related to:
» analysis of the critical attributes of protein;
» verification of the genetic construct;
» development of analytical methods for characterising the protein obtained;
» optimisation of the conditions for introducing the vector into host cells;
» preselection of chromatographic resins and preliminary optimisation of conditions for antibody purification.

### Cooperation with Plexus Ventures LLC

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



### Production capacity

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

### Retrofitting an existing plant

The investment, which is the subject of permit No. 301 for conducting business activity within the Łódź Special Economic Zone, consists in increasing the production capacity of the current plant and includes:
» retrofitting of the existing production line 2x2500L, and
» purchase and installation of production equipment for the second production line 2x2500L, which will be located in the existing building.

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

As at 30 June 2019, on account of permit No. 301, the Company incurred expenditures in the amount of PLN 2.8 million.

### Expansion of an existing plant

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

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

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

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



## 3.2. Significant achievements and failures of Mabion S.A. in the first half of 2019 and until the date of publication of the report

On 20 March 2019, an audit was carried out on the implementation by the Company of the condition of permit No. 203 of 12 April 2012 to operate in the Łódź Special Economic Zone (ŁSEZ) concerning the completion, by 31 December 2018, of the construction of a new manufacturing plant for technologically innovative biotechnological drugs used in targeted therapies for cancer, immune system disorders and metabolic diseases within the Łódź Special Economic Zone – Łódź Subzone, Complex 1. On the basis of the audit activities, it was concluded that the condition was met. The Company incurred investment expenditures in the total amount of approximately PLN 74.6 million, of which PLN 45 million are eligible investment costs. Subsequently, on 12 June 2019, an audit was held to verify whether the condition of this permit was fulfilled with respect to maintaining employment in the ŁSEZ at the level of at least 30 employees in the period from 1 January 2017 to 31 March 2019. This was the last condition required to be fulfilled by the Company under this permit in order to obtain the right to benefit from the tax exemption as part of business activity conducted within the territory of the ŁSEZ. The Company informed about obtaining the above mentioned permit in the EBI current report no. 10/2012 of 16 April 2012, and about the fulfilment of the permit conditions in the current reports no. 5/2017 of 11 January 2017, 5/2019 of 20 March 2019, and 16/2019 of 12 June 2019.

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

On 3 April 2019, the Management Board of Mabion S.A., as a result of the annual update of the development strategy for medicinal products, adopted a resolution approving the changes in this strategy. In accordance with the resolution, the catalogue of projects which the Company is interested in implementing, now or in the future, either independently or with partners, has been changed. The Company has also qualified research and development projects into three groups of projects, i.e. active projects, new projects planned for 2019, and partnership projects. Detailed information on the strategy update is presented in point 3.1. of this report. The Company informed about the event in current report no. 8/2019 of 3 April 2019.

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

On 25 April 2019 Mr. Artur Chabowski tendered his resignation from the position of President of the Management Board of the Company. The resignation came into force on 30 June 2019. The reasons for the resignation were not indicated in therein. Until 30 June 2019, the Company was to present the target structure of the Company's Management Board together with the division of competences. On 28 June 2019, the Management Board of the Company received information from the Supervisory Board that the work on appointing a candidate for the new President of the Management Board of the Company is continuing and the Supervisory Board will inform the Company about the target structure of the Management Board after the election. The Company informed about the above events in its current reports no. 11/2019 of 25 April 2019 and no. 19/2019 of 28 June 2019.



On 6 May 2019, the Company received confirmation of the correct submission of a duplicate application to the EMA from the partner for a medicine under the working name of MabionCD20, and on 27 May 2019, the Company was informed about the favourable completion of the validation of the aforementioned application by the EMA and thus its acceptance into the assessment procedure. If the registration procedure is completed successfully, the duplicate application will enable the Company to obtain an additional trade name for the medicine for which the list of indications for the product will be limited and will not include rheumatoid arthritis (RA). In the Company's opinion, this action may accelerate the commercialisation of the drug under the working name of MabionCD20 in markets where RA is still protected by MabThera's patent. The Company informed about the events in its current reports no. 13/2019 of 6 May 2019 and 15/2019 of 27 May 2019.

On 1 July 2019 (an event after the balance-sheet date), the Company received the second round of questions from the European Medicines Agency as part of the drug registration procedure (Day 180). This is a typical stage of the EMA registration procedure and is included in the Company's schedules, so they remain unchanged. The Company is currently in the process of analysing the questions and preparing the answers. The Company informed about the event in its current report no. 20/2019 of 1 July 2019.

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

On 25 July 2019 (an event after the balance-sheet date), the Company received a letter from the EMA informing that on the basis of the inspection conducted by CPI on behalf of the EMA, classified as a pre-authorisation inspection concerning a drug under the working name of MabionCD20, the Inspectorate considers that the manufacturing processes conducted in the Company are in compliance with the principles and guidelines of Good Manufacturing Practice (GMP) set out in Directive

2003/94/EC. The findings of the inspection enable the inspectors to recommend the EMA the establishment of the Mabion S.A.'s Scientific and Industrial Complex for Medical Biotechnology in Konstantynów Łódzki as a manufacturing site for the medicine under the working name of MabionCD20. This is one of the milestones necessary to obtain MabionCD20's marketing authorisation, but not an event that guarantees registration. The Company informed about the event in its current report no. 22/2019 of 25 July 2019.

On 14 August 2019 (an event after the balance sheet date), the Management Board received information from the Mylan legal department that, in connection with the information on the intention to merge Mylan NV (Mylan) with Upjohn - an entity separated from the Pfizer group, they do not at this time expect any impact of the planned merger on the cooperation of the Mabion and Mylan teams in registering MabionCD20 in the European market and the binding agreement (Development and Commercialization Agreement), of which the Company informed in current report no. 31/2016 of 8 November 2016. The Company informed about the event in its current report no. 24/2019 of 14 August 2019.

On 19 August 2019 (an event after the balance-sheet date), the Company became aware that as a result of a CPI inspection, it obtained a GMP certificate for the Mabion S.A.'s Scientific and Industrial Complex for Medical Biotechnology in Konstantynów Łódzki for the following manufacturing operations: manufacture of sterile forms of biotechnological products, quality control tests, batch release and packaging of medicinal products This is the second GMP certificate obtained by the Company as a result of a CPI inspection commissioned by the EMA as part of the assessment of the marketing authorization application for MabionCD20 submitted by the Company. The Company informed about obtaining the first GMP certificate in the scope of active substance manufacturing (Rituximab) in current report no. 21/2019 of 23 July 2019.



This GMP certificate confirms that the Company conducts production processes in accordance with GMP principles in the above scope. The certificate is valid for 3 years from the date of the last day of inspection (i.e. 17 May 2019). Obtained GMP certificates are necessary for the manufacture, registration and commercialization of MabionCD20, however, obtaining GMP certificates does not guarantee product approval by the EMA. The Company informed about the event in current report no. 25/2019 of 19 August 2019.

## 3.3. Transactions with related parties

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

In the first half of 2019, a gratuitous surety granted to the Company in 2018 by Glatton Sp. z o.o. (a significant shareholder of the Company) was in force in the amount of up to PLN 45 million. The surety relates to the revolving loan agreement of 17 July 2018 entered into with Bank Zachodni WBK S.A. (currently Santander Bank Polska S.A.) for a period of two years to finance the Company's operating activities. As at 30 June 2019, the Company did not use the credit line granted.

## 3.4. Information on guarantees, credit sureties and loans granted

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

## 3.5. Description of basic threats and risks for Mabion S.A.

### Risk related to the macroeconomic, legal and political situation

Potential unfavourable changes in the macroeconomic, legal or political environment on the markets where the Company is planning to sell its medicines, for example the slowdown in the rate of economic growth or reduced healthcare expenditure, may have a negative impact on the Company's operations and financial results. Significant economic factors that have impact on the results achieved by our Company include the level of GDP, average wages, unemployment level, inflation level, volume of healthcare expenditure.

The Management Board monitors the macroeconomic, legal and political situation on an ongoing basis, trying to adapt the Company's strategy to changes in these areas sufficiently in advance.

### Risk of force majeure

In the event of unpredictable events such as war or terrorist attacks, adverse changes may occur in the economic situation and on the financial market, which may adversely affect the financial position of the Company. In addition, such random events as: fires, floods and other extraordinary action of forces of nature, may cause damage or destruction of material tangible property belonging to Mabion SA, as well as disruptions in business, which may negatively affect the financial results achieved by the Company.

### Risk related to operations carried out on an international scale

Operations on an international scale involve a number of risks, including:

- multiple, conflicting and changing laws and regulations, including those relating to privacy, tax, export and import restrictions, labour law, regulatory requirements and other administrative consents, permits and licences;
- failure to obtain or to keep by co-operating entities the regulatory permits for use of the Company's products in various countries;
- additional potentially significant patent rights of third parties;
- complex and difficult aspects of obtaining protection and pursuing intellectual property rights;
- difficulties in filling positions and management of foreign operations by the Company or by entities cooperating with the Company;
- complex aspects related to the management of multiple reimbursement systems, public payers or patient payment systems by cooperating entities;
- limitations of Company's capabilities and the possibilities of cooperating entities in the scope of entering international markets;
- financial risks such as long payment cycles, debt collection difficulties, the impact of local and regional financial crises on demand and payment for products, as well as exposure to the risk of exchange rate fluctuations;
- natural disasters, political and economic instability, including war, terrorism, civil unrest, outbreak of disease, boycotts,
- certain expenses, including travel, translation and insurance expenses;
- regulatory and compliance risks that relate to reliable information and control over sales and operations.

The Management Board monitors the situation on target markets on an ongoing basis, trying to adapt the Company's strategy to changes in the areas described above sufficiently in advance.

### Risk related to changes in legal regulations and their interpretation

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. Amendments to the above regulations may significantly reshape the Company's legal environment and thus alter its financial results. Also discrepancies in interpretation of the legal order prevailing in Poland and in the EU constitute a material factor which may have impact on the development prospects, results achieved and the financial position of the Company. 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.

### Risk related to administrative decisions

The Company is unable to ensure that it will obtain particular permits, licences and consents required to complete biotechnological or construction projects, or that no current or future permits, licences and consents will be revoked. 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.

### Exchange rate 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.



### 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 monitors the reference medicine market on an ongoing basis and is prepared to undertake work on other biosimilars in order to mitigate this risk. In addition, the Company actively develops innovative therapies.

### Risk of inventing and launching other medicines used in respect of the same indications as Mabion S.A.'s 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 the medicines applied in cancer therapies.

### Risk relating to competition

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.

Until the date of publication of this report, two companies - Celltrion and Sandoz, have introduced biosimilars to MabThera / Rituxan on the European market. According to previously reported information, this did not affect the schedule of Mabion's activities. Even if the commercialization of a medicine biosimilar to MabThera / Rituxan is successful for several entities, as the analysis shows, this market has a growth potential.

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, treatment with MabThera / Rituxan for NHL patients is not reimbursed by the public health system, and for patients with RA, access is even more limited.

The biosimilars market is a market with high entry barriers. They comprise, among other things, high requirements relating to 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 in November 2018, Sandoz resigned from applying for admission to trading in the US of its drug biosimilar to MabThera / Rituxan, after the regulator applied for additional data[5]. As of the date of publication of this report, Celltrion[6] (November 2018) and Pfizer[7] (July 2019) obtained FDA approval for marketing biosimilar rituximab in the USA.



### Partnering risk

On 8 November 2016, Mabion signed a long-term cooperation agreement with Mylan. The agreement provides Mylan with exclusive rights to sell the medicine under the working name of MabionCD20 in all EU and Balkan countries. In addition, under this agreement, Mylan provides support to Mabion for the registration of MabionCD20 by the EMA.

On 29 July 2019, Mylan announced its intention to merge with Upjohn, an entity separated from the Pfizer group. According to publicly available information, Pfizer will not contribute any biosimilar development projects to the new entity, which is important given that both Mabion and Pfizer are developing an oncology drug with rituximab as the active substance. In addition, there is information in the available materials that Pfizer will focus on innovative projects which may suggest that biosimilars will not be a key development area for the company.

On 14 August 2019, the Management Board of Mabion received information from Mylan's legal department that at present they do not expect the planned merger's impact on the binding agreement (Development and Commercialization Agreement) with respect to the registration of MabionCD20 on the European market.

However, it cannot be ruled out that Mylan's position will change in the future. Mabion has no influence on the scope of cooperation between third parties and it may happen that the strategy for the development of medicinal products adopted by the new entity competes with Mabion's offer.

The Company remains in current contact with representatives of Mylan and in case of significant changes in the scope of cooperation will inform the market on an ongoing basis.

5 http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681

6 https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm627035.htm

7 https://www.pfizer.com/news/press-release/press-release-detail/fda_approves_pfizer_s_biosimilar_ruxience_rituximab_pvvr_for_certain_cancers_and_autoimmune_conditions

### Risk related to the research and development process

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. Not only the possibility of launching the developed medicines 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. The Company uses most of the funds so far obtained 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 the Company is able to manufacture its own biosimilars and, in the Management Board's opinion, significantly reduce the risk of not achieving ultimate success. 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 of underestimating the costs of MabionCD20 manufacture and launch



According to assumptions very generally adopted by the biotechnological industry, the development and production of a single biosimilar which meets global standards lasts about 10 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 medicines cannot be precisely anticipated.

It cannot be precluded that the actual costs of production and launching of the developed medicines (including MabionCD20) on the market will be much higher than currently anticipated. A material increase in the costs of production and market launch of the developed medicines 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 medicine development and launch, which applies also to MabionCD20:

- amendments to the regulations concerning the production of medicines and the need to use more expensive technological solutions or creating entirely new ones;
- increase in the costs of purchase of raw materials and materials used to manufacture medicines, following from the market conditions or new guidelines;
- amendments to regulations concerning the scope of analyses needed to characterize the product, e.g. the need to perform additional costly analyses or develop new analytical methods or tools;
- increasing requirements concerning registration documentation, e.g. the need to perform additional trials or studies.

In order to prevent the above risk, the Company implements the policy of developing its own research and development competences, investing in its own production capacities and carrying out ongoing consultations with regulators. In the Company's opinion, this enables a significant reduction in the cost of medicine development in relation to industry assumptions.

### Risk related to the work schedule

The achievement of the Company's strategic goal, which is the registration and market launch of biosimilars as soon as possible after the expiry of patent protection of the original medicines, is connected with the need to develop a detailed work schedule for several years. The possibility of pursuing this schedule depends on 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 medicines and if necessary implements the required operating solutions to minimize the impact of unexpected events on adopted time schedules.

In 2017, the company initiated the research and development process for MabionCD20, which is a medicine directly competing with the existing market drug MabThera / Rituxan from Roche. The basic patent protection in Europe for this drug expired in the period: end of 2013 – before the end of 2014, while in the United States of America, it expired in July 2018[8].

The Company's goal is to market MabionCD20 as soon as possible after patent expiration, which would allow the Company to achieve a temporarily favorable competitive position. Any delays in the MabionCD20 registration procedure may result in the medicine being marketed later than it results from the current assumptions of the Company.

In order to prevent registration risks, the Company, since the start of work on the development of MabionCD20, has cooperated with EMA regarding compliance with guidelines and procedures related to the registration process in the European Union. It carried out numerous scientific consultations which were aimed at eliminating doubts and refining activities related to the preparation of registration documentation.

The company has also commenced a consultative process with FDA, the purpose of which is to determine and perform activities consistent with the FDA's expectations and necessary for the registration of MabionCD20 in the United States. There is a risk that after analysing the data presented by the Company in the consultation process, the FDA will indicate a need for the Company to carry out additional work, which may affect the drug registration timetable in the USA.



### 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 medicine production on a larger scale is very important for the process of developing and producing biotechnological medicines. 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 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. In addition, the original deposit of the biological material used by the Company for the production of medicines is stored in an independent storing place outside Poland so as to be able to continue its production in any other external facility in case of any unexpected events.

The Company also monitors the workflow of the production process and the quality of the manufactured products, introducing necessary organizational, personnel, and technological changes in the framework of improving the quality management processes.

### Risk related to the production process

One of the key elements in the production of biotechnological medicines is the production process, which must be carried out in compliance with the previously planned parameters. The process of producing such medicines consists of several stages and even the smallest change in any of them may negatively affect the properties of the drug (e.g. in terms of efficacy or safety). An extremely important element of the medicine manufacturing process is the transition from a small laboratory scale to the scale of industrial production (so-called up-scaling). It is very important to ensure continuity, stability and purity of the entire production process. The Company's laboratories are equipped with state-of-the-art equipment that ensures maximum accuracy and repeatability of the obtained results. The materials used in the production zone have appropriate certificates for use in the

[8] Global Data

pharmaceutical industry. The installed production line is based on sterile materials. The managing staff of the Company's departments are high-ranking specialists with a major education background, trained and properly prepared to carry out their scope of duties, both by internal and external experts.

The Company's production also depends on key suppliers. In the case of disposable technology, the Company depends on specialist solutions (disposable bags) and this may have an impact on production. In addition, the quality of the bags may vary and in some cases may affect the product, which will make it unsuitable. The Company is also dependent on timely deliveries and the quality of all raw materials essential for the effective production of products.

Even if the Company is able to successfully produce commercial quantities at our plant, it cannot guarantee that it will not face challenges in terms of guaranteeing a stable supply to global markets in the future.

Any unfavourable events having a negative impact on the Company's production activities could significantly increase costs and reduce the supply of the Company's products.

Even small deviations from the normal production process could lead to reduced productivity, product defects and other supply disruptions. If microbial, viral or other contamination is detected in the Company's products or production plant, the plant may have to be closed for a longer period of time to investigate and handle the contamination.

Any adverse event affecting the Company's product manufacturing operations may lead to shipping delays, lack of stock, batch failures, recalls or other interruptions in the supply of products. The Company may also be forced to make inventory write-downs and incur other fees and costs due to products not meeting the specification, costly repair work or looking for more expensive production alternatives.



The production process is monitored on a continuous basis and verified in accordance with the procedures adopted at the company, owing to which the Company systematically seeks to reduce the level of risk in this area. The company meets the requirements of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP), holds the necessary approvals and permits (including a GMP Certificate for the Complex in Konstantynów Łódzki, issued by the Main Pharmaceutical Inspector).

**Risk related to a possible failure in reaching capacity/demand balance**

Currently, it is difficult to estimate the precise demand for Mabion CD20, but the plans to sell the medicine on the US market and other markets are connected with the need to increase production capacity above the level possible at the present plant in Konstantynów Łódzki.

The company is aware of these needs and it took care of the possibility of erecting another building in the same location, on the same plot. This building can be used to a greater extent for the production process (the current building also has an office part).

The final date and scope of such an investment will depend on arrangements with distribution partners regarding the planned delivery of MabionCD2.

The company will implement the investment based on its own experience arising during the construction and operation of the plant in Konstantynów Łódzki, as well as cooperating with outstanding external experts. In order to eliminate the risk related to possible delays in the construction schedule, and to ensure its compliance with expectations and needs, the Company has an Investment and Qualifications Department, composed of experienced specialists in this field.

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

Maintaining appropriate conditions on the premises where work is conducted on the Company's products is extremely important. Currently, Mabion is in possession of all required approvals for equipment and for laboratory and manufacturing areas in both plants.

We managed to eliminate the risk of failure to obtain or delay in obtaining pharmaceutical of the Scientific and Industrial Complex in Konstantynów Łódzki acceptance by the Main Pharmaceutical Inspectorate. Nevertheless, due to the number of stakeholders (diverse supply and service channels, human factor, etc.), the Management Board of the Company cannot guarantee that these 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. Clinical trials are associated with the risk of insufficient efficacy or safety of the investigational medicinal product. This risk applies to current and any subsequent trials that will be carried out by the Company.

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

### Risk related to drug registration

The primary objective of the Company is the introduction of the developed biosimilars to global markets, primarily the EU and U.S. markets, which involves the obligation to register such drugs with the EMA and Food and the FDA, respectively. The drug development and implementation efforts completed by Mabion S.A. may be considered inconsistent with the EMA/FDA guidelines/standards.

There is a risk that in the case of, for example, procedural changes or errors, or gaps in the Company's documentation, the process of registering the medicine within the European Union may not take place on the planned date or registration will not be possible. In addition, there is a risk that subsequent regulations adopted by the FDA will be more restrictive in relation to the EMA guidelines or differ from them. In this case, the Company would be exposed to the need of incurring additional costs or ceasing activity on the US market altogether, which could have a negative impact on the financial results generated by the Company.



Since the beginning of work on the development of its biosimilar medicines, Mabion has been cooperating with EMA in respect of compliance with all guidelines and procedures related to the registration process on the territory of the European Union. In June 2018, the Company presented the collected data on the development of MabionCD20 in relation to MabThera the FDA. The Agency allowed the use of data held by the Company as supporting the application process. At the same time, the FDA proposed a general strategy for linking a product registered in the European Union (Mabthera) with a product admitted for sale in the US (Rituxan), without indicating the need for a completely separate MabionCD20 development process for the US market.

On 12 September 2019, the Company submitted the "Briefing Package" documentation, which contains detailed data from the clinical trial as well as from comparative analysis (comparison of MabionCD20 with Rituxan), to an external company (the Company's project representative in the USA) for submission to the FDA. There is a risk that, in the regulator's opinion, the presented data will require modification of the Company's scope of work, which may affect the drug registration strategy in the USA, as well as the timetable and cost of the entire process.

However, there is a risk of erroneous interpretation of guidelines or failure, in the opinion of authorities, to comply with the guidelines, as well as the risk of interpretation of the Company's activities as insufficient to register the medicine in the light of the guidelines, carried out by experts employed at the Agencies.

### Risk related to launching and maintaining medicines on the market

After registering the medicines, the Company is planning to launch them on the market as quickly as possible, which requires their preparation to the market product status (production, marketing, distribution and sales) and involves some substantial outlays and organizational preparedness. As the product is unique and the target markets of Mabion are diverse, the Management Board plans to implement a multi-faceted strategy for the promotion and distribution of its medicines.

According to the adopted assumptions, marketing and distribution of medicines in Poland and selected countries of Central and Eastern Europe will be carried out independently by the Company. In other European countries and other countries of the world, marketing and distribution activities will be carried out by global and local partners.

There is a risk that launching Company's medicines 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 medicines will prove to be unsellable on a given market which could have a negative impact on the sales revenue earned by the Company and on its financial results.

Mabion has acquired a distribution partner for the EU and the Balkans and is currently, through the intermediation of Plexus Ventures LLC, actively looking for an experienced and strong partner to effectively sell Mabion S.A. medicines on markets outside the European Union. The process is complex and long-lasting – it consists in 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 and the current shareholders with a significant stake in the Company and those who actively support it have significant legal and technical insight in organizing hospital sales and wide experience in launching and maintaining pharmaceuticals on the market.

### 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 medicines 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 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 medicines 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.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of Mabion's products will depend in part on the medical community, patients and third-party payers accepting our product candidates as medically useful, cost-effective and safe. Any product that the Company brings to the market may not gain market acceptance by physicians, patients, third-party payers and others in the medical community. The risk in this respect may have a negative impact on the level of sales revenues and financial results achieved by the Company.

Even if a Company's product displays an equivalent or more favourable efficacy and safety profile in preclinical and clinical trials, market acceptance of the product will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar products. If market acceptance of MabionCD20 is lower than that of MabThera or competing biosimilars, the price of MabionCD20 may need to be reduced or the Company may need to implement additional marketing endeavours in order to accrue market share, which will negatively affect Mabion's profitability. The Company's efforts to educate the medical community and third-party payers on the benefits of the Company's products may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If the Company's products are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payers and others in the medical community, Mabion will not be able to generate sufficient revenue to become or remain profitable.

The Company anticipates that its commercialization, sales and marketing strategy will include the distribution of future therapeutic products to hospitals and other public healthcare institutions that make bulk purchases of medicines selected through a public tender process. During the tender process, hospitals will establish a committee of recognized pharmaceutical experts, which assesses bids submitted by pharmaceutical suppliers. Winning bids result in contracts with hospitals for the

procurement of medicines. The interest of a hospital in a medicine is determined by the inclusion of this medicine on the hospital's formulary, which establishes the scope of drugs physicians at a hospital may prescribe to their patients, and the willingness of physicians at a hospital to prescribe a certain drug to their patients. The Company believes that effective marketing efforts are critical to making and keeping hospitals interested in purchasing the Company's products. As a tenderer, the Company will be obligated to provide detailed specifications and accurate quotes regarding its products, which will be compared to other suppliers. Any large or expensive tender is likely to attract a majority of the Company's competitors. A competitive bidding process may result in competitors reducing the price of their products to a level that the Company cannot compete with. If competitors are able to offer lower prices, Mabion's ability to win tender bids will be materially harmed. This may result in loss of market share and could reduce Mabion's total revenue or decrease its profitability.

**Risk of withdrawal of marketing authorisations or manufacturing certificates for the Company products and the risk of product liability**

Any regulatory approvals that the Company or its collaboration partners receive may be subject to limitations regarding the approved indicated uses for which the product may be marketed or to the conditions of approval, or may contain requirements for potentially costly additional clinical trials and surveillance to monitor the safety and efficacy of the product. The Company will be required to report certain adverse reactions and production problems, if any, to the FDA, EMA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to ensure compliance.

The Company's collaboration partners will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions in certain countries and must be consistent with the information in the product's approved label. As such, the Company's collaboration partners are not allowed to promote Mabion products for indications or uses for which they have not been approved. The Company could also be required to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing authorisation.



If a regulatory agency discovers previously unknown problems with an approved product, such as adverse events of unanticipated severity or frequency or problems with our manufacturing facilities, or disagrees with the promotion, marketing or labelling of a product, such regulatory agency may impose restrictions on that product, the Company's collaboration partners or the Company, including the requirement to withdraw the product from the market.

If the Company receives marketing authorisation, regulatory agencies including the FDA, EMA and other foreign regulatory agency regulations require that it reports certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of the Company's obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. The Company may fail to report adverse events it becomes aware of within the prescribed timeframe. The Company may also fail to recognise that it has become aware of a reportable adverse event, especially if it is not reported to it as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the Company's products. If the Company fails to comply with its reporting obligations, the FDA, EMA or other foreign regulatory agencies could take action including but not limited to criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

If product liability lawsuits are brought against the Company, it may incur substantial liabilities and may be required to limit commercialisation of its current or future products, and the Company's existing insurance coverage may not be sufficient to satisfy any liability that may arise.

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, in case of 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. The withdrawal of authorisation for Mabion S.A. medicinal products would have a significant unfavourable impact on the Company's development perspectives and on the financial results achieved.

Notwithstanding the foregoing, in certain circumstances (for instance, whenever a justified suspicion occurs that medicinal products do not comply with the applicable requirements), the voivodship 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 of 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. The Company may also be unable to attract or retain qualified personnel due to strong competition for such personnel among biotechnology, pharmaceutical and other companies. If the Company is unable to attract, retain and motivate the necessary staff to achieve its business objectives, it may face constraints that will make it significantly more difficult to achieve its growth objectives, as well as limit its ability to raise capital and pursue the Company's business strategy.

The Company's future performance will also depend, in part, on its ability to successfully integrate newly hired executive officers into its management team and the Company's ability to develop an effective working relationship among senior management. If it is not possible to integrate these people and establish good employee relations between them and other members of management, this may have a negative impact on the Company's performance.

In order to counteract the above risk, the Company's Management Board pursues an active HR policy aimed at retaining the most valuable specialists in the company and supporting their development. The success of the Company depends, among other things, on the continuous ability to attract, maintain and motivate highly qualified management and scientific staff. Since September 2017, the Mabion team has been using support in the area of human resources development. With the help of an employee development specialist, professional development projects for all employees are carried out. The Company's employees can also count on the possibility of comprehensive professional development ("Mabion Academy" Project), including participation in internal and external training, support in undertaking doctoral studies, as well as the promotion procedure - the rules of obtaining the above mentioned benefits are formalized, open and objective (e.g. promotion procedures, implementation of bonus programmes for employees with long work experience, implementation of loyalty programmes and bonus programmes).

### Risk related to disclosure of trade secrets

The actual implementation of the Company'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 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.

The Company has taken a number of legal steps to eliminate this risk.

### Risks related to patent protection

The company is aware that it is entering to a very competitive pharmaceutical market. Successful competitors on the pharmaceutical market have demonstrated the ability to successfully discover, patent, develop, test and obtain approvals of regulators for products, and to effectively commercialise, market and promote the approved products. Numerous companies, universities and research institutions are involved in the development, patenting, manufacturing and marketing of products that may compete with the Company's products.

The Company's objective is to effectively secure its intellectual and industrial property by providing the widest possible patent protection for the inventions made in the Company. However, it cannot be ruled out that there is a risk that patent offices will undermine the legitimacy of patent protection in applied for by the Company, and the arguments presented by the Company will be insufficient to grant this protection.

In order to prevent this and other risks associated with the granting of patent protection, the Company's Management Board cooperates with professional advisors and experts in the field in question.

### Risk related to industrial and intellectual property disputes

The Company 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 so as to avoid any infringements of such third party rights. However, 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

In the reporting period, Mabion was a party to the following funding agreements in connection with its R&D and implementation projects:

» *"Development and scaling of the innovative process for manufacturing the therapeutic recombined monoclonal antibody to enable the industrial implementation of the first Polish biotechnological medicine for oncological and autoimmune therapies".*
  - Value of the project: PLN 54,188,035.17
  - Value of co-financing (contribution from the EU Funds): PLN 27,094,017.84
  - Project implementation period: 01.11.2016 - 31.12.2019.

In June 2019, the Company filed an application with the National Centre for Research and Development to extend the project implementation by 9 months, i.e. until 30 September 2020. This change is crucial for the implementation of development work (the necessity to adapt to the guidelines of the regulator and to the duration of ongoing experiments - additional analytical series) and to achieve the planned milestones. As at the date of publication of this report, the National Centre for Research and Development has not issued any decision on this matter.

» *"Development of a biotechnological medicine through the development of an innovative monoclonal IgG1 subclass antibody with reduced content of unfavourable glycoforms compared with the reference medicine – targeted against EGFR."*
  - Value of the project: PLN 39,965,267.64
  - Value of co-financing (contribution from the EU Funds): PLN 28,354,422.06
  - Project implementation period: 01.08.2017 - 30.07.2022.

In December 2018, the Company filed an application with the National Centre for Research and Development to extend the first stage of the project by 10 months (from the assumed deadline of 31 December 2018 to 31 October 2019). Such a change results from the need to adjust the schedule of material progress to the ongoing research works. In July 2019, the National Centre for Research and Development agreed to this change.

» *"The clinical development and registration of a humanized monoclonal antibody that binds to HER2 receptor, used in breast cancer treatment."*
  - Value of the project: PLN 23,949,430
  - Value of co-financing (contribution from the EU Funds): PLN 10,000,000
  - Project implementation period: 01.06.2014 - 31.05.2019.

In 2017, the Company decided to end the aforementioned project at its current stage of development. The decision resulted from the high scientific risk related to the implementation of research on a Herceptin biosimilar and was made after analysis of the competitive environment. So far, the Company has used the funds of PLN 177 thousand from the received co-financing. As at the date of publication of this report, the Company has not received a final assessment of the submitted final project report from the NCRD. On 11 September 2019 the Company received information from NCRD concerning the reimbursement of PLN 149 thousand and interest calculated as for tax arrears from the date of transfer of funds, i.e. from 10.12.2014, as a return of co-financing under the INNOMED project. Taking into account the completion of the project covered by the subsidy without achieving the assumed objectives and planned ratios and high probability of the need to return the received funds, in previous reporting periods the Company created an appropriate provision in full to cover the potential amount necessary to return with interest. As at the date of publication of this report, the Company has not taken a decision on the appeal against the NCRD call. The legal department of the Company undertook work aimed at analysing the legitimacy of a possible appeal.



» *"Expansion of the Research and Development Centre of Mabion S.A. - research on the new generation of medicines".*
  - Value of the project: PLN 172,876,340.70
  - Value of eligible costs: PLN 140,549,870.50
  - Value of ERDF co-financing: 63,247,441.60
  - Project implementation period: 20.01.2018 – 31.12.2021

The agreements made stipulate in detail the dates and scope of tasks which may be subsidized.

There is a risk that if the Company fails to carry out the assumed work in the timeframes set by the Intermediate Body, uses all or part of the co-financing improperly or without following the applicable procedures, collects all or part of the co-financing unduly or in an excessive amount, it will be obliged to return part or the full amount of the grant plus interest. There is also a risk that the Intermediate Body does not grant consent in the event of further problems related to substantive or financial progress, which may be related to the termination of co-financing agreement(s) and the necessity to return the funds collected together with interest.

As a result, if the conditions giving rise to the liability are met, the Company's financial position may deteriorate significantly, which in the long run may jeopardise the achievement of the Company's strategic objectives.

In order to counteract the above risk, the Company has put in place internal procedures for the ongoing monitoring of project expenditures – the spending methods used and the schedule of spending implementation, as well as closely cooperates with intermediary institutions, informing on the ongoing basis on any possible risks.

### 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 funds obtained from the share issue, available credit lines, public funding and, to some extent, proceeds from distribution partners and the sale of R&D services. The Management Board obtains funds to finance the Company's ongoing operations from credits and loans.

The issue of series P shares adopted by the Extraordinary General Meeting on 18 April 2018 made it possible to obtain significant funds to cover the costs of further operations of the Company. Moreover, pursuant to the terms of the agreement with Mylan, on 27 August 2018 the Company received a payment of USD 5 million for reaching the milestone specified in the mutual cooperation agreement in the form of acceptance by the EMA of registration documents for a drug with the working name MabionCD20.

Mabion is expected to receive further payments from Mylan for the remaining stages of the agreement in the form of marketing authorisation for the drug with the working name MabionCD20 and its marketing in key EU countries. In addition, the Company is entitled to royalties based on annual net sales revenues. Any delays in meeting the schedule may delay Mabion's receipt of subsequent payment tranches from the distributor.

Failure to apply for new EU aid funds may also expose Mabion to problems related to financial liquidity and the need to obtain an alternative source of financing.

**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-Industrial Complex in the Łódź Special Economic Zone (ŁSEZ). In accordance with the Act on Special Economic Zones,

the income earned on business activities in a special economic zone, under the permit received, is exempt from Corporate



Income Tax. Mabion S.A. is exempt from the tax until 31 December 2026.

There is a risk of changes in law provisions concerning the operation of special economic zones or in tax advantages applicable in those zones. There is also a risk that the Company will cease meeting the conditions specified in the permit which entitles it to avail itself of these advantages. Upon the expiry of the permit or if the Company loses the permit before its expiry Mabion's further operations in the ŁSEZ may become unfavourable and increase tax burden.

# 4. Analysis of the financial and asset situation of Mabion S.A.

## 4.1. Rules for drawing up the abridged semi-annual financial statement

The interim condensed financial statements of the Company for the period from 1 January 2019 to 30 June 2019 were prepared using accounting policies consistent with International Financial Reporting Standards (IFRS), including International Accounting Standards (IAS) and interpretations by the Standing Interpretations Committee (SIC) and the International Financial Reporting Interpretations Committee (IFRIC), which were approved by the European Union (EU) and came into force by the end of 2017. The financial statements were prepared on the historical cost basis. The interim condensed financial statements, except for the cash flow statement, have been prepared on the accrual basis.

The interim condensed financial statements of the Company for the period from 1 January 2019 to 30 June 2019 were prepared in accordance with International Accounting Standard 34 "Interim Financial Reporting" approved by the European Union ("IAS 34"). To prepare the condensed interim financial statement, the accounting principles were applied in the unchanged scope in relation to the principles applied in the preparation of the annual financial statement for 2018, except for the income tax, which was calculated using the expected average annual effective tax rate.

In the first half of 2019 there were no changes in the rules of determining the value of assets and liabilities and measuring the financial result.

The interim condensed financial statements of the Company for the period from 1 January 2019 to 30 June 2019 were not audited but were subject to review by the auditing firm PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k.

## 4.2. Asset situation of Mabion S.A. after the first half of 2019

### Sales, costs and financial result

The table below presents an analysis of the results achieved by the Company in the first half of 2019 (in PLN thousand):

| | 01.01-30.06.2019 | 01.01-30.06.2018 | Change (%) |
|---|---|---|---|
| Net income on sales and equal to them | 0 | 0 | n/d |
| Costs of products, goods and materials sold | 0 | 0 | n/d |
| Gross profit (loss) on sales | 0 | 0 | n/d |
| General and administrative expenses | -11 893 | -11 360 | 4.69% |
| Research and development costs | -21 094 | -26 730 | -21.08% |
| Other operating income and expenses, net | 735 | 1 201 | -38.80% |
| Profit (loss) on operating activities | -32 252 | -36 889 | -12.57% |
| Gross profit (loss) | -31 696 | -41 182 | -23.03% |
| Income tax | 0 | 0 | n/d |



In the first half of 2019, due to the Company's focus on completing the development of MabionCD20, it did not generate any sales revenues.

In the period of 6 months ended 30 June 2019, the Company incurred a tax loss of PLN 9,696 thousand. The Company did not recognize a deferred tax asset for this loss due to the fact that it did not meet the conditions of IAS 12 as to the probability of achieving tax revenues allowing to utilize the loss before the end of the period for its utilization.

The amount of tax losses from previous years was presented in the financial statements for the financial year ended 31 December 2018.

### Company assets and their financing

| Assets | 30.06.2019 | | 31.12.2018 | | Change (%) |
|---|---|---|---|---|---|
| | Value (PLN thousand) | Structure | Value (PLN thousand) | Structure | |
| **Fixed assets** | **73335** | **62%** | **72555** | **50%** | **1%** |
| Tangible and intangible fixed assets | 73335 | 62% | 72445 | 50% | 1% |
| Long-term receivables | 0 | 0% | 110 | 0% | 0% |
| Long-term investments | 0 | 0% | 0 | 0% | 0% |
| Long-term prepayments and accruals | 0 | 0% | 0 | 0% | 0% |
| **Current assets** | **44619** | **38%** | **72162** | **50%** | **-38%** |
| Inventories | 8950 | 8% | 10298 | 7% | -13% |
| Short-term receivables | 4313 | 4% | 2606 | 2% | 66% |
| Advances | 546 | 0% | 840 | 1% | -35% |
| Cash and cash equivalents | 30810 | 26% | 58418 | 40% | -47% |
| **Total assets** | **117954** | **100%** | **144717** | **100%** | **-18%** |

The value of Mabion S.A.'s assets as at 30 June 2019 is PLN 117,954.; this represents 82% of the value of assets as at 31 December 2018.

The sources of financing for the Company's operations in the first half of 2019 are mainly funds from the issue of P-series shares, and short-term liabilities and prepayments and accruals. The Company also used leasing financing and loans in the scope of purchased fixed assets.

| Liabilities and equity | 30.06.2019 | | 31.12.2018 | | Change (%) |
|---|---|---|---|---|---|
| | Value (PLN thousand) | Structure | Value (PLN thousand) | Structure | |
| **Equity capital** | **10430** | **9%** | **42139** | **29%** | **-75%** |
| **Liabilities and provisions for liabilities** | **107524** | **91%** | **102578** | **71%** | **5%** |
| Bank loans and borrowings | 1908 | 2% | 2286 | 2% | -17% |
| Long-term liabilities | 2469 | 2% | 2027 | 1% | 22% |
| Short-term liabilities | 60730 | 51% | 62063 | 43% | -2% |
| Prepayments and accruals | 42417 | 36% | 36202 | 25% | 17% |
| **Liabilities and equity in total** | **117954** | **100%** | **144717** | **100%** | **-18%** |



### Cash flow statement

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

| | 01.01.2019 -30.06.2019 | 01.01.2018 -30.06.2018 | Change (%) |
|---|---|---|---|
| Net cash flows from operating activities | -19324 | -34 214 | -44% |
| Net cash flows from investment activities | -7041 | -2 362 | 198% |
| Net cash flows from financial activities | -1243 | 103 635 | -101% |
| **Total net cash flow** | **-27608** | **67 059** | **-141%** |

In the first half of 2019, the Company generated a negative balance of cash flows from operating activities. The most significant impact on the value of generated cash flows from operating activities was the costs of research and development incurred by the Company.

Cash flows from the Company's investment activities were higher than in the comparable period of the previous year due to the decisions taken by the Company to retrofit laboratories in order to reduce the costs of external services and investments in IT systems supporting the work of various departments of the Company, whereas the investments in tangible fixed assets were financed to a large extent through financial lease and loans from financial institutions.

Selected assessment metrics for the company's financial standing

The company did not sell in 2018 and 2019. At the same time, the Company incurred operating costs in connection with the costs of ongoing development works, investments in machinery and equipment for conducting development works and for the production of medicines in the future, as well as general and administrative costs related to, among others with financing for ongoing operations.

Due to the above, both in 2018 and 2019, the Company recognized an operating loss and net loss, therefore it is not possible to determine the Company's financial ratios related to profitability.

## 4.3. Description of factors and events that have a material impact on the abridged financial statements

In the first half of 2019, there were no factors or events other than those indicated in other points of the report, including events of extraordinary nature, which could have a significant impact on the abridged financial statements of the Company.

As at 30 June 2019, owing to the proceeds from the issue of P shares, the Company holds positive equity. In the opinion of the Management Board of the Company, support from shareholders (both strategic and stock market participants) and a long-term cooperation agreement with Mylan Ireland Limited will provide the Company with the funding necessary to complete the development work related to MabionCD20 and its commercialisation and justify the continuation of the Company's operations in accordance with the adopted development strategy.

Until the end of 2019, the Company's balance sheet may show negative equity. In such a situation, in accordance with applicable regulations, the Management Board of the Company will immediately convene an Extraordinary General Meeting in order to adopt a resolution on the continued existence of the Company.

The company cooperates with financial institutions and has access to financing of a loan from Santander bank. To a significant extent, the company finances its activities with EU funds and grants and establishes cooperation with financial institutions interested in supporting innovative solutions at an early stage of their development.



## 4.4. Factors that will affect the achieved results in the perspective of at least the following six months

The main factors that will affect the Company's results in the next half of the year are as follows:

- the EMA's decision on the authorisation of the medicine under the working name of MabionCD20;
- costs of conducted research and development work concerning MabionCD20 and other drugs in the Company's pipeline, including costs of manufacturing validation series (possible repetitions depending on the results achieved);
- the possibility of financing the projects undertaken in line with the approved strategy, including the launch of a bridging study;
- financing the projected capacity increase, taking into account the intensification of activities in the new plant construction project;
- personnel costs including the increase in the number of employees and general and administrative expenses of the Company;
- foreign exchange differences resulting from changes in foreign exchange rates;
- proceeds from the aid granted from the EU funds;
- proceeds from expected fees from distribution partners for MabionCD20.

The amount of proceeds/reimbursement of costs incurred may be affected by possible delays in discussions or unforeseen deviations from the schedules of agreements already signed.

Taking into account the further development of the Company and the expenditures incurred on research and development, there is a justified probability that by the end of 2019 the Company's balance sheet may show negative equity capital. In such a situation, in accordance with the applicable regulations, the Management Board of the Company will immediately convene the General Meeting in order to adopt a resolution on the continued existence of the Company.

## 4.5. The Management Board's position regarding the possibility of meeting the previously published forecasts for the year

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

# 5. Shares and shareholders

## 5.1. Share capital structure

As at 30 June 2019 and as at the submission date of this report, the share capital of the Company amounts to PLN 1,372,077.20 and is divided into 13,720,772 shares with a nominal value of PLN 0.10 each, including:

- 450,000 registered preference A shares,
- 450,000 registered preference B shares,
- 450,000 registered preference C shares,
- 450,000 ordinary bearer D shares,
- 100,000 registered preference E shares,
- 100,000 registered preference F shares,
- 20,000 registered preference G shares,
- 2,980,000 ordinary bearer H shares,
- 1,900,000 ordinary bearer I shares,
- 2,600,000 ordinary bearer J shares,
- 790,000 ordinary bearer K shares,
- 510,000 ordinary bearer L shares,
- 360,000 ordinary bearer M shares,
- 340,000 ordinary bearer N shares,
- 300,000 ordinary bearer O shares,
- 1,920,772 ordinary bearer P shares.



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

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

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

To the knowledge of the Management Board, as at the date of submitting the report for the first half of 2019 (12 September 2019), the following shareholders hold at least 5% of the total number of votes at the Company's General Meeting:

| I.P. | Shareholder | Number of shares | Number of votes | Participation in the share capital | Share in the total number of votes |
|---|---|---|---|---|---|
| 1. | Twiti Investments Limited | 2,380,072 | 2,974,372 | 17.35% | 19.45% |
| 2. | Maciej Wieczorek*: | 1,626,576 | 2,119,426 | 11.85% | 13.86% |
| | Glatton Sp. z o.o. | 1,006,226 | 1,006,226 | 7.33% | 6.58% |
| | Celon Pharma S.A. | 620,350 | 1,113,200 | 4.52% | 7.28% |
| 3. | Polfarmex S.A. | 1,437,983 | 1,920,833 | 10.48% | 12.56% |
| 4. | Funds managed by Generali PTE S.A. | 1,629,847 | 1,629,847 | 11.88% | 10.66% |
| 5. | Nationale Nederlanden PTE S.A. Funds** | 1 140 600 | 1 140 600 | 8.31% | 7.46% |
| 6. | Funds managed by Investors TFI S.A.*** | 1 068 007 | 1 068 007 | 7.78% | 6.98% |
| 7. | Others | 4 437 687 | 4 437 687 | 32.34% | 29.02% |
| | **Total** | **13,720,772** | **15,290,772** | **100%** | **100%** |

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

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

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



The number of shares registered at the Ordinary General Meeting of Mabion S.A. on 18.06.2019 was by 202,569 higher than the number of shares previously reported. Apart from that, the Company has no other information about any change in the number of its shares held by significant shareholders. The Company's shareholder structure as at the date of submitting the report for the first quarter of 2019 (16 May 2019), to the knowledge of the Management Board, was as follows:

| I.P. | Shareholder | Number of shares | Number of votes | Participation in the share capital | Share in the total number of votes |
|---|---|---|---|---|---|
| 1. | Twiti Investments Limited | 2,380,072 | 2,974,372 | 17.35% | 19.45% |
| 2. | Maciej Wieczorek*: | 1,626,576 | 2,119,426 | 11.85% | 13.86% |
| | Glatton Sp. z o.o. | 1,006,226 | 1,006,226 | 7.33% | 6.58% |
| | Celon Pharma S.A. | 620,350 | 1,113,200 | 4.52% | 7.28% |
| 3. | Polfarmex S.A. | 1,437,983 | 1,920,833 | 10.48% | 12.56% |
| 4. | Funds managed by Generali PTE S.A. | 1,629,847 | 1,629,847 | 11.88% | 10.66% |
| 5. | Funds managed by Investors TFI S.A. ** | 1,068,007 | 1,068,007 | 7.78% | 6.98% |
| 6. | Nationale Nederlanden PTE S.A. Funds** | 938,031 | 938,031 | 6.84% | 6.13% |
| 7. | Others | 4,640,256 | 4,640,256 | 33.82% | 30.35% |
| | **Total** | **13,720,772** | **15,290,772** | **100%** | **100%** |

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

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

## 5.3 Number of shares held by managing and supervising persons

| | Shares held as at the submission date of the report for the first half of 2019 (12 September 2019) |
|---|---|
| **Supervisory Board** | |
| Maciej Wieczorek | indirectly, through Glatton Sp. z o.o. (in which he holds 100% of the share capital) and Celon Pharma S.A. (in which he holds indirectly, through Glatton Sp. z o.o., 66.67% of the share capital) holds 1,626,576 shares of the Company in total with a nominal value of PLN 0.10 each, constituting 11.85% of the share capital of the Company and 13.86% of votes at the General Meeting. |

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



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

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

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

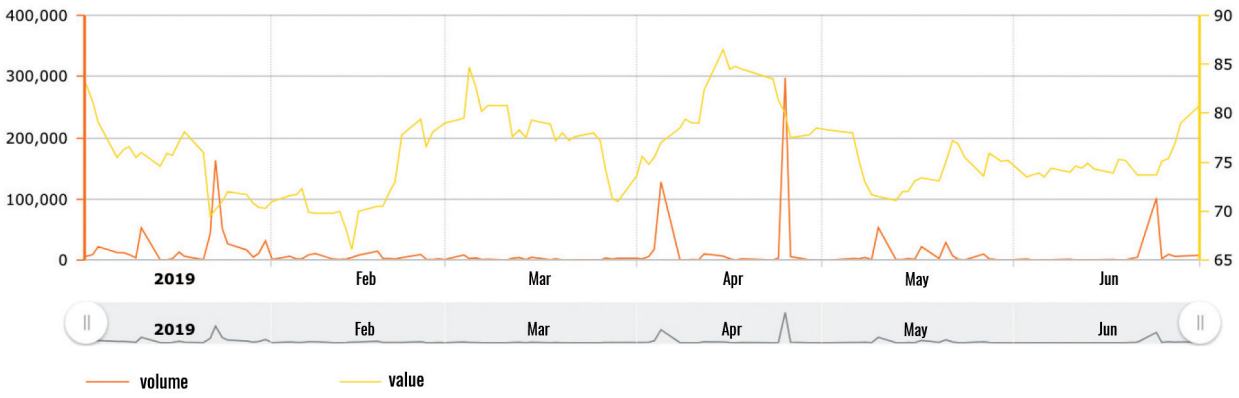
- Mr Jarosław Walczak - the right to subscribe for up to 1,411 A warrants,
- Mr. Sławomir Jaros - the right to subscribe for up to 5,644 A warrants and granted 4,043 B warrants.

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

## 5.4. Quotations of shares on the Warsaw Stock Exchange

Data for H1 2019:

| | |
|---|---|
| Reference price: | PLN 86.6000 (18-12-28) |
| Start date: | 2019-01-02 |
| End date: | 2019-06-28 |
| Change: | -8,78% |
| Change: | PLN -7.6000 |
| Minimum: | PLN 66.0000 (19-02-14) |
| Maximum: | PLN 88.2000 (19-04-15) |
| Average: | PLN 75.6910 |
| Trading volume | 1 423 374 pcs. |
| Average volume | 11 667 pcs. |
| Turnover: | 105.296 million |
| Average turnover: | 0.863 million |




Source: www.gpw.pl

# 6. Other significant information and events

## 6.1. Proceedings before a court, arbitration authority or public administration authority

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

## 6.2. Other information important for the assessment of the personnel, property, financial and assets situation, financial result and their changes, as well as information that is important for the assessment of the ability of Mabion S.A. to meet its obligations.

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

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



On 28 March 2019, the Company obtained information from the Polish Agency for Enterprise Development (PARP) on the adoption of the Company's report on the dissemination of industrial research results in the project entitled "An innovative double cutting technology for obtaining modern analogues of the human insulin hormone". The report has been accepted, thus meeting the condition for granting a bonus for broad dissemination of results, in accordance with the provisions of the agreement on co-financing of the project in question (agreement of 2 February 2012). The project was implemented by the Company in the years 2011-2016. In 2015, the Company submitted an application to PARP for early ending of the project. The technology developed as part of the project was used to obtain an exemplary prototype of an insulin analogue, but it was not possible to develop an appropriate formulation, i.e. a solution in which the drug would be stable over a longer period of time, long enough for a pharmaceutical product. In 2016, the Company received from PARP a letter informing about the acceptance of the report on the implementation of industrial research and development work together with economic analysis and market research concerning the implementation of the project. At the same time, it was stated that it was not advisable to implement the results obtained under the co-financing agreement. In connection with the above, the Company was exempted from the necessity to implement the results of industrial research or development work in the form, scope and time specified in the application for co-financing. During the project duration period (3 years from the project completion date – i.e. until 7 March 2019), the Company was obliged to disseminate the results of the related industrial research. The said work (dissemination of results by means of open source software) was carried out by the Company and reported to PARP. The letter received on 28 March 2019 confirms the correctness of the work and the final settlement of the project with regard to its merit.

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

## Management Board of the Company

Konstantynów Łódzki, 12 September 2019



| | | |
|---|---|---|
| **Sławomir Jaros** | **Grzegorz Grabowicz** | **Jarosław Walczak** |
| Member of the Management Board | Member of the Management Board | Member of the Management Board |