

**MABION**

**MABION S.A.  
Directors' Report  
for the year 2021**

Konstantynów Łódzki, 21 April 2022

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# 1 ORGANISATION OF MABION S.A.

## 1.1 Basic information about the Company

Mabion S.A. ("Company", "Mabion") was established on 29 October 2009 as a result of transforming Mabion spółka z ograniczoną odpowiedzialnością (limited liability company) registered on 30 May 2007, into a joint-stock company. Mabion S.A. is registered in the Register of Entrepreneurs of the National Court Register kept by the District Court for Łódź-Śródmieście in Łódź, 20th Department of the National Court Register, with reference number KRS 0000340462. The Company was also assigned a tax identification number (NIP): 7752561383 and a REGON statistical identification number: 100343056.

|                             |   |
|-----------------------------|---|
| Contact details             |   |
| Company name:               | Mabion Spółka Akcyjna                                 |
| Registered office:          | Konstantynów Łódzki                                   |
| Address:                    | Mariana Langiewicza 60,<br>95-050 Konstantynów Łódzki |
| Telecommunications numbers: | phone (+48 42) 207 78 90                              |
| E-mail address:             | info@mabion.eu  |
| Website                     | www.mabion.eu   |

Mabion is a biotech company specialising in the development and manufacture of originator medicines using the recombinant protein technology which is currently a prerequisite for the development of advanced products to combat the most serious diseases, for example in the field of oncology, neurology, or autoimmunity. From 2021 onwards, the Company also employs technologies it has developed not only to advance its own targeted therapy projects, but also to execute commercial orders for partners.

The Company's experience in the research and development, analytical and regulatory areas made it possible for it to complete a commercial order for its partner, Novavax Inc., consisting of the transfer of analytical methods and manufacturing process used to produce a recombinant protein vaccine antigen which is the active substance of a vaccine against SARS-CoV-2 infection. The success of the transfer of technology, as well as the available GMP-compliant production capacity, enabled the Company to sign and commence implementation of another agreement with Novavax for the contractual commercial manufacturing of the vaccine antigen.

As regards the Company's own projects, the most advanced one is MabionCD20, a proposed biosimilar to the reference drug MabThera/Rituxan (Roche). To date, the Company has completed most of the work within the project (development of technology, analytical tools, Phase III clinical trials, scaling up production to commercial scale with validation). The remaining

tasks include a clinical bridging trial in a limited patient population to demonstrate the equivalence of the commercially manufactured medicine with the product previously tested in the Phase III trial and originating from the clinical manufacturing scale, as well as an analytical study. At present, the Company is updating its work schedules so that the structure of activities in the context of the implementation of its own projects and commercial orders would enable optimum use of its resources and financial results, which would translate into an optimum structure of income in the short, medium and long term.

## 1.2 Branches

The Company has no isolated branches within the meaning of the Accounting Act.

Currently, the Company has two centres (plants) – the Research and Development Centre (Centrum Badawczo-Rozwojowe, CBR)<sup>1</sup> in Łódź, ul. Fabryczna 17, and the Scientific-Industrial Complex for Medical Biotechnology (Kompleks Naukowo-Przemysłowy Biotechnologii Medycznej) in Konstantynów Łódzki, ul. Gen. Mariana Langiewicza 60, which is also the Company's statutory registered office.

## 1.3 Changes in the Company's management rules

In 2021, no significant changes were noted in the basic principles of management in the Company.

## 1.4 Organisational or equity relationships

Mabion S.A. does not own any shares in any entities; there are no circumstances which could lead to the conclusion that the Company is a parent company within the meaning of Article 4 § 1.4) of the Polish Code of Commercial Companies (CCC). The Company does not belong directly or indirectly to any other entity – to the Company's best knowledge, there are no entities which would meet the premises of the definition of the Company's parent pursuant to Article 4 (14) of the Act on Public Offering, Conditions Governing the Introduction of Financial Instruments to Organised Trading, and Public Companies (Public Offering Act) and of the definition of the Company's parent pursuant to Article 4 § 1(4) of the Polish Code of Commercial Companies. In addition, to the Company's best knowledge, the shareholders and members of the Company's bodies are not bound by an agreement referred to in Article 87(1)(5) and Article 87(4) of the Act on Public Offering. Significant shareholders have no voting rights other than those resulting from the shares held by them.

<sup>1</sup> Proper name.

## 2 OPERATIONS OF MABION S.A.

### 2.1 Calendar

|          |  |
|----------|--|
| January  | <p>On 27 January 2021, the Management Board of Mabion S.A. adopted a long-term strategy for financing the Company's operations, including the overall capital requirements required to carry out all activities which, in the Management Board's opinion, are necessary to complete the registration of MabionCD20 with the EMA and commence its sales. The financial strategy consists of parallel processes: issues of the Company's shares and commencement of activities aimed at acquiring a strategic investor.</p>  |
| February | <p>On 16 February 2021, the Board of Giełda Papierów Wartościowych w Warszawie S.A. (Warsaw Stock Exchange S.A., "WSE") adopted a resolution on the admission and introduction, as of 18 February 2021 to exchange trading on the WSE Main Market of 500 S series ordinary bearer shares of the Company issued as part of the Incentive Scheme. On the same day, the National Depository for Securities ("Krajowy Depozyt Papierów Wartościowych", "KDPW") issued a notice on the registration of 500 S series ordinary bearer shares of the Company in the depository for securities as of 18 February 2021.</p> <p>On 18 February 2021, 500 S series ordinary bearer shares of the Company were recorded on the securities accounts of eligible persons, and therefore the share capital of the Company was increased to PLN 1,373,077.20.</p> <p>On 23 February 2021, the Extraordinary General Meeting of the Company adopted a resolution on the Company's continued existence and a resolution on increasing the Company's share capital through the issue of up to 2,430,554 U series ordinary bearer shares (in the form of a private placement with exclusion of pre-emptive rights).</p>   |
| March    | <p>On 3 March 2021, the Company entered into a framework agreement with Novavax, Inc. with its registered office in the United States ("Novavax") and was awarded the first order for contractual services related to the COVID-19 vaccine programme. Pursuant to the framework agreement and the order accompanying it, the Company, with the participation of Novavax, has conducted activities related to the transfer of vaccine antigen manufacturing technology and the technical runs at the Company's facility of the manufacturing process on a commercial scale.</p> <p>On 3 March 2021, the Company entered into an agreement with Polski Fundusz Rozwoju S.A. ("PFR") regarding the entry conditions for PFR's investment of up to PLN 40 thousand for the purposes of increasing the Company's production capacity, in particular for the Company's potential broader cooperation with Novavax. The agreement is non-binding, with the investment of PLN 10 million being made by PFR in March 2021 through taking up shares as part of the Company's issue of U ordinary bearer shares.</p> <p>On 15 March 2021, the Company completed the issue of U series ordinary bearer shares. All the offered 2,430,554 U shares of the Company were taken up and paid for. The U shares were taken up by 65 investors, including three significant shareholders of the Company, i.e. Glatton sp. z o.o., Twiti Investments Limited, and Polfarmex S.A. The issue value, defined as the product of the number of shares taken up and the issue price (PLN 55.00 per share), amounted to over PLN 133 million.</p> <p>On 23 March 2021, the Board of the WSE adopted a resolution on the admission and introduction of 2,430,554 rights to U series ordinary bearer shares of the Company to stock exchange trading as of 25 March 2021.</p> |
| April    | <p>On 2 April 2021, an increase of the Company's share capital as a result of the issue of U shares, up to PLN 1,616,132.60, was registered in the National Court Register.</p>  |

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| April    | <p>On 14 April 2021, the KDPW issued a statement on the conditional registration in the securities depository of 2,430,554 U series ordinary bearer shares.</p> <p>On 14 April 2021, the Board of the WSE adopted a resolution on the admission and introduction of the U series ordinary bearer shares of the Company to stock exchange trading as of 19 April 2021</p> <p>On 29 April 2021, the Company signed an annex to the Development and Commercialization Agreement of 2016 with Mylan Ireland Ltd. ("Mylan"), under which the parties agreed to limit the collaboration with Mylan in the field of commercialisation of MabionCD20 and to terminate Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries and Mylan's right of first refusal to enter into a commercialisation agreement for MabionCD20 in the United States.</p>   |
| June     | <p>On 23 June 2021, the Company received a second order from Novavax to carry out defined activities under the framework agreement of March 2021. The order allowed the Company to procure key raw materials in advance for the then potential future commercial manufacturing of the active substance for Novavax.</p>   |
| July     | <p>W dniu 30 lipca 2021 roku Spółka przyjęła wspólny program prac dla dopuszczenia MabionCD20 do obrotu na rynkach europejskim i amerykańskim oraz ukończyła proces uzgadniania z regulatorami i tym samym wypracowała ostateczny zakres danych oraz badania klinicznego do wniosku rejestracyjnego na rynku europejskim. Kluczowe elementy strategii regulacyjnej Spółki nie uległy zmianie.</p>   |
| August   | <p>On 10 August 2021, the Company received a positive decision of the Minister of Development, Labour and Technology on the amendment of permit no. 301 to conduct business activity in the Łódź Special Economic Zone. The amendment was made at the Company's request and involved an extension of the deadline for incurring capital expenditure in the Zone and completing the investment until 31 December 2024.</p>   |
| October  | <p>On 8 October 2021, the Company entered into a Master Contract Manufacturing Agreement) with Novavax, together with a Statement of Work, pursuant to which the Company was commissioned with manufacturing on a commercial scale, in compliance with the GMP (Good Manufacturing Practice) standard, an antigen for a COVID-19 vaccine called Nuvaxovid® for Novavax. The Agreement has been concluded for a fixed period of time until the end of 2025, with an option for renewal. The total value of the agreement over its duration was estimated at USD 372 million. Under the Agreement, the parties have agreed on the volume and production schedule for each year which, however, may be subject to modifications.</p> <p>On 11, 14, and 22 October 2021, respectively, the Company was informed that the competent institutions had issued permits for the Company to conduct a clinical trial of MabionCD20 in patients with rheumatoid arthritis in Poland, Georgia, and Belgium.</p> |
| November | <p>On 17 November 2021, the Company received a statement of termination from Mylan regarding the cooperation agreement of 2016 for the commercialisation of MabionCD20, as amended by an annex of April 2021. The agreement was terminated subject to a 90-day notice period and did not result in any payments or additional financial obligations for the Company.</p> <p>On 19 November 2021, the Company entered into a Quality Agreement with Novavax, covering technical and regulatory arrangements for the commercial production of the antigen for a COVID-19 vaccine under the name of Nuvaxovid®, including relevant GMP standards. The agreement is valid until the end of the Manufacturing Agreement of October 2021. On the same day, the Company submitted a notification to the Chief Pharmaceutical Inspectorate ("GIF") concerning the conclusion of the aforementioned agreement.</p>   |

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|----------|---|
| November | On 30 November 2021, the Company entered into an agreement with Adolf Kühner AG with its registered office in Switzerland for the purchase of 4 bioreactors with a capacity of 2,500 litres each. Two of these bioreactors will form part of the Company's second production line and the another two will be used to replace the existing bioreactors as part of the facility upgrade, and the purchase of the above bioreactors will allow the Company to double its current manufacturing capacity. The Company expects the new bioreactors to be operational as of Q2 2023. |
| December | <p>On 20 December 2021, the Company was informed that the Ministry of Health in Ukraine had granted permission for the Company to conduct a clinical trial of MabionCD20 in patients with rheumatoid arthritis in Ukraine.</p> <p>On 15 December 2021, the subscription of the Company's S series ordinary bearer shares issued under the Incentive Scheme for 2020 was completed. The eligible persons submitted statements on taking up S shares in the total number of 500 shares.</p>   |

## 2.2 Market environment

The activity of Mabion S.A. focuses on research and development work enabling the implementation of new biotechnological medicines, including biosimilars, obtained owing to the achievements of modern genetic engineering.

The Company's business also includes contract development and manufacturing services (in which the Company acts as a CDMO). The Company's first customer is Novavax, Inc., and the cooperation includes, inter alia, the manufacturing of a COVID-19 vaccine antigen by Mabion. The Company has expanded its operations to include such services based on its available GMP-compliant manufacturing capacity and the experience of its staff in the research and development, analytical, clinical, and regulatory areas.

In the area of own therapeutic products, the strategic goal of the Company is to develop, manufacture, and sell drugs used in the treatment of the most serious diseases, including neoplastic or autoimmune diseases. Biological medicines developed by the Company are targeted preparations characterised by the ability to recognise a disease-related factor, e.g. a receptor whose overexpression is associated with the existence/development of cancer, and to interact only with that factor. Appropriate engineering of the structure of such medicines and thereby, a high degree of similarity to the proteins of the patient's body, makes the immune system treat the therapeutic antibody as its own protein. This guarantees a possible lower toxicity of the therapies developed by the Company and is a significant benefit for the patient. Currently, the Company's most advanced project is MabionCD20, a biosimilar medicine for which MabThera/ Rituxan (rituximab) (Roche) are reference drugs.

### COVID-19 vaccines

In 2021, the COVID-19 infection vaccine market has experienced rapid growth, expanding globally.

In the EU, by the end of 2021, the total number of doses of COVID-19 infection vaccine administered was 772 million, with a two-dose vaccination rate of 68.8% and a three-dose vaccination rate of 32.7% in the total population. According to current scientific evidence,<sup>3</sup> all vaccines authorised for use in the EU are highly effective in protecting against hospitalisation, severe course of disease, and death, with an effectiveness rate of over 80% in the general population. There is a clear link between vaccination rates and hospitalisation and death rates: the higher the vaccination rate, the lower the risk of hospitalisation or death.

The evidence suggests that booster doses significantly increase protection against infection and severe course of disease<sup>4</sup>. Due to the mutagenicity of the virus and the need to adapt vaccines to the needs of different age groups (e.g. vaccines dedicated to children), as well as declining vaccine-induced immunity over time, it is necessary to ensure the availability of vaccines with a safety profile that allows long-term use, further development, and deployment of new vaccine types. Taken together, all this makes the COVID-19 vaccine market an attractive one, with high growth potential. According to Coherent Market Insights' report, the global COVID-19 vaccine market was estimated at USD 38.56 billion in 2021 and it was expected to grow at a CAGR of 56.1% between 2021 and 2028 to reach USD 95.98 billion by 2028<sup>5</sup>.

Currently, the available types of vaccines can be classified into one of four basic groups: genetic, protein, vector, and inactivated/attenuated. A detailed description of the groups together with information on the companies developing each product is presented in the table below.

<sup>2</sup> <https://vaccinetracker.ecdc.europa.eu/public/extensions/covid-19/vaccine-tracker.html#uptake-tab>

<sup>3</sup> [https://www.ecdc.europa.eu/en/current-risk-assessment-novel-coronavirus-situation; Sikora, Dominika, and Piotr Rzymiski. "COVID-19 Vaccination and Rates of Infections, Hospitalizations, ICU Admissions, and Deaths in the European Economic Area during Autumn 2021 Wave of SARS-CoV-2." Vaccines 10.3 \(2022\): 437. https://www.mdpi.com/2076-393X/10/3/437/htm](https://www.ecdc.europa.eu/en/current-risk-assessment-novel-coronavirus-situation; Sikora, Dominika, and Piotr Rzymiski. )

<sup>4</sup> [https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans\\_pl](https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_pl)

<sup>5</sup> <https://www.coherentmarketinsights.com/market-insight/corona-virus-vaccines-market-4320>

**Table 1: COVID-19 vaccines market<sup>6</sup>.**

|                         | COVID-19 vaccine types   | selected developing entities (approved, Ph3 or Ph 2)                               |
|-------------------------|--|--|
| ▲<br>Increasing novelty | genetic vaccines<br>vaccines that deliver one or more of the coronavirus's own genes into our cells to provoke an immune response      |  |
|                         | peptide and protein-based vaccines<br>vaccines that contain coronavirus proteins but no genetic material                               |  |
|                         | viral vector vaccines<br>vaccines that contain viruses engineered to carry coronavirus genes   |  |
|                         | inactivated or attenuated vaccines<br>vaccines created from weakened coronavirus or coronaviruses that have been killed with chemicals |  |

The Novavax' vaccine (Nuvaxovid®) was authorised in the European Union in December 2021 and contracted by the European Commission at 100 million doses, plus possibly additional 100 million doses between 2021 and 2023<sup>7</sup>. Nuvaxovid® is a protein-based vaccine that utilises a novel recombinant technology for S protein of the SARS-CoV-2 coronavirus. The innovative feature of this vaccine relates to the production of the S protein of the virus by recombination in insect cells (and not in yeast cells as for example in the Hepatitis B vaccine). The insect cells in this case act as small factories that produce the recombinant coronavirus protein. As a result, the production of the vaccine is faster compared to conventional vaccines. The vaccine's safety and clinical efficacy were assessed in two randomised controlled trials involving more than 45,000 volunteers aged ≥ 18 years. A combined analysis of the results of phase III clinical trials carried out in the US and the UK indicates that the efficacy of the vaccine averages 90% in preventing the symptomatic COVID-19.<sup>8</sup>

With its GMP-compliant production facilities and a unique, in Poland, experience in the development of technologically advanced biological drugs, Mabion has become a natural partner for global companies developing protein vaccines, both in terms of clinical and regulatory development as well as commercial scale manufacturing of the product. On 8 October 2021, following the successful completion by Mabion of the transfer of the manufacturing process and analytical methods, the Company entered into a manufacturing agreement with Novavax for the commercial contract manufacturing of the antigen for the Nuvaxovid® vaccine.

By the date of this report, work under the agreement has proceeded to schedule and details of the processes being carried out are presented in section 4.2 of this report.

The cooperation with Novavax started an important new chapter in the Company's operations. Complementing its profile as a manufacturer of originator medicines, Mabion started to offer contract manufacturing services – as a CDMO (Contract Development and Manufacturing Organisation) – in order to effectively use its available capacities and competences.

In 2021, the global CDMO market is estimated to be worth around EUR 70 billion, of which the CDMO market for biologics is EUR 22 billion with an expected average annual growth rate of 5.9% over the period of 2020–2022<sup>9</sup>. As an integrated biotech company with competencies across the biosimilar development value chain, Mabion has a good opportunity to win contracts in the CDMO market despite strong competition. The CDMO market is a market with enormous growth prospects because of the steady increase in R&D spending in pharmacology, the increase in the number of molecules in development, and the growing willingness of pharmaceutical and biotechnology companies to outsource production<sup>10</sup>.

### Biosimilar medicines

Biosimilar medicines form a dynamically developing area in the global pharmacy. According to the definition adopted by pharmaceutical regulators, a biosimilar is a biological medicine similar to another biological medicine that has already been

<sup>6</sup> Information of the Company, L.E.K. WHO.

<sup>7</sup> [https://malta.representation.ec.europa.eu/news/commission-approves-new-contract-potential-covid-19-vaccine-novavax-2021-08-04\\_en](https://malta.representation.ec.europa.eu/news/commission-approves-new-contract-potential-covid-19-vaccine-novavax-2021-08-04_en)

<sup>8</sup> <https://szczepienia.pzh.gov.pl/piata-szczepionka-przeciw-covid-19-dopuszczona-do-obrotu-w-unii-europejskiej/>

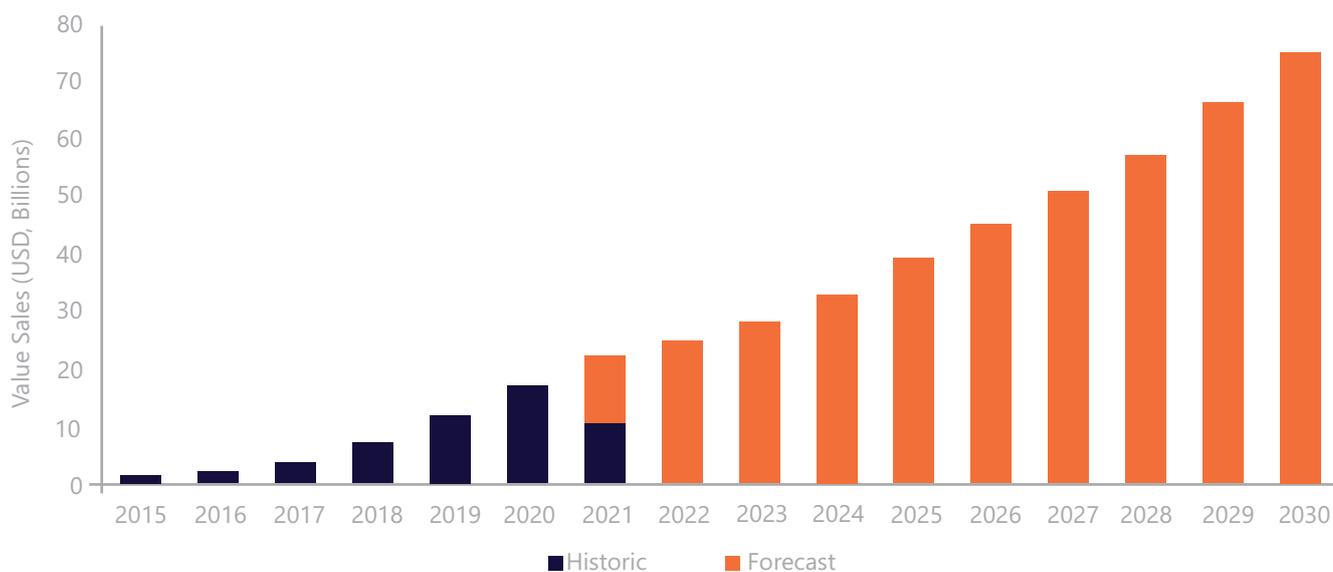
<sup>9</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022: Mordor Intelligence; Daedal Research; BCC Research; Visiongain; L.E.K. interviews and analysis

<sup>10</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

authorised. In registration, a biosimilar product is compared and evaluated against a reference product. It should be as similar to it as possible and not show clinically significant differences. As shown in reports and analytical studies, the share of biosimilars in global sales increases year by year. This is mainly due to the increasing demand for biologic medicines and the expiry of patents on reference medicines. According to IQVIA, between 2015 and 2020, the compound annual growth rate (CAGR) for biosimilar medicines was 78%, with the market reaching USD 17.9 billion in 2020.<sup>11</sup>

Depending on the source and time frame, the CAGR for the biosimilars market in the years to come should oscillate within between 15%<sup>12</sup> and 25.6%<sup>13</sup>, with an estimated global market value in 2028 reaching approx. USD 225 billion (according to "Biosimilar Market Global Biosimilar Market Insights and Forecast to 2028"<sup>14</sup>). IQVIA experts offer more conservative estimates (USD 75 billion in 2030), but their assumptions also imply a dynamic and continuous growth of the biosimilar market.

**Table 2. Evolution of global biosimilar sales value<sup>15</sup>.**  
(USD)



Among the factors supporting the development of the biosimilars market, the authors of the studies list such factors as:

- > a global increase in the incidence of oncological and immunological diseases,
- > the introduction of biosimilar drugs by various players (both pharmaceutical giants and smaller companies with a global reach) to the market,
- > a favourable environment for this type of investment translating into an increase in the number of marketed biosimilar medicines,
- > expiry of patents for best-selling biological medicines (on average, over the period of 2021–2030 medicines with a

total sales value in 2020 of approx. USD 144 billion will go off the cliff),

- > positive perception of biosimilar medicines among physicians and patients,
- > lower prices of biosimilars compared to originator medicines (on average around 30–40%)<sup>16</sup>, which allows wider access to advanced and modern therapies for patients.

At the same time, it is pointed out that the costs and complexity of developing biosimilar medicines may challenge the growth of this market. Current data indicate that the cost of developing a biosimilar medicine ranges from USD 100 to 200 million and lasts 8–10 years on average<sup>17</sup>.

<sup>11</sup> <https://www.iqvia.com/blogs/2021/12/biosimilars-to-continue-rapid-growth-over-the-next-decade>

<sup>12</sup> <https://www.iqvia.com/blogs/2021/12/biosimilars-to-continue-rapid-growth-over-the-next-decade>

<sup>13</sup> [https://www.globenewswire.com/news-release/2022/02/14/2384085/0/en/Biosimilars-Market-to-Reach-\\$-103-94-Billion-by-2028-Low-Priced-Biosimilars-to-Boost-the-Market-Demand-Vantage-Market-Research.html](https://www.globenewswire.com/news-release/2022/02/14/2384085/0/en/Biosimilars-Market-to-Reach-$-103-94-Billion-by-2028-Low-Priced-Biosimilars-to-Boost-the-Market-Demand-Vantage-Market-Research.html)

<sup>14</sup> <https://reports.valuates.com/reports/QYRE-Othe-0T469/biosimilar>

<sup>15</sup> <https://www.iqvia.com/blogs/2021/12/biosimilars-to-continue-rapid-growth-over-the-next-decade>

<sup>16</sup> In response to high costs of biological medicines used in oncology indications, several countries have introduced legislation to increase the use of biosimilar medicines. For example, in Spain and Poland, respectively, prices of biosimilars have to be at least 25% and 40% lower than the originator drugs, and in Norway biosimilars used in oncology have won the majority of hospital contracts, which has contributed to an increase in the number of biosimilar medicines. Based on:

<https://www.iqvia.com/blogs/2021/12/biosimilars-to-continue-rapid-growth-over-the-next-decade>

<sup>17</sup> <https://www.gabionline.net/reports/comparison-of-the-cost-of-development-of-biologicals-and-biosimilars>

The European Medicines Agency (EMA), a body that coordinates the evaluation and supervision of medicinal products for human use throughout the EU, is at the forefront of the development of regulations for biosimilar products. In 2004, the EMA established a legal framework for the review and development of biosimilar medicines and in subsequent years, developed and refined a comprehensive set of regulatory guidelines.

Due to its global leadership in the regulation and approval of biosimilar products, the European biosimilars market has been the one most rapidly growing to date. At present, 90% of global sales of biosimilar medicines take place in Europe<sup>18</sup>.

In line with the reports prepared annually by IQVIA for the European Commission, entitled: "The Impact of Biosimilar Competition in Europe"<sup>19</sup>, one of the premises for introducing biosimilar medicines was to increase price competition, which would press down the medicine prices for health systems and patients. Biosimilar medicines and their impact on the market continue to deliver significant savings to healthcare systems. Despite the impact of the COVID-19 pandemic in 2020, the number of biosimilar prescriptions has generated record savings resulting from the competition from the biosimilars. Savings resulting from the list price (excluding confidential rebates and discounts) by 2020 amounted to EUR 5.7 billion compared to the cost of a originator drug before the marketing of a biosimilar, and this figure would likely be even higher if based on net prices<sup>20</sup>.

Increased competition resulting from the marketing of biosimilars affects not only the price of the reference medicine for a particular biosimilar, but often also the price of the whole class of products in a specific therapeutic group. For most therapeutic classes, there is often an increase in sales following the introduction of biosimilars to the market, due to the increased availability of therapies to patients. Increasing availability of biosimilar medicines and growing competition among their manufacturers, supports greater savings to be achieved in the healthcare systems of individual European countries in the long term.

The American regulator (FDA) opened its market to biosimilar medicines a little later than in Europe, but as of 2018 there has been a noticeable increase in the dynamics of work in the

legislative field. The actions taken primarily concerned changes in the regulatory approach and consisted in adapting it to the real possibilities of manufacturers of drugs to obtain biosimilarity to an original medicine. This move was aimed at reducing barriers to the development of biosimilar medicines in the US market and achieving significant savings in the health system. These assumptions turned out not to be entirely accurate, and the slower market penetration of biosimilars in the US than in Europe was largely due to ongoing patent disputes between medicine manufacturers.

In 2021, there have been several important developments in the field of biosimilar medicines, including the expected first FDA designation of substitutes. The biosimilars market displayed a steady growth, but due to fewer FDA authorisations in 2020 and 2021, there was a decline in commercial deployments. It is estimated that between 2021 and 2025, the US healthcare system can save approximately USD 38 billion owing to the introduction of biosimilar drugs, whereas the most optimistic scenarios forecast savings exceeding even USD 120 billion<sup>21</sup>.

### MabionCD20

In its work aimed at registering MabionCD20, the Company continuously monitors the competitive environment of medicines biosimilar to MabThera/Rituxan (Roche), as well as the sales results of the originator medicine, and adapts its activities to the market situation.

With regard to Roche's MabThera/Rituxan, since the introduction of the first biosimilar in Europe in 2017, sales of the reference medicine have started to fall. This trend has continued in the following years, with the biggest falls in the USA, Europe and Japan. At the same time, it is worth highlighting that a dynamic growth in sales was shown by rituximab biosimilar drugs authorised on the European and US markets. There are currently three medicines approved on the European market that are biosimilar to MabThera/Rituxan: Truxima (Teva), Rixhaton (Sandoz), and Ruxience (Pfizer), and in the USA: Truxima (Teva), Ruxience (Pfizer), and Riabni (Amgen/Allergan). Based on market analyses, it can be assumed that Amgen's product will still be authorised on the European market<sup>22</sup>.

<sup>18</sup> <https://www.gabionline.net/biosimilars/research/the-us-needs-to-learn-from-europe-to-increasing-access-to-biosimilars>

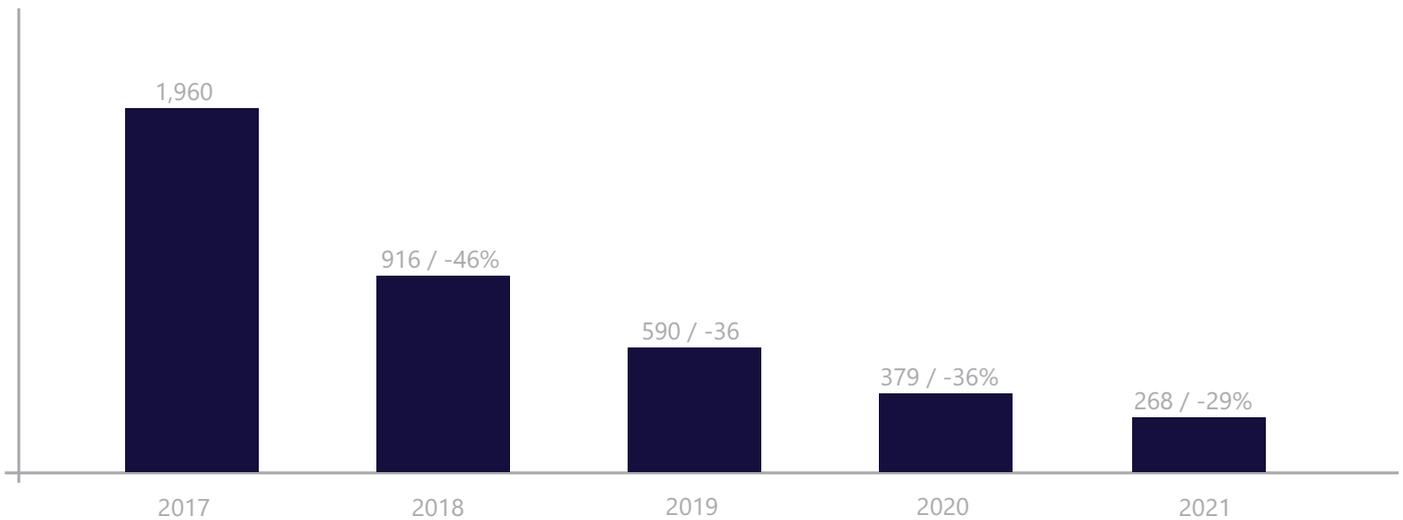
<sup>19</sup> The most recent IQVIA report was published in December 2021 – <https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2021>

<sup>20</sup> "The Impact of Biosimilar Competition in Europe", December 2021.

<sup>21</sup> <https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025>

<sup>22</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

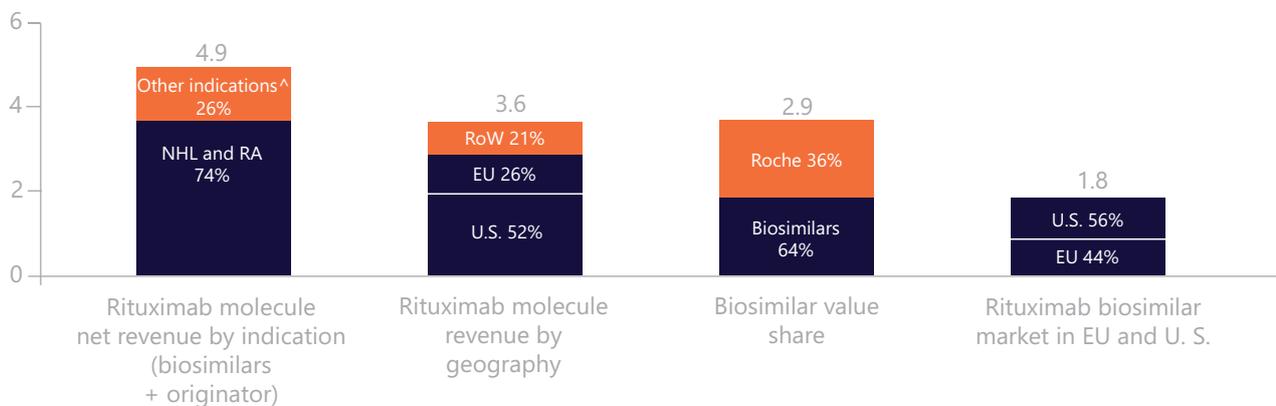
**Table 3. Sales of MabThera/Rituxan in Europe in 2016–2020<sup>23</sup>.**



In its financial statements for 2021, Roche reports that its global sales of MabThera/Rituxan amounted to CHF 2.5 billion, which is a drop of 38% YoY<sup>24</sup>.

As expected by market analysts, sales results for MabThera/Rituxan in the following years will fall. It is currently estimated that the global market for the rituximab molecule is worth EUR 4.9 billion, of which EUR 1.8 billion is generated by biosimilars<sup>25</sup>.

**Table 4. Rituximab market value segmentation<sup>26</sup>.**  
(2021) Billions of Euros



- > CLL and other indications, including off-label, estimated to be c.27% of value
- > U.S. And EU represent c.80% of Rituxan pre-biosimilar entry
- > Biosimilar volume penetration estimated to be c.55% in the U.S. and c.80% in Eu
- > Biosimilar list prices are c.15-25% below originator list prices

The European market for rituximab biosimilars in the indications of NHL (non-Hodgkin’s lymphoma) and RA (rheumatoid arthritis) is estimated to be worth around EUR 784 million. It is expected that the growth in biosimilars market penetration<sup>27</sup>.

<sup>23</sup> <https://www.roche.com/investors/rofis.htm>

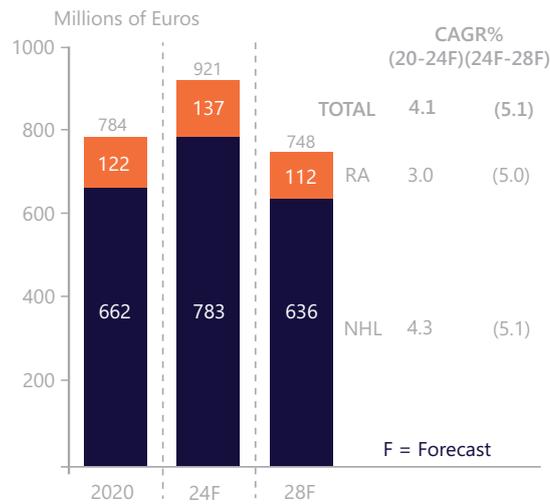
<sup>24</sup> <https://www.roche.com/investors/reports/>

<sup>25</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

<sup>26</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

<sup>27</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

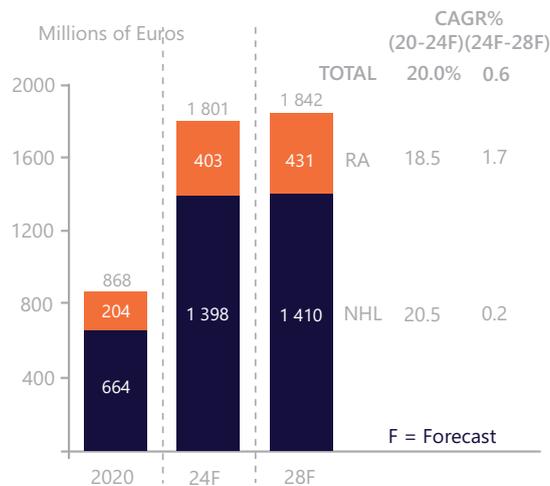
**Sales of MabThera biosimilars in Europe for the indications of NHL (non-Hodgkin's lymphoma) and RA (rheumatoid arthritis)<sup>28</sup>.**



By 2024, the US market for rituximab biosimilars could be worth around EUR 1.7 billion. A further increase in the

penetration of biosimilars is expected to drive value growth of 0.6% per year in 2024–28<sup>29</sup>.

**Table 6. Sales of Rituxan biosimilars in the US for the NHL and RA indications<sup>30</sup>.**



Currently, demand for medicines for oncology and autoimmune diseases exceeds the production capacity of suppliers and is limited by the financial capacity of national health systems. In Europe, the available market (defined as the market available for biosimilar competition, among other things due to expiry of patent protection for

originator medicines) represents between 10% and 40% of the total biosimilar market in the different countries<sup>31</sup>. The use of biosimilar medicines provides an opportunity to reduce treatment costs and thus to include more patients in therapy, which is why it is so important for healthcare systems.

<sup>28</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

<sup>29</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

<sup>30</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

<sup>31</sup> "The Impact of Biosimilar Competition in Europe", December 2021.

## 2.3 Regulatory environment

Registration of a biosimilar medicine in the European Union and the United States requires meeting a number of quality, efficacy and safety standards. The analytical, pre-clinical and clinical testing programme must be aligned with the stringent and sometimes contradictory guidelines recognised by the European and US registration authorities (EMA and FDA), which, in addition to the standard regulations relevant to the development of originator biological drugs, also include stringent provisions for comparative testing with the reference product. The last year has not brought fundamental changes to the regulation of trials and data to be submitted for registration of a biosimilar medicine. Meanwhile, new guidelines have been published that affect the preclinical and clinical development process of biosimilars, as well as COVID-19 vaccines, whose contract manufacturing is a new working area in the Company's business. In Europe, to enable the implementation of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, a number of new guidelines have emerged with the aim of harmonising activities related to clinical trials between Member States, as well as increasing their transparency.

Below, we present a description of the most important regulations issued in 2021 by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) that directly or indirectly affect Mabion's business.

### Guidelines of the European Medicines Agency (EMA) of 2021

- > EMA/698382/2021 "Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol", 13 December 2021

The guideline presents ways to notify serious breaches of the clinical trial protocol, which according to the new clinical provisions (Regulation (EU) No 536/2014) are to be reported by the Sponsor to local authorities in EU Member States on an ongoing basis. Before the entry into force of the guideline, there was no notification obligation, so the Company has developed procedures and designates necessary staff to oversee the CRO (Clinical Research Organization) in this regard.

- > EMA/CHMP/ICH/544570/1998 "ICH guideline E8 (R1) on general considerations for clinical studies Step 5", 14 October 2021

Revision of a guideline published in 1997. The document describes the following matters:

- internationally accepted principles and practices in the design and conduct of clinical studies that will ensure the protection of study participants and facilitate acceptance of data and results by regulatory authorities;
- manners of ensuring quality in the design and conduct of clinical studies, including the early identification of factors that are critical to the quality of the study, and

- the management of risks to those factors;
- the types of clinical studies performed during the product lifecycle, and study design elements that support the identification of quality factors and risks referred to above.

To ensure compliance with these regulations, the Company will need to implement additional training for clinical staff and verify compliance of the multidisciplinary risk analysis carried out previously and a review of the existing documentation.

- > EMA/CHMP/138502/2017 "Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development", 26 July 2021

The document describes statistical approaches followed during medicine development for the comparative analysis of quality attributes, inter alia in the case of biosimilarity assessment or manufacturing process changes. In its evaluation plans, the Company takes into account the recommendations resulting from the guideline to reduce the risks associated with the registration of MabionCD20 with the EMA as a biosimilar medicine.

- > EMA/CHMP/ICH/337843/2021 "ICH guideline E6 on good clinical practice Draft ICH E6 principles", 24 June 2021

The document contains a draft of the new edition of the GCP guidelines, which are currently being developed by the ICH E6(R3) expert group. The document describes the general principles of the new version, including the emphasis on quality by design, the role of the different parties involved, proportionate management and addressing critical factors affecting the trial quality. The Company monitors emerging GCP guidelines to ensure that provisions are quickly implemented into the internal quality system as soon as they are officially published.

- > EMA/319183/2021 rev. 21, 2 "Draft EU Common Standard for electronic product information for human medicines (ePI)", 7 June 2021

The document presents standards for the scope and format of information to be provided in electronic product information (ePI).

The content of the electronic information will have to be produced by the Company as part of the registration procedure for MabionCD20.

- > EMA/117973/2021 "Reflection paper on the regulatory requirements for vaccines intended to provide protection against variant strain(s) of SARS-CoV-2", 23 February 2021 and EMA/175959/2021 "Procedural guidance for variant strain(s) update to vaccines intended for protection against Human coronavirus: Regulatory and procedural requirements", 16 December 2021

The guidelines specify the requirements for updating the COVID-19 vaccine formulation with new variants, including schedules of activities, the necessary scope of analytical and

preclinical data and the structure of the dossier (eCTD format). The document is supposed to help in the seamless registration of vaccines that respond to virus mutations.

### Guidelines of the US Food and Administration Agency (FDA) of 2021

- > GUIDANCE DOCUMENT "Inspection of Injectable Products for Visible Particulates Draft Guidance for Industry", December 2021

The guideline describes the methodology recommended by the FDA for testing parenterals for the presence of visible particulates to enable compliance with GMP requirements. To align its quality system with FDA requirements, the Company will analyse the impact of the proposed provisions on the current content of its quality system procedures.

- > GUIDANCE DOCUMENT "Study Data Technical Conformance Guide - Technical Specifications Document", November 2021

The guideline includes the Administration's technical recommendations on the format and structure of the dossier to be submitted for the registration of a medicinal product in the United States. The recommendations also cover biological and biosimilar medicines (BLA, Biologics License Application). The Company will seek to ensure that documents produced for the new dossier of MabionCD20 and the data contained therein comply with the standard format and structure accepted by the FDA.

- > GUIDANCE DOCUMENT "Benefit-Risk Assessment for New Drug and Biological Products", September 2021

The guidance clarifies how considerations about a drug's benefits, risks, and risk management options factor into certain regulatory decisions taken by the FDA. The document will make it easier for pharmaceutical companies to understand the decision-making process and the motives behind certain Administration's actions, including the approval or rejection of a medicinal product application.

- > GUIDANCE DOCUMENT "Questions and Answers on Biosimilar Development and the BPCI Act Guidance for Industry", September 2021

A new version of a Q&A document on methods for developing and testing biosimilar medicines. The contents of this document will help the Company to prepare an appropriate set of analytical and clinical data needed to register MabionCD20 as a biosimilar medicine in the US.

- > GUIDANCE DOCUMENT "FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards", August 2021

Guidelines for Sponsors, Investigators and Bioethics Committees on the conduct of clinical trials during the COVID-19 pandemic. Although the document is primarily concerned with trials

conducted in the United States, the recommendations contained therein may help the Company design solutions to reduce possible health risks to patients participating in the trials and to reduce regulatory risks due to the possible impact of a pandemic on the quality of clinical data. With knowledge of the aforementioned regulations, the Company is able to assess which risk minimisation measures will be acceptable from the FDA's perspective and will not pose a risk during the planned registration procedure.

- > GUIDANCE DOCUMENT "Providing Regulatory Submissions in Electronic Format - Standardized Study Data", June 2021

The guideline summarises the requirements regarding the format in which preclinical and clinical trial data are provided as part of an electronic application for registration of a medicinal product in the US. The Company will have to ensure that the data generated for the new dossier of MabionCD20 comply with the format defined therein.

- > GUIDANCE DOCUMENT "Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry", May 2021

The document provides guidance on the data required by the FDA for a conditional registration of COVID-19 vaccines. The guidelines are important for the planned registration of Nuvaxovid® manufactured by Novavax on the US market.

- > GUIDANCE DOCUMENT "Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products Draft Guidance for Industry", May 2021

The document presents the FDA's viewpoint on statistical methods for covariance analysis in randomised clinical trials. Covariance analyses have been and continue to be used in all clinical trials sponsored by the Company, including the ongoing MabionCD20-003RA project. The method of analysis of the final results of this study, as declared among others in the protocol and statistical plan, will have to take into account the recommendations in question in order to increase the likelihood of successful registration of MabionCD20 in the USA.

- > GUIDANCE DOCUMENT "E9(R1) Statistical Principles for Clinical Trials: Addendum: Estimands and Sensitivity Analysis in Clinical Trials Guidance for Industry", May 2021

Guidelines outlining ways to define estimands and complementary statistical analyses in clinical trials. The requirement to define estimands when designing clinical trials will oblige the Company to adapt the above guidelines to its internal procedures (including protocol development procedures).

- > GUIDANCE DOCUMENT "Q3D(R2) – Guideline for Elemental Impurities Draft International Council for Harmonisation; Draft Guidance for Industry", May 2021

Draft version of the ICH Q3D(R2) guideline on the contamination of medicinal products by chemical elements.

The Company is monitoring the content of this draft guideline in view of the need to present a risk analysis on elemental impurities in MabionCD20 as part of the registration procedures at the EMA and the FDA.

## 2.4 Information on the scope of Company's business

The Company's core business consists of the development, analytics and manufacture of its own drug candidates, as well as contracting activities as a CDMO (Contract Development and Manufacturing Organisation).

In 2021, the Company generated first income from the technology transfer agreement and the manufacturing agreement with Novavax concerning the production of the antigen for the Nuvaxovid® vaccine.

At the same time, the Company continued its work on the preparation of a bridging trial of MabionCD20, on its own projects, and the selection of additional projects to be carried out in a partnership.

The Company has the capability and resources to conduct R&D and manufacturing in the development of biological drugs, including vaccines in response, among others, to the SARS-CoV-2 pandemic.

In 2021, Novavax, Inc. was a recipient of services provided by the Company with a value exceeding 10% of sales income. The income resulting from the cooperation with this entity, recognised in the financial statements, reached a value corresponding to 58.31% of the Company's sales income.

The Company also recognised income from non-reimbursable advances received in previous periods for distribution rights as a result of discontinuation of the collaboration with Mylan, which represented 36.59% of the Company's sales income generated in 2021. There are no formal relationships between the Company and Mylan.

Despite the significant shareholding, in the Company's opinion no dependence on the above-mentioned entities exists, as the Company is also active in the field of its own biosimilar projects whose implementation is not dependent on the existing cooperation with Novavax. There are no formal relationships between the Company and Novavax other than under the agreements entered into in 2021.

Details of the generated revenue are presented in Note 7 to the Financial Statements.

Detailed information on agreements concluded and advances received on distribution rights is presented in Note 19 to the Financial Statements.

## 2.5 Sourcing information

The Company carries out work in the field of development and manufacturing of biologics. In 2021, work carried out by the Company was related to very diverse areas (both in-house and contract projects) – small scale process work, scale-up process work, commercial scale process work, research and development analytical work, quality control analytical work. In consequence of the advancement of technologies developed in Mabion and the much differentiated level of project topics, the Company uses a wide range of products and services available on the market. This is reflected in the number of sources of supply used by the Company.

Producing an advanced biotechnological product as a monoclonal antibody or vaccine protein antigen requires maintaining appropriate sterility conditions and cleanliness areas, as well as certified input materials, including disposable materials. The final product is subject to release procedures of the Quality Control Department, which often require using appropriately characterised reagents or outsourcing analyses to appropriately certified bodies.

Suppliers that the Company purchased from in 2021 in excess of 10% of the Company's annual operating costs (less the cost of employee wages) are presented in the table below.

**Table 7. Key suppliers of Mabion S.A.**

| Supplier   | PLN thousand | %      |
|--|--------------|--------|
| Global Life Sciences Solutions Poland Sp. z o.o. | 9,120        | 33.87% |
| Sartorius Stedim Poland Sp. z o.o.               | 4,049        | 15.04% |
| Myonex Limited                                   | 3,916        | 14.54% |
| Parexel International (IRL) LTD                  | 3,337        | 12.39% |
| Merck Life Science Sp. z o.o.                    | 2,916        | 10.83% |

No entities presented in the table above are related to the Company Mabion S.A.

The Company cooperates with the entities listed above in the area of supply of process equipment, consumables, substances, as well as services related to the projects implemented by the Company.

In the Company's opinion, the entities listed above are the Company's key suppliers on which it is materially dependent. In order to prevent possible risks of dependence on listed suppliers, the Company takes into account alternative solutions by monitoring the market of producers and suppliers. This has allowed diversification in terms of suppliers, although it should be noted that there are technological limitations in the existing Company's facility, so the room for change is limited. The Company exercises due diligence to ensure that all orders are prepared well in advance to prevent possible delays in the supply chain.

## 2.6 Main domestic and foreign investments

In 2021, the Company did not make any significant investments in securities, financial instruments, or intangible assets.

In the reporting period of 2021, the Company implemented agreements with foreign contractors for the supply of property, plant and equipment to retrofit an existing manufacturing facility. The value of agreements signed with 3 key suppliers of property, plant and equipment (I.M.A. Industria Macchine Automatiche S.p.A. – an order for a packaging line, EbeTech GmbH – an order for a filling line, Adolf Kuhner AG – an order for bioreactors) in previous periods and 2021 amounted to EUR 8,383 thousand, of which – as at the balance-sheet date of 31.12.2021 – the value of the liabilities amounts to EUR 5,609 thousand. The Company intends to fund these purchases from its own resources and by using debt opportunities with banks or financial institutions.

## 2.7 Agreements in the area of the Company's operations

### 2.7.1 Material contracts concluded in 2021

#### Collaboration with Novavax, Inc. on the COVID-19 vaccine programme - framework agreement, commercial manufacturing agreement, and quality agreement

##### Framework Agreement

On 3 March 2021, the Company entered into a framework agreement (Framework Agreement) with Novavax, Inc. based in the United States, pursuant to which the Company, with the participation of Novavax, has undertaken activities related to the technology transfer related to the manufacturing process of a COVID-19 vaccine antigen for Nuvaxovid® vaccine (formerly vaccine candidate antigen for COVID-19 under the working name of NVX-CoV2373) and carrying out technical runs of the

process on a commercial scale at the Company's facility. The Framework Agreement will be in force until 31 December 2023. The intention of the parties to the Framework Agreement was that the Company's facility, in the event of the manufacturing cooperation considered at that time is pursued, might be integrated into the Novavax manufacturing chain for the commercial manufacturing of the active substance of the vaccine for Novavax.

The Framework Agreement did not specify minimum order quantities. At the stage of entering into the Framework Agreement, it was too early to determine the target scale of the cooperation initiated with Novavax and the target scope of work that will ultimately be performed, and thus to estimate the impact of the cooperation with Novavax on the Company's financial results. Pursuant to the Framework Agreement, Novavax retained the right to terminate the Framework Agreement in whole or in part, and the Company's undertaking of potential cooperation with other entities in the area of COVID-19 vaccine manufacturing required prior approval from Novavax.

##### Orders under the Framework Agreement

On 3 March 2021, with the conclusion of the Framework Agreement, the parties agreed on the scope and budget of the work contracted to the Company as part of the first order to carry out the technology transfer and a technical runs for the antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order included technology transfer from Novavax to the Company. In addition, it included: the transfer and verification of analytical methods, together with implementation of the transferred methods and documentation related to the manufacturing process into the Company's quality system, completion of one technical run and one confirmatory run demonstrating the repeatability in batch production of the product in the Company's facility. No significant investment on the part of the Company was required to complete the first order. The technical run was funded by a non-refundable consideration that the Company has received from Novavax in connection with the first order. On 25 March 2021, the Company received the first payment from Novavax, Inc. as part of the fulfilment of the aforementioned order placed under the framework agreement, amounting to USD 1,030 thousand. The funds received represented the first tranche of remuneration amounting to USD 530 thousand and an advance on materials and reagents amounting to USD 500 thousand. The first order under the Framework Agreement was completed in 2021.

On 23 June 2021, the Company received a second order from Novavax to carry out defined activities under the Framework Agreement. The order was placed in conjunction with ongoing negotiations for a manufacturing agreement under which the Company could manufacture the vaccine active ingredient on a commercial scale for Novavax. To facilitate the Company's future production process, Novavax and the Company have signed the second order under the existing framework agreement, allowing the Company to procure key raw materials

for production in advance within a budget agreed by the parties and funded by Novavax. The order concerned the procurement of raw material volumes sufficient for the future commercial production of the active substance involving the Mabion's full production capacity by the end of the first half of 2022 (as estimated by the Company). In line with the arrangements outlined in the order, the Company received on 15 July 2021, a full prepayment from Novavax for the raw materials to be procured, amounting to USD 15,226 thousand. Contracting raw materials for production at that stage of the cooperation, i.e. in advance, was to enable commercial manufacturing services to commence more promptly if the manufacturing agreement is concluded. All procurement of raw materials related to the implementation of the agreement in question has been carried out. As at the date of publication of this report, the execution of the second order under the Framework Agreement has been completed.

Novavax made further payments in the period September – November 2021, representing partial settlement of the first order under the agreement of 3 March 2021 and the arrangement to cover expenditure related to the adaptation of the manufacturing process for a total amount of USD 1,830 thousand.

### **Commercial manufacturing agreement**

On 8 October 2021, the Company entered into a commercial contract manufacturing agreement (Manufacturing Agreement, Master Contract Manufacturing Agreement) with Novavax, together with a Statement of Work, pursuant to which the Company manufactures on a commercial scale, on a GMP standard basis, an antigen for a COVID-19 vaccine called Nuvaxovid®.

The Manufacturing Agreement is unconditional, and its conclusion and commencement are independent of the registration procedure of the Novavax' vaccine on the respective markets. The Agreement has been concluded for a fixed period of time until the end of 2025, with an option for renewal. The Agreement's total value over its entire term has been estimated at USD 372 million (an estimate based on a theoretical assumption of future zero inflation over the Agreement's term). The Manufacturing Agreement will be implemented and settled per batch of the product, at the unit price per batch specified in the Agreement (unit prices are subject to indexation based on future inflation). Under the Manufacturing Agreement, the parties have agreed on the volume and production schedule for each year in the period 2022–2025, based on which the Company will manufacture the number of product batches required by Novavax. The production schedule has been set for the entire duration of the Manufacturing Agreement, but the parties may agree on modifications to the schedule and volume of deliveries.

The possibility of completing the agreed scope of work under the Manufacturing Agreement in the future years depends on the Company's available production capacity, therefore the objective of the Management Board of Mabion S.A. is to expand the production capacity in the first quarter of 2023 and

equipping the facility with new bioreactors, which will result in the Company having four bioreactors in the years 2023–2025. The Company's Management Board estimates that during the first two years of commercial manufacturing covered by the Manufacturing Agreement (i.e. 2022–2023), the Company may realise approximately 40% of the total value of the Agreement, and in the following two years (i.e. 2024–2025), including as a result of increased production capacity, approximately 60% of the total value of the Agreement. In 2021, the Company carried out the preparatory work specified in the Order, including, among other things, the installation of additional systems and equipment, the acquisition and quality control of materials, and updating documentation specific to commercial manufacturing.

In Q4 2021, the first manufacturing activities commenced under the agreement with Novavax.

### **Quality Agreement**

On 19 November 2021 (an event after the balance-sheet date), the Company entered into a Quality Agreement with Novavax, covering technical and regulatory arrangements for the production of Nuvaxovid® antigen, including relevant GMP standards. The Quality Agreement remains in force until the end of the term of the Manufacturing Agreement, subject to updating if required. The Quality Agreement sets forth the obligations and technical and regulatory arrangements required for the manufacture, testing, storage and shipment of the product. It also sets out the principles of cooperation between the departments involved in the implementation of the Agreement. The Quality Agreement represented an important step in the implementation of the Manufacturing Agreement.

On the same day, the Company submitted a notification to the Chief Pharmaceutical Inspectorate (GIF) concerning the conclusion of the aforementioned Quality Agreement. The next step was to submit a notification to the GIF on the change of manufacturing conditions, and an application for entry into the National Register of Manufacturers, Importers and Distributors of Active Substances for the active substance SARS-CoV-2 rS. On 19 April 2022 (an event after the balance-sheet date), the Company received information that the Company's activity as a manufacturer of active substance SARS-CoV-2 rS was entered into the National Register of Manufacturers, Importers and Distributors of Active Substances kept by the Chief Pharmaceutical Inspectorate.

The Company informed about the events related to the cooperation with Novavax in Current Reports no. 15/2021 of 3 March 2021, no. 30/2021 of 25 March 2021, no. 45/2021 of 23 June 2021, no. 52/2021 of 8 October 2021, and no. 63/2021 of 19 November 2021.

### **Information on cooperation with Mylan Ireland Ltd.**

On 29 April 2021, the Company signed an annex to the agreement on cooperation in the commercialisation of MabionCD20, concluded in November 2016 (Development and

Commercialisation Agreement) with Mylan Ireland Ltd. Under the Annex, the parties decided to continue cooperation, but the territorial scope of the agreement has been changed. Mylan remained Company's non-exclusive distribution partner for MabionCD20 in selected countries in regions such as, in particular, Australia, New Zealand, Mexico, Central America, southern Africa, south-eastern Asia. At the same time, it was decided that Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries, as well as Mylan's priority right to enter into a commercialization agreement for MabionCD20 in the United States (USA), shall expire.

The annex did not affect the activities carried out by the Company in order to obtain the marketing authorisation for MabionCD20 from the European Medicines Agency, or their schedule.

At the same time, the parties have agreed that the Company will reimburse to Mylan part of the advances, in an amount lower than the advance payments received by the Company under the agreement before the date of the annex, constituting repayable advances for distribution rights, which will be tantamount to the final settlement of all payments made so far between the parties. Pursuant to the annex, the Company repaid to Mylan the first tranche of advances received for distribution rights on 20 July 2021 in the amount of USD 6,000 thousand and on 29 October 2021, the Company repaid the second (final) tranche in the amount of USD 3,500 thousand. As at the balance-sheet date and as at the date of this report, the related liabilities amount to USD 0 (zero).

Then, on 17 November 2021, the Company received from Mylan a statement of termination of the cooperation agreement referred to above. The Agreement was terminated subject to 90 days' notice. The termination of the agreement did not involve any payments or additional financial obligations for the Company – all payments between the parties to date have been settled pursuant to the aforementioned annex of 29 April 2021.

At present, the Company has the full and necessary flexibility to commercialise MabionCD20 in all markets, which may have a positive impact on acquiring a strategic investor.

The Company informed of the above events in Current Reports no. 35/2021 of 29 April 2021 and no. 62/2021 of 17 November 2021.

### **Conclusion of an agreement for the supply of bioreactors to the Company's manufacturing facility**

On 30 November 2021, Mabion S.A. entered into an agreement with Adolf Kühner AG, Switzerland ("Supplier") for the purchase of four bioreactors with a capacity of 2,500 litres each, together with additional services ("Agreement"). Under the Agreement, the Supplier will manufacture and deliver to the Company four bioreactors in accordance with the specifications set out in the Agreement. Two of these bioreactors will form part of the Company's second production line and the another two will be

used to replace the existing bioreactors as part of the Company's facility upgrade. The Supplier will be responsible for commissioning and setup of the devices at the Company's manufacturing facility in Konstantynów Łódzki and for training the Company's staff. The equipment procured is to meet both European and US GMP (Good Manufacturing Practice) requirements.

The purchase of the aforementioned bioreactors will enable the Company to replace its existing bioreactors and to double its current manufacturing capacity, and is in line with the Company's development plans. The capacity expansion will first of all enable an increase in contract manufacturing of the COVID-19 vaccine antigen for Novavax, Inc., and together with the contemplated construction of a new factory equipped with additional bioreactors, it will allow to secure capacity for the planned contract manufacturing services for further business partners, as well as for the possible future production of MabionCD20.

The assembly, installation, and commissioning of the devices will be completed within 15 months of the date of the Agreement. The Company expects the new bioreactors to be operational as of Q2 2023.

The Company informed of the above event in Current Report no. 64/2021 of 30 November 2021.

### **2.7.2 Agreements concluded after the balance-sheet date**

#### **An order to manufacture cell banks under the Manufacturing Agreement with Novavax, Inc.**

On 14 January 2022, Mabion S.A. and Novavax, Inc. signed an additional order under the Manufacturing Agreement in the form of a Statement of Work #3 ("SOW#3"). Based on the SOW#3, in addition to its existing work, the Company has produced GMP-compliant cell banks for Novavax, which will be used as key biological material to form the basis for the production of vaccine antigens of the Nuvaxovid® product. The production was carried out in compliance with the technical and quality requirements specified in SOW#3.

In line with the assumptions, the Company has produced cell banks in accordance with the GMP standard and confirmed the sterility of the resulting material in Q1 2022. The cell banks were sent to external entities for an additional series of analytical tests. The external analyses are scheduled to be completed around mid-2022. Upon the completion of all analytical testing, Mabion will place the cell banks at Novavax's disposal within the existing network of entities involved in the production of the Nuvaxovid® vaccine.

Despite the fact that, in relation to the originally signed Manufacturing Agreement, the financial value of SOW#3 itself is not relevant for the assessment of the materiality of the order for the Company, the extension of the cooperation with Novavax into another new area, i.e. the production of cell banks, remains an important and key business value for the

Company. At the same time, the event in question represents a major operational action to increase Novavax's vaccine production capacity.

In the opinion of the Management Board, the Company's selection in the bidding process held by the contractor confirms the Company's qualifications as a Contract Development and Manufacturing Organisation (CDMO).

The Company informed of the event in Current Report no. 2/2022 of 14 January 2022.

### **Order for product quality control analytical services under the Manufacturing Agreement with Novavax, Inc.**

On 18 January 2022, Mabion S.A. and Novavax, Inc. signed an additional order under the Manufacturing Agreement in the form of a Statement of Work #2 ("SOW#2"), under which the Company will provide additional analytical services to Novavax for analytical testing related to quality control of the Nuvaxovid® vaccine ("Product"). Based on SOW#2, the Company has first performed and duly documented feasibility studies for certain analytical methods not covered by previous contracts or orders and is carrying out the transfer of methods in accordance with Novavax's specifications. The above work commenced in January 2022 and will be completed, as expected by both parties, no later than in the third quarter of 2022. Thereafter, during the term of the Manufacturing Agreement, i.e. from 2022 to 2025, the Company will perform, using the aforementioned analytical methods, the testing of the Product samples designated by Novavax, whereas, pursuant to SOW#2, the testing may include samples originating from the Company's facility as well as samples supplied by Novavax from other facilities involved in contract manufacturing for Novavax.

The value of SOW#2 depends on the number of analytical tests carried out by the Company in each year, and according to the Company's current estimates, despite the high margin of the contract, the financial value in relation to the originally signed Manufacturing Agreement should not be significant in assessing the materiality of the additional order for the Company. Nevertheless, the extension of the cooperation with Novavax to another new area, i.e. the implementation of additional contract analytics in the key scope, i.e. related to the release of individual Product batches on the market, remains a very important business aspect for the Company. In the Management Board's opinion, the Company's selection in the bidding process held by the contractor confirms once again the Company's qualifications as a Contract Development and Manufacturing Organisation (CDMO).

The Company informed of the event in Current Report no. 3/2022 of 18 January 2022.

### **Conclusion of an annex to the agreement on co-financing the project entitled "Expansion of the Research and Development Centre of Mabion S.A. - research on the new generation of medicines"**

On 19 April 2022, the Company's Management Board concluded, with the Ministry of Development Funds and Regional Policy, an annex to the agreement on co-financing of the project entitled "Expansion of the Research and Development Centre of Mabion S.A. - research on the new generation of medicines". According to the annex, the period of expenditure eligibility for the Project was extended until 31 December 2023 (previously 31 December 2021). Moreover, due to the inclusion of an additional research area in the Company's activity, i.e. vaccine therapies, the objective and material and financial scope of the Project were changed to the extent enabling the introduction of the aforementioned research area to the Project.

The Company informed about the event in Current Report no. 10/2022 of 19 April 2022.

## **2.8 Financing agreements**

### **2.8.1 Loan and borrowing agreements entered into or terminated in 2021**

#### **Conclusion of a borrowing agreement with Twiti Investments Ltd.**

On 5 February 2021, the Company entered into a borrowing agreement with Twiti Investments Ltd. – a related party and shareholder holding as at that day 17.33% of the Company's share capital ("Lender"), for the total amount of up to PLN 10 million. The Company's Supervisory Board approved the conclusion of the Borrowing Agreement. The Borrowing could be disbursed in tranches, in amounts and on dates agreed by the parties in a separate disbursement schedule, and the Lender was obliged to disburse each tranche at the written request of the Company. The borrowing agreement does not specify the purpose of the funds, and it was the Company's intention to use the funds raised to cover current expenses. Out of the borrowing in question, whose date was valid until 31.12.2021, the Company has drawn tranches totalling PLN 3.5 million. The interest rate on the Borrowing has been agreed on an arm's length basis as a variable interest rate based on WIBOR 3M plus a margin. The principal receivable under both of the above borrowing was repaid in March 2021 in a portion amounting to PLN 1.2 million by way of conversion into U series ordinary bearer shares issued by the Company pursuant to a resolution of the Extraordinary General Meeting of 23 February 2021. To this end, the Company performed a contractual set-off of part of the claim against Twiti Investments Limited for payment of the issue price for the U series shares subscribed for by Twiti Investments Limited as part of the issue with the claim of Twiti Investments Limited under the said borrowing agreement. On 15 April 2021, the Company settled the remaining unpaid liabilities under the above-mentioned agreement, i.e. the amount of PLN 2.3 million of principal and interest, and therefore the borrowing was repaid in full as used. The borrowing represented a further step in the implementation of the declaration of support for the Company by key shareholders made to the Company in letters of support. At the date of this report, the Company is not utilising the borrowing.

The Company informed about the events in Current Reports no. 5/2021 of 5 February 2021, no. 20/2021 of 8 March 2021, and no. 23/2021 of 15 March 2021.

### Conclusion of an annex to the borrowing agreement with Glatton Sp. z o.o.

On 17 December 2021, the Company concluded with Glatton Sp. z o.o. – a related party and shareholder holding, as at that day, directly and indirectly, a total of 10.63% of the share capital of the Company (lender) – an annex to the borrowing agreement of 15 July 2020 amounting to PLN 15 million, pursuant to which the borrowing repayment date was extended to 12 July 2022 (previous date: 31 December 2021). The Company informed of the above event in Current Report no. 66/2021 of 17 December 2021.

### 2.8.2 Borrowings granted

In the financial year 2021, the Company did not grant any borrowings.

### 2.8.3 Sureties and guarantees

During the reporting period ended 31 December 2021, the Company did not issue or receive any sureties or guarantees.

## 2.9 Factors and events in the Company's operations

Information on the agreements concluded in the area of operations and financing is presented in sections 2.7 and 2.8 of this report. Other significant factors and events occurring in the Company's operations include mainly those set out in the sections below.

### 2.9.1 Significant events in the financial year

#### Adoption of a long-term strategy for financing the Company's activities

On 27 January 2021, the Management Board of Mabion S.A., on the basis of an in-depth analysis of the Company's needs and estimated benefits, adopted a new long-term strategy for financing the Company's activities. The strategy covers the Company's overall capital needs which has to be fulfilled in order to carry out all activities which, in the opinion of the Company's Management Board, are necessary to complete the registration of MabionCD20 with the EMA and to start selling MabionCD20 and generate operating cash flows thereby. The arrangements for the Company's financing strategy were positively reviewed by the Company's Supervisory Board on the same date. The financial strategy adopted on 27 January 2021 assumed concurrent implementation of the following processes: the acquisition of a strategic investor and two issues of the Company's shares.

As part of the strategy, the following directional funding decisions were taken, and then the following activities were carried out to implement them:

- 1) decision to initiate the search for a strategic investor for the Company.

In order to effectively carry out this process, on 27 January 2021 the Company signed an agreement with the financial advisor Rothschild & Co. The scope of the advisor's responsibilities includes, inter alia, searching for a potential strategic investor, advising on the structure of a potential transaction, support in drafting transaction documentation and in negotiations with the potential strategic investor. As at the date of this report, decisions have not been made regarding the type of investor, the expected level of capital commitment, or the transaction formula. These decisions will be made in the course of a process designed to select the most beneficial way for the Company to achieve its long-term business objectives; As at the date of this report, the process is being actively pursued.

- 2) decision to conduct an offering of the Company's shares in the first quarter of 2021 under the "accelerated bookbuilding" procedure, addressed to eligible investors who are shareholders of the Company and who are qualified investors or who acquire shares with a total value of at least EUR 100 thousand, as indicated by the Company's Management Board.

In order to put the above decision into effect, the Company's Management Board convened an Extraordinary General Meeting for 23 February 2021, which adopted Resolution no. 4/II/2021 on increasing the Company's share capital by an amount not less than PLN 0.10 and not more than PLN 243,055.40 by way of an issue of at least one and not more than 2,430,554 U series ordinary bearer shares with a par value of PLN 0.10 each ("EGM Resolution"). The purpose of the U series share issue was to generate the necessary financing for the Company's working capital, in particular for the development of MabionCD20 and activities aimed at carrying out the registration procedure at the EMA as soon as possible.

The issue of the U series shares was effected upon the execution of agreements for the taking-up of all the U series shares and upon payment in full of the contributions to cover the shares (no allotment of shares within the meaning of the Commercial Companies Code was necessary). The conclusion of the agreements for taking up U series shares was completed on 12 March 2021. Contributions for the U series shares were paid in full by 15 March 2021. 2,430,554 U shares were taken up, as a result of which the Company leveraged PLN 133.7 million. The Company's share capital increase through the issue of U series shares was registered with the National Court Register on 2 April 2021. Detailed information on the issue of U shares can be found in section 3.7 of this report.

- 3) decision on the intention to make a prospectus-based offer of the Company's shares within the meaning of the relevant legislation.

To implement the above decision, concurrently with the issue of U shares, in early 2021 the Company started preparations related to the prospectus and the offering of the Company's

shares on the basis of the prospectus. On 22 February 2021, the Company's Management Board convened an Extraordinary General Meeting for 22 March 2021 to adopt a resolution on increasing the Company's share capital by an amount not less than PLN 0.10 and not more than PLN 1,050,000 by way of an issue of at least one and not more than 10,500,000 V series ordinary bearer shares with a par value of PLN 0.10 each.

On 16 March 2021, the Management Board of the Company announced the cancellation of the Extraordinary General Meeting of the Company which was to be held on 22 March 2021. The decision of the Management Board of the Issuer to cancel the General Meeting resulted from the need to verify available sources of funding necessary to cover financing needs, inter alia, following the successful issue of U shares and the conclusion of a framework agreement together with the first order for contractual services with Novavax, Inc. regarding the COVID-19 vaccine programme. The funds raised from the issue of U series shares and the fact of concluding an agreement with Novavax Inc. enabled the Company to potentially access additional, not yet fully available sources of financing, including potential debt financing from Polski Fundusz Rozwoju S.A. (PLN 30,000 thousand), an awarded and unused subsidy from the European Regional Development Fund (approximately PLN 63,000 thousand) and potentially a loan from the European Investment Bank (up to EUR 30,000 thousand in total). Up to the date of the report, the Company has not made any changes to the contractual terms of the funding mobilisation.

As at the date of this report, the Management Board of the Company still does not recognise a need for the Company to raise capital by way of a share issue at this time and therefore is not currently undertaking any steps in this area. To date, the Company has financed its operations with cash received from shareholder borrowings, capital issues, bank loans, grants and proceeds from MabionCD20 distribution partners. The agreement with Novavax has provided the opportunity to realise positive cash flows over the next 4 years until the end of 2025 and has become the main source of funding for ongoing operations and manufacturing capacity expansion. In addition, the Company does not exclude the use of other sources of financing such as external debt financing, grants, subsidies from EU funds, earmarked funds for the implementation of new projects, or other sources. The Management Board of the Company is also undertaking activities aimed at starting cooperation with other entities operating on the market, in the case of which such cooperation may bring profits to the Company in the area of development and production of biologics.

The Company informed of the above events in Current Reports no. 3/2021 and no. 4/2021 of 27 January 2021, no. 11/2021 of 22 February 2021, no. 12/2021 of 23 February 2021, no. 23/2021 of 15 March 2021, no. 25/2021 of 16 March 2021, no. 26/2021 of 22 March 2021 and no. 31/2021 of 2 April 2021.

### **Adoption of resolutions on the continued existence of the Company pursuant to article 397 of the CCC and on extending the Company's scope of business**

On 23 February 2021, the Extraordinary General Meeting of Mabion S.A. adopted Resolution No. 3/II/2021, according to which, in connection with the occurrence of the circumstances provided for in Article 397 of the CCC, the General Meeting of the Company decided on the continued existence of the Company. Pursuant to Article 397 of the Commercial Companies Code, "[i]f the balance sheet drawn up by the management board shows a loss exceeding the aggregate of the supplementary and the reserve capitals and one third of the share capital, the management board shall immediately convene the general assembly so that a resolution on the continued existence of the company can be adopted". Due to the fact that as at 30 September 2020 the Company has met the aforementioned prerequisite, the Management Board of the Company has included in the agenda of the forthcoming General Meeting an item providing for the adoption of a resolution concerning the Company's continued existence, pointing to circumstances indicating material uncertainty that may cast significant doubt upon the Company's ability to continue as a going concern, at the same time justifying that the main reason for the negative financial result for the financial year 2020 is the lack of realised sales revenue, the high costs of research and development, as well as the general and administrative expenses incurred and their increase resulting from growth and changes in the structure of employment. The Extraordinary General Meeting of Mabion S.A. unanimously decided on the continued existence of the Company.

On 23 February 2021, the Extraordinary General Meeting of Mabion S.A. also adopted Resolution No. 5/II/2021 on amending the Company's Articles of Association by changing the Company's scope of business. The change concerned the extension of the Company's scope of business to include freight transport by road (PKD 49.41. Z) and other postal and courier activities (PKD 53.20. Z). The amendment of the Company's Articles of Association in the above scope was registered with the National Court Register on 2 April 2021.

On 22 June 2021, the Ordinary General Meeting of Mabion S.A. adopted resolution no. 20/VI//2021 on another amendment to the Company's Articles of Association by further extending the Company's scope of business. The amendment concerned the expansion of the scope of business by, inter alia, warehousing and storage of goods, activities of agents engaged in the sale of goods, wholesale and retail sales, professional, scientific and technical activities. The amendment of the Company's Articles of Association in the above scope was registered with the National Court Register on 10 August 2021.

The aforementioned changes in the Company's scope of business were introduced as a result of the Company's analysis of opportunities to increase the efficiency of its operations using its resources, particularly within its available transport network, and additional operations consisting in the provision of new services, considered by the Company. The above changes will allow the Company to undertake operations in additional and complementary areas, and thus they will not have a material impact on the Company's main business; therefore, the General Meeting resolved to implement the change without redeeming the shares of shareholders who do not agree thereto.

The Company informed about the above events in Current Reports no. 12/2021 of 23 February 2021, no. 31/2021 of 2 April 2021, no. 42/2021 of 22 June 2021, and no. 51/2021 of 10 August 2021.

### **Conclusion of an agreement with Polski Fundusz Rozwoju S.A.**

On 3 March 2021, the Company entered into an agreement with Polski Fundusz Rozwoju S.A. ("PFR") regarding the entry conditions for PFR's investment of up to PLN 40 million ("PFR's Investment" and "Agreement") for the purpose of increasing the Company's production capacity, in particular for the Company's broader cooperation with Novavax, Inc. regarding serial production of a COVID-19 vaccine active substance which was pending registration at that time.

The parties' intention is to implement the PFR Investment in the form of (i) an interest-bearing three-year loan (or bond issue) granted to the Company up to the amount of PLN 30 million ("Debt Investment") and (ii) subscription for the Company's shares up to the amount of PLN 10 million under the issue of U series shares made pursuant to the resolution of the Extraordinary General Meeting of the Company dated 23 February 2021 ("Equity Investment"). The Equity Investment has been completed in line with the intention of the parties. The Debt Investment in turn, pursuant to the Agreement, was conditional upon the Company's execution of a Manufacturing Agreement with Novavax, Inc. providing for certain net revenues to the Company from the performance of the agreement (the condition was met in October 2021) and, in addition, the Debt Investment will be implemented if the conditions precedent are met including, among other things, the raising of additional financing from the issuance of the Company's U shares (the condition was met in March 2021), the preparation and agreement by the parties as to the terms of the transaction documentation and the establishment or filing of applications for the establishment of potential collateral. The agreement is non-binding in nature, does not create obligations for any of the parties thereto and that the PFR's Investment is conditional and requires the negotiation and execution of appropriate transaction documentation. As at the date of this report, the Parties have not yet made a final decision on the procedure for potential debt financing with a limit of up to PLN 30,000 thousand.

The Company informed about the event in Current Report no. 16/2021 of 3 March 2021.

### **Adoption of a joint work programme for the marketing authorisation of MabionCD20 on the European and US markets and definition of the final scope of data and clinical trial for the purposes of the registration on the European market**

On 30 July 2021, following a round of interactions with the European regulatory agencies as part of the Scientific Advice procedure (two consulting sessions with the EMA and two consulting sessions with PEI, the German national regulator that closely cooperates with the EMA) and with the FDA, the

Company established a strategy for the co-development of MabionCD20 for registration in the European and US markets. The essential elements of the Company's regulatory strategy include:

1. A three-arm bridging clinical trial in patients with rheumatoid arthritis ("RA");
2. A three-arm analytical bridging trial;
3. Implementing the aforementioned tasks using MabionCD20 originating from the target, i.e. large, commercial production scale (5000L)
4. Including, in the registration procedure for the European market, the results of the already completed Phase III clinical trial with MabionCD20 originating from a small manufacturing scale (500L); the trial was carried out with 709 patients for the RA (rheumatoid arthritis) indication and 143 patients with NHL (non-Hodgkin's lymphoma).

At the same time, following a round of interactions with the regulators over the several months preceding the establishment of the MabionCD20 co-development strategy, the Company has completed the reconciliation process and developed the final scope of data (including the scope of the bridging clinical trial) for the application for registration and marketing authorisation of MabionCD20 under the central procedure for the European market.

Considering the outcome of the arrangements with the European regulators, the Company's Management Board assumed in July 2021 – under the base scenario – to maintain the assumed schedule, i.e. to complete the trials and submit the registration dossier to the EMA for the European market in the second half of 2022 (with an update to the project schedule in progress at the date of this report). The above mentioned three-arm clinical and analytical bridging trials include:

- (a) MabionCD20 originating from large-scale manufacturing,
- (b) MabThera as the European reference and
- (c) Rituxan, being the US reference, which is the basic assumption of the co-development strategy for MabionCD20.

At a further stage, the Company will clarify with the FDA the scope of additional trials (which may, as expected by the Company, include a clinical trial in an oncology indication) required for MabionCD20 to be approved for the US market and will report on these arrangements once they have been made.

The three-arm bridging clinical trial in patients with RA referred to in item 1 above is expected to include as a target a population of 280 patients, which is in accordance with the Company's assumption that it is not necessary to carry out separate new Phase III clinical trials in order to register MabionCD20 on the European market.

The primary endpoint of the trial is to analyse pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. Such a patient population will also allow assessment of treatment

efficacy, which constitutes the secondary endpoint of the trial. To carry out the clinical trial, the Company has entered into an agreement with Parexel International (CRO), has qualified several dozen clinical sites, and has finalised the documentation necessary to launch the trial. Furthermore, the Company has initiated the process of applying to local competent bodies for approval of the clinical trial, as a result of which the approvals referred to above for Poland, Georgia, Belgium, and Ukraine have been obtained.

With respect to item 2, the Company has defined with the EMA and the PEI the target quality profile of MabionCD20 based on data obtained from validation batches of MabionCD20 produced at the target manufacturing scale and has established the scope of analytical trials for MabionCD20 produced on a commercial scale. The analytical trials are aimed at confirming analytical similarity to reference drugs and comparability to MabionCD20 originating from small-scale manufacturing, used in earlier clinical trials.

In the Company's opinion, the aforementioned trials and the scope of data (items 1.-4.) developed as part of the arrangements with the EMA and the PEI are sufficient for the submission of a registration application to the EMA.

With the aforementioned arrangements and assumptions in mind, the Company's Management Board estimated the budget for marketing authorisation of MabionCD20 (the target product manufactured on a commercial scale) on the European market, including the costs of the trial arm in the RA indication for the US market and the costs accompanying it and, based on the best estimates, determined the expected net expenditure at PLN 105–115 million over the period assumed (i.e. until the expected registration of the product on the European market).

The estimated budget includes the costs already incurred by the Company for the project starting from Q1 2020. The estimates include the expenditures required for the development of the medicine, including the costs of the three-arm bridging clinical trial, the three-arm analytical trial, manufacturing costs, operational maintenance costs, costs of the regulatory procedures (before the EMA and the FDA), and expenditures for quality assurance and control.

The aforementioned budget items reflect the estimated full costs to be incurred in connection with authorising MabionCD20 on the European market, while for the US market they reflect the project budget with the exception of the costs of the additional trial in the oncology indication (which, in the Company's opinion, is a necessary element of the registration application in the US market).

The estimates outlined above do not take into account the costs of day-to-day operations of the Company and capital expenditure associated with increased production capacity. The above assumptions may be subject to change in the future (due to the fact that they are based on a number of factors that may affect the time-frame, including factors beyond the Company's control such as the speed of clinical trial recruitment). Moreover, the assumptions made and actions

performed do not guarantee the registration of the product. In planning the scope and timing of the clinical trial, the foreseeable constraints of the COVID-19 pandemic were taken into account.

The Company informed about the above event in Current Report no. 49/2021 of 30 July 2021.

### **Change of the permit to operate in the Łódź Special Economic Zone**

On 10 August 2021, the Company received a decision of the Minister of Development, Labour and Technology on the amendment of permit no. 301 to conduct business activity in the Łódź Special Economic Zone ("Zone"). By virtue of the above mentioned decision, the deadline for incurring investment expenditure in the Zone within the meaning of § 6.1 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 in special economic zones, in the amount of at least PLN 20 million, was extended from 30 June 2021 to 31 December 2024. At the same time, the deadline for completion of the investment was extended from 31 December 2021 to 31 December 2024. The Company has applied to change the above dates due to the need to update the schedule of planned investments, on the basis of the Company's current needs.

The Company informed about the above event in Current Report no. 50/2021 of 10 August 2021.

### **Permits to conduct a bridging clinical trial of MabionCD20 in patients with rheumatoid arthritis in Poland, Georgia, Belgium and Ukraine**

On 11 October 2021 (an event after the balance-sheet date), the Company became aware that on 6 October 2021 the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products issued a permit for the Company to conduct a clinical trial of MabionCD20 in Poland in patients with rheumatoid arthritis, entitled "A double-blind, parallel-group, randomized clinical trial to evaluate the pharmacokinetics and clinical similarity of MabionCD20 (manufactured commercially) with MabThera® approved in the European Union and Rituxan® approved in the United States in patients with moderate-to-severe rheumatoid arthritis".

On 14 October 2021, the Company became aware that the President of the Medical and Pharmaceutical Regulatory Agency of Georgia had issued a permit for the Company to conduct the trial in Georgia.

On 22 October 2021, the Company became aware that the Federal Agency for Medicines and Health Products in Belgium has issued a permit for the Company to conduct the trial in Belgium.

On 20 December 2021, the Company became aware that the Ministry of Health in Ukraine had granted a permit for the Company to conduct the trial in Ukraine.

The Company also holds approvals from the competent bioethics committees in all the above countries.

The above-mentioned permits will enable the Company to commence the clinical trial necessary for MabionCD20's authorisation, in the first instance, in the EU, including the cooperation with clinical sites in Poland, Georgia, Belgium and Ukraine and the recruitment of patients to the trial.

The MabionCD20 clinical trial is a three-arm bridging clinical trial in RA patients using MabionCD20 originating from the target manufacturing scale, MabThera as the European reference and Rituxan as the US reference. In accordance with the trial protocol, the bridging clinical trial will ultimately involve 280 patients from no less than 35 clinical sites located in Poland, Belgium, Georgia, and Ukraine. Also, the Company does not exclude extending the trial to other countries. The primary endpoint of the trial will be to analyse pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. Such a patient population will also allow assessment of treatment efficacy, which constitutes the secondary endpoint of the trial. The primary observation period for patients will be 6 months ("primary endpoint"). In addition, a long-term follow-up of the safety and immunogenicity of the therapy will be carried out ("follow-up period"), up to 48 weeks following the first administration of the medicine.

In view of the current state of war in Ukraine, the inclusion of clinical centres and patients from that country will take place should the current situation allow. The planned number of patients from Ukraine may be offset by increased enrolment in other countries where the Company already holds approvals or by expanding the list of countries involved in the project.

The Company informed of the above events in Current Reports no. 53/2021 of 11 October 2021, no. 54/2021 of 14 October 2021, no. 57/2021 of 22 October 2021 and no. 69/2021 of 20 December 2021.

## 2.9.2 Other events

Other events that occurred in the financial year 2021 include:

- > Receiving, on 31 March 2021, the statement of claim filed by Altiora d. o.o., based in Zagreb ("Altiora"). As set out in the statement of claim, Altiora sought an award against the Company of the amount of EUR 359 thousand in respect of the remuneration charged by Altiora in connection with one of the agreements between the parties concerning the performance of clinical trials ("Master Service Agreement" of July 2013). In the opinion of the Company, the disputed value was not significant and, moreover the agreement was not strategically important to the Company as there were other CRO companies that can provide such services. The Company contested the claim both in principle and in amount. The Company is of the opinion that the action filed against it was groundless and the claims submitted therein had no legal or factual basis. The Company filed a response to the lawsuit, in which it presented claims and evidence together with allegations proving that the lawsuit is groundless. Considering the perspective of a long-term court dispute, and the related legal costs, as well as reasonable assumptions as to Altiora's suspected lack of solvency after the Company filed a separate claim for improper performance of the agreement for the full amount of the suffered damage, the Company decided to resolve the matter amicably. On 13 January 2022 (an event after the balance-sheet date), the Parties signed a composition agreement before a court mediator, under which the Company agreed to pay Altiora the amount of PLN 363 thousand (which was paid in February 2022). The parties specified that the payment of the aforementioned amount exhausts all their claims, including the costs of the trial, covered by the proceedings before the District Court in Łódź. Further to that, the Parties have unconditionally and irrevocably waived all claims under the Master Service Agreement of July 2013. On 27 January 2022, the Regional Court in Łódź approved, by way of a decision, the composition agreement in the part concerning payment of the aforementioned amount and discontinued the proceedings.
- The scheduled GMP inspection conducted in January 2021 at the Company's premises by the Chief Pharmaceutical Inspectorate to verify the compliance of the manufacturing conditions of the medicinal products under the trials and to assess the Company's activities with respect to the extended scope of the Authorisation to Manufacture and Import Tested Medicinal Products. The inspection concluded with a positive recommendation for certification of the Company in both areas. On 13 April 2021, the Company received a GMP certificate covering the manufacture and import of studied medicinal products.
- > In July 2021, IMA S.p.A. of Bologna with its registered office in Bologna, Italy ("IMA") delivered the equipment purchased by the Company under the agreement with IMA of 31 January 2019 under which IMA undertook to manufacture and sell to the Company the packaging line necessary to carry out the process of packaging the vials with the finished product in an outer packaging, including delivery, installation, commissioning, qualification and training. The value of the agreement was EUR 1,830 thousand.

### 2.9.3 Events after the balance-sheet date

The following material events occurred after the balance-sheet date:

1. The Company's Management Board's decision to abandon further implementation of the research project concerning the development of MabionEGFR, as discussed in section 4.2 of this report,
2. Conclusion of an agreement to register up to 500 S series ordinary bearer shares of the Company with the securities depository (see section 3.7 of this report),
3. Recording, on 28 January 2022, 500 S series ordinary bearer shares issued by the Company in connection with the exercise by the eligible persons of their rights under B series subscription warrants granted as part of the Incentive Scheme for 2020, in the securities accounts of the eligible persons and thus shares were allotted within the meaning of Article 451 §2 of the Commercial Companies Code and the share capital of the Company was increased in accordance with Article 452 §1 of the Commercial Companies Code (see point 7.3.1 of this report),

4. Entering of the Company, on 19 April 2022, into the National Register of Manufacturers, Importers and Distributors of Active Substances kept by the Chief Pharmaceutical Inspectorate as a manufacturer of active substance SARS-CoV-2 rS.
5. Adoption, on 20 April 2022, of a resolution by the Board of the Warsaw Stock Exchange ("WSE") on the admission and introduction to exchange trading, as of 26 April 2022 on the WSE Main Market, of 500 S series ordinary bearer shares of the Company, subject to the assimilation of these shares with the outstanding shares of the Company by the KDPW on 26 April 2022.

### 2.10 Transactions with related parties

The Company's transactions with related parties are presented in Notes 20 and 24 of the financial statements.

In 2021, the Company did not enter into transactions with related parties on terms other than arm's length.

## 3 ANALYSIS OF THE COMPANY'S FINANCIAL AND ASSETS POSITION

### 3.1 Selected financial data

**Table 8. Selected financial data of Mabion S.A.**

| Selected financial data                    | in PLN thousand   |                   | in EUR thousand   |                   |
|--|-------------------|-------------------|-------------------|-------------------|
|  | 2021              | 2020              | 2021              | 2020              |
| Net income from sales                      | 56,873            | 0                 | 12,424            | 0                 |
| Operating profit (loss)                    | -9,832            | -54,653           | -2,148            | -12,215           |
| Profit (loss) before tax                   | -10,255           | -55,772           | -2,240            | -12,465           |
| Net profit (loss)                          | 1,903             | -55,772           | 416               | -12,465           |
| Net cash flows from operating activities   | -32,910           | -35,239           | -7,190            | -7,876            |
| Net cash flows from investing activities   | -31,283           | -3,005            | -6,834            | -672              |
| Net cash flows from financing activities   | 110,505           | 12,669            | 24,141            | 2,832             |
| Total net cash flows                       | 46,312            | -25,575           | 10,117            | -5,716            |
|  | <b>31.12.2021</b> | <b>31.12.2020</b> | <b>31.12.2021</b> | <b>31.12.2020</b> |
| Total assets                               | 184,237           | 78,321            | 40,057            | 16,972            |
| -/Cash and cash equivalents**              | 48,707            | 2,395             | 10,590            | 519               |
| Liabilities and provisions for liabilities | 130,924           | 155,709           | 28,465            | 33,741            |
| Long-term liabilities                      | 34,787            | 51,138            | 7,563             | 11,081            |
| Current liabilities                        | 96,137            | 104,571           | 20,902            | 22,660            |
| Equity                                     | 53,313            | -77,388           | 11,591            | -16,770           |
| Share capital                              | 1,616             | 1,373             | 351               | 298               |
| Number of shares (in pcs)                  | 16,161,326        | 13,730,272        | 16,161,326        | 13,730,272        |
| Weighted average number of shares (in pcs) | 15,555,287        | 13,721,917        | 15,555,287        | 13,721,917        |
| Net profit (loss) per ordinary share       | 0.12              | -4.06             | 0.03              | -0.91             |
| Book value per share                       | 11.40*            | 5.71*             | 2.48              | 1.24              |
| Dividend declared or paid per share        | 0                 | 0                 | 0                 | 0                 |

\* Total assets/Weighted average number of shares

\*\* Part of Total assets

Individual items of the balance sheet were translated into EUR at the average exchange rate for a specific balance sheet date, announced for the euro by the National Bank of Poland; (31 December 2021: PLN 4.5994, 31 December 2020: PLN 4.6148). Individual items of the income statement and cash flow

statement have been converted into EUR at the exchange rate being the arithmetic average of the average exchange rates announced by the National Bank of Poland for the euro effective on the last day of each month of the financial year (2021: 4.5775, 2020: 4.4742).

## 3.2 Accounting principles applied to preparing financial statements

The separate financial statements of Mabion have been drawn up in accordance with the International Financial Reporting Standards (IFRS) approved by the European Union as at the reporting date.

The separate annual financial statements of Mabion S.A. include

- > statement of financial position as at 31 December 2021 and drawn up for the financial year from 1 January to 31 December 2021;
- > statement of comprehensive income;
- > statement of changes in equity;
- > cash flow statement;

and

- > additional information containing a description of the adopted accounting principles and other explanatory information.

The financial statements cover the annual reporting period from 1 January to 31 December 2021 and the comparative period from 1 January to 31 December 2020.

The financial statements have been drawn up on the historical cost basis except for derivative financial instruments, available-for-sale financial assets which have been measured at fair value. The separate financial statements, with the exception of the separate cash flow statement, have been prepared on an accruals basis.

The financial statements have been drawn up in accordance with the going concern principle, which provides that the Company will continue to operate in the foreseeable future (presented in more detail in Note 3 to the financial statements). Therefore, no adjustments have been made to the financial statements which might be necessary if there was a risk that the Company would not continue as a going concern.

Mabion is a biotech company specialising in the development and manufacture of originator medicines using the recombinant protein technology which is currently a prerequisite for the development of advanced products to combat the most serious diseases, for example in the field of oncology, neurology, or autoimmunity. Since its establishment, the Company focused on research and development activities in order to develop and commercially launch its products. As a result, in the past reporting periods the Company has incurred operating losses and generated negative cash flows from operating activities. From 2021 onwards, the Company also employs technologies it has developed not only to advance its own targeted therapy projects, but also to execute commercial orders for partners. The Company's experience in the research and development, clinical and regulatory areas, as well as its available GMP-certified (Good Manufacturing Practice) manufacturing capacity enabled the Company to execute a commercial order for a partner, Novavax Inc., with participation

in the development of new recombinant protein vaccines related to the prevention of COVID-19 infection. In the COVID-19 prevention area, cooperation in the field of production of a protein vaccine used in the fight against the COVID-19 pandemic, is currently of strategic importance for Mabion S.A.

As at 31 December 2021, the Company has generated a net profit of PLN 1,903 thousand. On 23 February 2021, the Extraordinary General Meeting of the Company adopted Resolution No. 3/II/2019 concerning confirmation of further existence of the Company in connection with the occurrence of the circumstances provided for in Article 397 of the Code of Commercial Companies. The implementation of the manufacturing agreement as part of the cooperation with Novavax and further acquisition of financing available on the market, including exclusive agreements with future distribution partners, should ensure that the Company has the funding necessary to operate and invest in its current activities which include the completion of the registration process and commercialisation of MabionCD20.

In the financial statements for the year 2021, the same accounting principles (policies) as in the financial statements for the year 2020 were applied. The accounting policy applied in 2021 has been supplemented in accordance with the applicable IFRSs with the first-time application of revenue accounting for the manufacturing agreement under the CDMO formula. There were no changes in the rules for measuring assets and liabilities and financial result in 2021.

The scope of the annual report of the Company is consistent with the Minister of Finance Regulation of 29 March 2018 on current and periodic reporting by issuers of securities and the rules of equal treatment of the information required by the laws of non-member states (Polish Journal of Laws of 2018, item 757) and covers the annual reporting period from 1 January to 31 December 2021.

## 3.3 Key economic and financial figures, including a description of extraordinary events and factors

In the presented reporting period, the Company generated income from its core activities consisting in the provision of manufacturing and sales services under the CDMO formula, as well as from research services.

In the reporting period, an agreement with Novavax was implemented. As part of the agreement, which was entered into in October 2021, the Company has committed to manufacture a specified number of batches of the active substance within a specified period (until 2025). The production is carried out on the basis of technology provided by the contracting party, which – due to binding contractual provisions and issues related to intellectual property rights is also the only entity entitled to receive the manufactured batches of the active substance.

Income from the production of the active substance, which is accounted for over time using the input-based method, and the fulfilment of long-term obligations under the CDMO

agreement, and income from operating leases where the Company is the lessor, related to the implementation of this agreement. The income from the contract manufacturing services is recognised in the amount of costs incurred plus the expected recoverable margin. The income is based solely on costs directly related to the fulfilment of the obligation and does not take into account overheads, possible inefficiencies, excess consumption, etc. Where the incurred costs are not proportionate to the degree of fulfilment of the contractual obligation, income is recognised only up to the amount of the incurred costs.

Implementing the agreement in question, the Company has also accounted for the lease elements of the contract manufacturing agreements as operating leases. Lease income is recognised from the lease origination date, i.e. the date on which the Company as the lessor makes the underlying asset available for use by the lessee, taking into account the full production cycle, including test production.

Advance payments received in previous periods for distribution rights in the total amount of PLN 20,810 thousand are shown under income as at 31 December 2021 in connection with the termination of the cooperation agreement by Mylan. The Company has assessed the rights and obligations of the parties as at the termination of the agreement and concluded that all rights and obligations under the agreement have been extinguished in their entirety. Therefore, it has been assumed that the Company has an unconditional right to retain the non-reimbursable amounts agreed by the parties. In the reporting period, income from the performance of services (development of the antibody production technology) for Celon Pharma S.A. was recognised by the Company in the amount of PLN 1,590 thousand. Pursuant to an arrangement entered into on 10 June 2021 between the companies, it was decided to close the project and settle the cooperation as of 17 June 2021.

The costs of operating activities in the period of 12 months of 2021 amounted to PLN 47,090 thousand. Their volume was mostly influenced by the general administration costs, which in 2021 amounted to PLN 29,980 thousand, and the costs of development work, which amounted to PLN 13,604 thousand. The loss on operating activities for 2021 stood at PLN 9,832 thousand and was PLN 44,821 thousand lower than in 2020. The Company's net profit during the 12 months of 2021 amounted to PLN 1,903 thousand.

In the 2021 financial statements, the Company recognised deferred tax assets for the first time and measured the amount expected to be deducted from income tax in the foreseeable future based on the prudence principle.

The Company has historically realised significant negative temporary differences to tax, resulting mainly from ongoing research and development work that will reduce the income tax base in the future. In addition, the Company holds zone permits and the resulting gross subsidy equivalents and has generated deductible tax losses from non-zone activities in the last 5 years. The existing entitlements to exercise the deduction from the tax base and the right to benefit from public aid have

been verified, considering the expected income from both the activities within the zone and outside it in a period most probable from the point of view of the estimates.

The tax asset as at 31.12.2021 was estimated at PLN 12,158 thousand.

The Company's balance-sheet total at the end of December 2021 amounted to PLN 184,237 thousand and increased by PLN 105,916 thousand in relation to the end of December 2020. At the end of 2021, a significant share in the total assets, i.e. PLN 101,847 thousand, were fixed assets, including property, plant and equipment (mainly fixed assets related to the implementation of investments in Konstaktyńów Łódzki). Cash as at the end of December 2021 amounted to PLN 48,707 and was mainly derived from capital issues, advances received for purchases of materials and raw materials, grants and VAT refunds.

In turn, on the equity and liabilities side of the Company at the end of 2021, there is an increase in the value of equity, by PLN 130,701 thousand in relation to the end of December 2020, resulting from share issues and the net profit realised in the reporting period. In the opinion of the Company's Management Board, implementation of the agreement with Novavax product, support from shareholders (both strategic shareholders and stock market participants), external financing in the form of loans and borrowings, grants, and under an agreement with other possible distribution partners can provide the Company with funds necessary to carry out operating and investment activities, and to complete the development of MabionCD20 and commercialise it, and justify the continuation of the Company's operations in accordance with the adopted development strategy. At the same time, as at the date of this report, work is under way to update the medicinal product development strategy and project work schedule for MabionCD20, which also includes the financial area of the Company's operations and research and development activities. The above may affect decisions regarding the sources of financing of the Company's activities in the future, although it is not expected that such changes will significantly exceed the financing methods considered to date.

### **3.4 Current and projected financial situation of the Company**

Since its inception up to the third quarter of 2021, the Company's core business has been conducting research and development activities with a view to developing and commercially marketing medicinal products. As a result of the specific nature of its activity, the Company has incurred operating losses and generated negative cash flows from these activities.

In view of the aforementioned characteristics of the Company's operations and the long-term prospect of generating positive cash flows, on 27 January 2021 the Company's Management Board, on the basis of an in-depth analysis of needs and estimated benefits, adopted a new long-term strategy for financing the Company's activities.

To date, the Company has financed its operations with cash received from shareholder borrowings, capital issues, bank loans, grants and proceeds from MabionCD20 distribution partners. The agreement with Novavax has provided the opportunity to realise positive cash flows over the next 4 years until the end of 2025 and has become the main source of funding for ongoing operations and manufacturing capacity expansion.

The Agreement with Novavax is unconditional, and its conclusion and commencement were not dependent of the registration procedure of the Novavax vaccine in the respective markets. The Agreement has been concluded for a fixed period of time until the end of 2025, with an option for renewal. The total value of the Agreement during its term was estimated at USD 372 million i.e. PLN 1.46 billion based on the average exchange rate of the National Bank of Poland as at 7 October 2021 (the Agreement's value was estimated at the USD exchange rate applicable on the day before the day on which the agreement was signed, and on the theoretical assumption of future zero inflation during the entire term of the Agreement). The Agreement is implemented and settled per batch of the product, at the unit price per batch denominated in USD specified in the Agreement (unit prices are subject to indexation based on future inflation). Under the Agreement, the parties have agreed on the volume and production schedule for each year in the period 2022–2025, based on which Mabion will manufacture the number of product batches required by Novavax. The production schedule has been set for the entire duration of the Agreement, but the parties may agree on modifications to the schedule and volume of deliveries.

The possibility of completing the agreed scope of work under the Agreement in the future years depends on the Company's available production capacity, therefore the Management Board's objective will be to expand the production capacity in late 2022 and early 2023 and equipping the facility with new bioreactors with accompanying equipment, which will result in the Company having four bioreactors in the years 2023–2025. What is more, the Company does also exclude a future use of other sources of financing such as external debt financing, grants, subsidies from EU funds, earmarked funds for the implementation of new projects, or other sources where a decision is taken to start implementing an investment aimed at a substantial increase in manufacturing capacity by constructing a new manufacturing facility with a research and development centre located next to the existing facility. The current financial position is detailed in Note 3 to the financial statements.

### 3.5 Financial and non-financial performance indicators

In 2021, in accordance with its accounting policies and principles, the Company has recognised income from its core operations derived from the provision of CDMO manufacturing and sales services and the provision of research services. The sources of generated income, which include in particular the cooperation with Novavax started in 2021, are presented in section 3.3 of this report. In total, the Company's net sales

income realised in 2021 amounted to PLN 56,873 thousand, and gross profit on sales for 2021 amounted to PLN 35,886 thousand. Net profit for 2021, after accounting for deferred tax estimates of PLN 12,158 thousand, amounted to PLN 1,903 thousand.

The Company has set the following financial indicators\* for 2021 in connection with the achievement of net sales income in 2021:

- > EBITDA (i.e. operating loss adjusted for depreciation and amortisation) amounted to PLN (986) thousand.
- > The return on assets (ROA, i.e. the ratio of net profit to the closing balance of assets) in 2021 was 1.03%.
- > The return on equity (ROE, i.e. the ratio of net profit to the closing balance of equity) in 2021 was 3.57%.
- > The return on revenue (ROR, i.e. the ratio of net profit to total income) in 2021 was 3.35%.

In the comparative year, i.e. 2020 and in previous years, the Company did not realise any income from its core operations, while incurring operating expenses in connection with the costs of conducted development work, investments in machines and equipment used for conducting development work and for the production of medicines in the future, as well as general administration costs related to, among others, obtaining funds for current operations. Therefore in 2020, the Company recognised a loss on operating activities and a net loss, and therefore it is not possible to determine comparable financial ratios related to the Company's profitability for 2020.

The sales income recorded in 2021 was mainly due to the collaboration established with Novavax and the recognition of income from the non-reimbursable advance on distribution rights as a result of the termination of the agreement with Mylan. The agreement relating to the Company's manufacturing of the vaccine antigen has been entered into for a period until 2025, which will allow the Company to continue to generate sales income in future reporting periods. With full scale commercial production to be achieved, the Company expects its profitability ratios to improve, but this will eventually be driven by a number of factors, including factors beyond the Company's control.

At present, the Management Board of the Company does not identify non-financial performance indicators significant for the assessment of the development, results and situation of the Issuer.

\* The financial indicators presented here are Alternative Performance Measures (APMs) within the meaning of the ESMA Guidelines on Alternative Performance Measures. Alternative Performance Measures do not constitute a measure of financial performance under International Financial Reporting Standards and should not be regarded as measures of financial performance. These figures were not audited by an independent auditor. Furthermore, the indicators are not uniformly defined and may not be comparable to indicators presented by other companies. APMs should only be analysed as additional financial information. The selected scope of the

APMs presented in the report was based on the assessment by the Company's Management Board of the individual indicators commonly used in financial analysis as to their usefulness and meaningfulness in the context of the present stage of development of the Company's business. The APMs presented in the report may, in the opinion of the Company's Management Board, provide additional information on the

Company's financial and operating position as well as facilitate the analysis and evaluation of the financial results achieved by the Company. In previous years, the Company did not report APMs due to the fact that the Company's business is research and development and as a result, the Company did not generate sales income.

### 3.6 Product and geographical structure of revenues

| in PLN thousand                               | 2021          | Income from sales to domestic entities | Income from sales to foreign entities |
|---|---------------|--|---------------------------------------|
|   |               | 2020                                   |                                       |
| Lease income                                  | 1,311         | -                                      | 1,311                                 |
| Income from non-reimbursable advance payments | 20,811        | -                                      | 20,811                                |
| Other income                                  | 34,751        | 1,590                                  | 33,161                                |
| <b>Total income</b>                           | <b>56,873</b> | <b>1,590</b>                           | <b>55,283</b>                         |

Due to the nature of the sales income generated by the Company in 2021, it is not possible to quantify the services performed in each income group.

In 2021, the Company generated income from a long-term agreement for the manufacture and sales of an active substance implemented under the CDMO formula. Income from this agreement is accounted for over time, using the input-based method. The costs associated with manufacturing and the amount of income may change over time. The balance-sheet measurement of assets related to the implementation of the agreement and the expected amount of income and implementation costs are determined on the basis of estimates of the Company's Management Board.

The Company classifies a single lease component as an operating lease based on the criteria listed in the IFRS. Due to the fact that all components are interrelated and interdependent, and they are treated as one lease component, the classification of a lease as an operating lease is made for the lease as a whole and not for each component separately.

The non-reimbursable advances, totalling PLN 20,810 thousand, received for distribution rights as a result of the completion of the agreement with Mylan which confirms performance of the services, and since there are no additional obligations existing between the parties, have been classified in full as income at the point of time in the profit and loss account of these financial statements for 2021. The Company has assessed the rights and obligations of the parties as at the termination of the Agreement and concluded that all rights and obligations under the agreement have been extinguished in their entirety. Therefore, it has been assumed that the Company has an unconditional right to retain the non-reimbursable amounts agreed by the parties.

In the reporting period, income from the performance of services (development of the antibody production technology) for Celon Pharma S.A. was recognised by the Company in the amount of PLN 1,590 thousand. Pursuant to an arrangement entered into on 10 June 2021 between the companies, it was decided to close the project and settle the cooperation as of 17 June 2021.

In the period covered by these financial statements, the Company's business activities were conducted only in Poland.

### 3.7 Issues of securities

#### Issue of U series ordinary bearer shares

On 23 February 2021, the Extraordinary General Meeting of the Company adopted Resolution no. 4/II/2021 on increasing the Company's share capital by an amount not higher than PLN 243,055.40 by way of an issue of not more than 2,430,554 U series ordinary bearer shares with a par value of PLN 0.10 each ("EGM Resolution"). The purpose of the U series share issue was to generate the necessary financing for the Company's working capital, in particular for the development of MabionCD20 and activities aimed at carrying out the registration procedure at the EMA as soon as possible.

On 3 March 2021, the Company's Management Board passed a resolution on, inter alia, determining the rules of offering and conducting the book-building process, subscription, taking-up and allotment of U series shares. On 4 March 2021, the Company and mBank S.A. as the offering manager entered into a conditional share placement agreement and commenced the book-building process by way of a private placement of U series shares. The book-building process was carried out between 4 and 9 March 2021. Subsequently, on 9 March 2021 the Company's Management Board resolved that the issue price of the U series shares will be PLN 55.00 per one share and the Company will make offers to investors to acquire a total of 2,430,554 U series shares.

The U series shares were offered by way of private placement within the meaning of the Commercial Companies Code in a public offering on the basis of the exceptions from drawing up and publishing a prospectus referred to in Article 1(4)(a) and (d) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus. The

Company's shareholders meeting the criteria indicated in the EGM Resolution ("Eligible Investors"), who participated in the book-building process, were entitled to priority take-up of the U series shares under the rules set out in the Resolution. Pursuant to the EGM Resolution, upon meeting the requirements set forth therein, the Eligible Investors were entitled to pre-emptively take-up the U series shares in a number allowing them to maintain a share in the total number of votes at the General Meeting of the Company not lower than the share held at the end of the day on the date of adoption of the Resolution. Moreover, under the terms of the EGM Resolution, the Eligible Investors, being qualified investors, holding, at the end of the preference day, shares in the Company with an aggregate nominal value of at least 0.5% of the Company's share capital, were given a pre-emptive right to acquire U series shares before the other investors.

The issue price of the U series shares was determined by the Company's Management Board based primarily on the results of the book-building process among institutional investors and taking into account all circumstances with a bearing on the determination of the issue price, including in particular the macroeconomic and economic environment, the current situation on the capital markets at the time of the book-building process for the U series shares, the Company's financial standing at the time of the public offering, current events and their impact on the Company's business prospects, as well as based on the recommendations of the offering manager.

The issue of the U series shares was effected upon the execution of agreements for the taking-up of all the U series shares and upon payment in full of the contributions to cover the shares (no allotment of shares within the meaning of the Commercial Companies Code was necessary). The conclusion of the agreements for taking up U series shares was completed on 12 March 2021. As part of the issue, the Company entered into agreements with investors for taking up all 2,430,554 U series ordinary bearer shares.

The required cash contributions to cover all U Series Shares were made in entirety by 15 March 2021, whereby the Company made: (i) a contractual set-off of the entire claim against Glatton sp. z o.o. for payment of the issue price of the U series shares against Glatton Sp. z o.o.'s claim under the borrowing agreement of 12 August 2020, up to a total amount of approx. PLN 5 million; and (ii) a contractual set-off of a part of the claims against Twiti Investments Limited for payment of the issue price of the U series shares against the claims of Twiti Investments Ltd. under the borrowing agreements of 12 August 2020 and 5 February 2021 up to a total amount of approx. PLN 12.2 million, whereby the remaining part of the issue price of the U series shares subscribed for by Twiti in the amount of approx. PLN 5 million was paid by Twiti in cash. The conversion report was reviewed by an independent auditor in line with applicable regulations.

As a result of the issue of 2,430,554 U shares, the Company acquired PLN 133.7 million. Following the conversion of the receivables referred to above and the settlement of the issue

costs amounting to PLN 4.9 million, the Company allocated the remaining funds from the issue of U shares: for the Company's working capital, in particular for the needs related to the development of MabionCD20.

On 19 March 2021, the KDPW issued a statement on the conditional registration, in the securities depository, of 2,430,554 rights to U series ordinary bearer shares. The condition for the registration of the RTS was their admission to trading on the regulated market. On 23 March 2021, the WSE's Board adopted a resolution on the admission and introduction to trading on the WSE's Main Market of rights to U series shares of the Company, pursuant to which the Board stated that 2,430,554 rights to U series shares are admitted to trading on the primary market as of the date of their registration by the KDPW. At the same time, the WSE Board decided to introduce the RTS, as of 25 March 2021, provided the KDPW's registration of the RTS on 25 March 2021 at the latest and assigned it with the relevant ISIN code. On 23 March 2021, the KDPW published a notice on the registration, as of 24 March 2021, in the depository of securities under the relevant ISIN code, of 2,430,554 rights to U shares of the Company. Thus, the condition for the introduction of the RTS to trading on 25 March 2021 was met.

The Company's share capital increase through the issue of U series shares was registered with the National Court Register on 2 April 2021.

On 14 April 2021, the KDPW issued a statement on the conditional registration in the securities depository of 2,430,554 U series ordinary bearer shares of the Company. The condition for the registration of the U shares was their introduction to trading on the regulated market. On 14 April 2021, the WSE's Board adopted a resolution on the admission and introduction to trading on the WSE's Main Market of U series shares, pursuant to which the Board stated that 2,430,554 U series ordinary bearer shares of the Company are admitted to trading on the primary market. At the same time, the WSE's Board decided to introduce, as of 19 April 2021, the above mentioned Company's shares to trading, provided that the KDPW has registered these shares on 19 April 2021 and assigned it with the relevant ISIN code. On 15 April 2021, the KDPW published a notice on the registration, as of 19 April 2021, in the depository of securities under the relevant ISIN code, of 2,430,554 U shares of the Company. Thus, the condition for the introduction of the shares to trading on 19 April 2021 was met. The U series shares were registered with the KDPW in connection with the closure of the accounts maintained for the RTS. On 14 April 2021, the WSE's Board adopted a resolution on determining the last day of listing the RTS on the WSE Main Market for 16 April 2021.

The Company informed of the above events in Current Reports no. 12/2021 of 23 February 2021, no. 19/2021 of 4 March 2021, no. 20/2021 of 8 March 2021, no. 21/2021 of 9 March 2021, No. 23/2021 of 15 March 2021, No. 26/2021 and No. 27/2021 of 22 March 2021, No. 28/2021 and No. 29/2021 of 23 March 2021, No. 31/2021 of 2 April 2021, No. 33/2021 of 14 April 2021, and No. 34/2021 of 15 April 2021.

### Issues of S series ordinary bearer shares

Mabion S.A. has an Incentive Scheme adopted by Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the introduction of the Incentive Scheme. As part of the Incentive Scheme, the Company issues periodically S series shares in performance of Resolution No. 25/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the issue, for the purpose of implementing the Incentive Scheme, of A and B series subscription warrants with the exclusion of the pre-emptive right of the existing shareholders, entitling to take up R series shares and S series shares, and on the conditional increase of the share capital through the issue of R series shares and S series shares, with the exclusion of the pre-emptive right of the existing shareholders, and the related amendment of the Company's Articles of Association.

As part of the Incentive Scheme, on 18 February 2021, 500 S series ordinary bearer shares with a nominal value of PLN 0.10 each taken up by the eligible persons on 23 June 2020 were allotted within the meaning of Article 451 § 2 of the Commercial Companies Code, i.e. recorded on the securities accounts, in connection with the exercise of rights under the B series subscription warrants granted to those persons as part of the Incentive Scheme for 2019. The shares were taken up for cash contributions made in full before the shares were allotted. Along with the allocation of the aforementioned shares, the share capital of the Company was increased.

On 16 February 2021, the WSE Board adopted a resolution on the admission and introduction to exchange trading on the WSE Main Market of S shares of the Company, in which the WSE's Board stated that 500 S series ordinary bearer shares of the Company are admitted to trading on the main market. At the same time, the WSE's Board decided to introduce, as of 18 February 2021, the above mentioned Company's shares to trading, provided that the KDPW has registered these shares on 18 February 2021 and assigned it with the relevant ISIN code. On 16 February 2021, the KDPW published an announcement on the registration of the S shares under the relevant ISIN code in the securities depository as of 18 February 2021. Thus, the condition for the introduction of the shares to trading on 18 February 2021 was met.

The Company informed of the above events in Current Reports no. 8/2021 and 9/2021 of 16 and 17 February 2021 and no. 10/2021 of 18 February 2021.

Then, as part of the Incentive Scheme, on 2 July 2021, the Company issued 500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2020. The subscription warrants were taken up on 18 November 2019, free of charge, by eligible persons, i.e. persons appointed by the Company's Supervisory Board. Each B series subscription warrant entitled to take up 1 S series ordinary bearer share of the Company at the issue price equal to the nominal value of shares of PLN 0.10 each. All eligible persons submitted declarations on taking up their S series shares in the period ended 15 December 2021. The S series shares (500 pcs) were

issued as part of a conditional share capital increase, therefore no allocation of shares took place. The allocation of S shares within the meaning of Article 451 § 2 of Commercial Companies Code took place upon their registration in the securities accounts of the eligible persons, which took place on 28 January 2022 (an event after the balance-sheet date). A total of 500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were allotted. The shares were taken up for cash contributions made in full before the shares were allotted. Along with the allocation of the aforementioned shares, the share capital of the Company was increased.

On 18 January 2022 (an event after the balance-sheet date), the National Depository for Securities (KDPW) issued a statement announcing that, in response to the Company's application, an agreement had been concluded for the registration with the Depository for Securities of up to 500 S ordinary bearer shares of the Company with a nominal value of PLN 0.10 each. The above-mentioned shares were registered on the basis of settlement orders, in connection with the deregistration of subscription warrants under which the right to take up the above-mentioned shares was exercised.

On 20 February 2022 (an event after the balance-sheet date), the WSE Board adopted a resolution on the admission and introduction to exchange trading on the WSE Main Market of S shares of the Company, in which the WSE's Board stated that 500 S series ordinary bearer shares of the Company are admitted to trading on the main market. At the same time, the WSE's Board decided to introduce, as of 26 April 2022, the above mentioned Company's shares to trading, on the condition of assimilation, on 26 April 2022, of these shares with outstanding shares of the Company by the KDPW.

The Company informed about the above events in Current Reports no. 68/2021 of 20 December 2021, no. 4/2022 of 18 January 2022, no. 5/2022 of 31 January 2022 and no. 22/2022 of 20 April 2022

### 3.8 Financial instruments used

In 2021, the Company did not use any financial instruments in the scope of risk related to: changes in prices, credit, significant distortions of cash flows and loss of financial liquidity.

In 2021, the Company did not use any derivative instruments.

### 3.9 Financial risk management objectives and methods

The Company does not have a formal financial risk management system. The Company does not apply hedging instruments. Transactions are planned based on up-to-date analyses of the Company's situation and its environment.

The Company's Management Board is responsible for financial risk management.

Significant information regarding liquidity risk is presented in Note 3 to the financial statements.

Information on financial risk management is detailed in Note 23 to the financial statements.

The Company's principal objective is to maintain the Company's current and long-term liquidity using all instruments available on the market and, in particular, to implement the agreement with a partner for contract manufacturing in a CDMO formula. As regards a significant expansion of production capacity by constructing a new facility, the decision will be taken once an appropriate level of funds for the planned project has been secured.

### 3.10 Assessment of financial resource management

#### Going concern assumption

Since its inception up to the third quarter of 2021, the Company's core business has been conducting research and development activities with a view to developing and commercially marketing medicinal products. As a result of the specific nature of its activity, the Company has incurred operating losses and generated negative cash flows from these activities.

In view of the aforementioned characteristics of the Company's operations and the long-term prospect of generating positive cash flows, on 27 January 2021 the Company's Management Board, on the basis of an in-depth analysis of needs and estimated benefits, adopted a new long-term strategy for financing the Company's activities.

The strategy adopted on 27 January 2021 covered the Company's overall capital needs which has to be fulfilled in order to carry out all activities which, in the opinion of the Company's Management Board, were necessary to complete the registration of MabionCD20 with the EMA and to start selling MabionCD20, allowing the Company to generate positive operating cash flows. The arrangements for the Company's financing strategy were positively reviewed by the Company's Supervisory Board.

Therefore, in 2021, the financing strategy assumed parallel processes such as the acquisition of a strategic investor and two issues of the Company's shares. As part of its implementation, the Company's Management Board made the following decisions and conducted the following activities:

- 1) in order to effectively carry out the process of acquiring a strategic investor, the Company signed an agreement with the financial advisor Rothschild & Co. The scope of the advisor's responsibilities included, inter alia, searching for a strategic investor, advising on the structure of a potential transaction, support in drafting transaction documentation and in negotiations with the potential strategic investor. As at the date of the financial statements, the process is still being actively pursued.
- 2) as regards share issues, the Management Board took a decision to conduct an issue of the Company's shares in the

first quarter of 2021 under the "accelerated bookbuilding" procedure, addressed to eligible investors who are shareholders of the Company and who were qualified investors or who acquired shares with a total value of at least EUR 100 thousand, as indicated by the Company's Management Board.

Therefore, the Company's Management Board convened an Extraordinary General Meeting (EGM) for 23 February 2021, which adopted Resolution 4/II/2021 on increasing the Company's share capital by an amount not less than PLN 0.10 and not more than PLN 243,055.40 by way of an issue of at least one and not more than 2,430,554 U series ordinary bearer shares with a par value of PLN 0.10 each. The Company's Management Board has proposed an issue structure with the exclusion of existing shareholders' pre-emptive right in its entirety, while taking into account the pre-emptive rights of eligible investors who are shareholders of the Company and who are qualified investors or who acquired shares with an aggregate value of at least EUR 100 thousand. Pursuant to the resolution, the issue price of U series shares could not be lower than 90% of the average market price of the Company's shares in the 30-day period preceding the book-building process aimed at attracting entities which would take up U series shares. Upon completion of the accelerated book-building process for U Series Shares on 9 March 2021, the Company's Management Board set the issue price of U Series Shares at PLN 55.00 per one New Issue Share and made offers to investors to take up a total of 2,430,554 U Series Shares. Ultimately, the Company concluded agreements with investors for subscription of all the offered U series ordinary bearer shares of the Company. The required cash contributions to cover all U Series Shares were made in entirety in the general amount of PLN 133,680 thousand, whereby the Company made a contractual set-off of the entire claim against Glatton Sp. z o.o. for payment of the issue price of the U Series Shares against Glatton Sp. z o.o.'s claim under the borrowing agreement concluded with the Company on 12 August 2020, up to a total of PLN 5,000 thousand, and a contractual set-off of part of the claims against Twiti Investments Limited (Twiti) for payment of the issue price of the U Series Shares against claims of Twiti Investments Limited under the borrowing agreements concluded with the Company on 12 August 2020 and 5 February 2021 up to the total amount of PLN 11,200 thousand, whereby the remaining part of the issue price of the U Series Shares subscribed for by Twiti in the amount of PLN 5,000 thousand was paid by Twiti in cash. The Company's share capital increase through the issue of U series shares was registered with the National Court Register on 2 April 2021.

- 3) In addition, as regards share issues, in parallel to issuing U shares, the Company considered preparatory work related to a prospectus. Eventually, as the funds had been raised from the U series share issue and under the framework agreement signed with Novavax on 3 March 2021, the Company's Management Board decided that it was not desirable to carry out the issue on the basis of a prospectus and therefore did not continue with the preparatory work.

In view of the above, the Management Board of the Company decided to cancel the EGM of the Company that was to be held on 22 March 2021 to decide on a further capital increase as part of share issues. The decision to cancel the EGM of the Company resulted from the need to verify available sources of funding necessary to cover financing needs, inter alia, following the successful issue of U shares and the conclusion of a framework agreement together with the first CDMO order for contractual services with Novavax regarding the COVID-19 vaccine programme. In the end, as mentioned above, the Management Board concluded that the issue on the basis of the prospectus was not desirable to ensure the continuation of the Company's business nor was it necessary to raise financing. As at the date of the financial statements, the Management Board does not recognise a need to raise capital through the issue of shares and is therefore not pursuing any activities in this area.

In addition to the activities described above, as part of securing funding for the Company's operations, on 3 March 2021 the Company entered into an agreement with Polski Fundusz Rozwoju S.A. (PFR) regarding the entry conditions for PFR's investment of up to PLN 40 000 thousand for the purpose of increasing the Company's production capacity, in particular for the Company's potential broader cooperation with Novavax regarding serial production of the COVID-19 vaccine antigen. The intention of the Company and the PFR was to implement the PFR Investment in the form of an interest-bearing three-year loan (or bond issue) granted to the Company up to the amount of PLN 30,000 thousand and of taking-up the Company's shares up to the amount of PLN 10,000 thousand. The intended taking-up of the shares has been put into practice as part of the issue of U series shares carried out pursuant to the resolution of the EGM of the Company of 23 February 2021. However, pursuant to the agreement, the PFR Debt Investment was conditional on the Company signing a manufacturing agreement with Novavax providing for certain net revenues of the Company from the implementation of the agreement and, in addition, the Debt Investment may be effected subject to the preparation of and reaching an agreement by the parties as to the terms of the transaction documentation, and the establishment or submission of applications for the establishment of possible collateral. The Parties have not yet made a final decision on the procedure for potential debt financing with a limit of up to PLN 30,000 thousand.

The PFR agreement referred to above was entered into on the date the Company entered into the framework agreement with Novavax, pursuant to which the Company, with Novavax's participation, undertook activities related to the transfer of process technology for the manufacturing of the antigen of the then COVID-19 vaccine candidate under the working name of NVX-CoV2373, necessary to conduct technical trials of the process on a commercial scale at the Company's facility. The Company has finalised the settlement of the first agreement confirming the successful transfer of technology.

As a result of the successful transfer of technology, on 8 October 2021 the Company entered into the Master Contract

Manufacturing Agreement with Novavax, pursuant to which the Company commenced commercial-scale GMP-compliant manufacturing, for Novavax, of the COVID-19 vaccine antigen under the name of Nuvaxovid®.

The Agreement with Novavax is unconditional, and its conclusion and commencement were not dependent of the registration procedure of the Novavax vaccine in the respective markets. The Agreement has been concluded for a fixed period of time until the end of 2025, with an option for renewal. The total value of the Agreement during its term was estimated at USD 372 million i.e. PLN 1.46 billion based on the average exchange rate of the National Bank of Poland as at 7 October 2021 (the Agreement's value was estimated at the USD exchange rate applicable on the day before the day on which the agreement was signed, and on the theoretical assumption of future zero inflation during the entire term of the Agreement). The Agreement is implemented and settled per batch of the product, at the unit price per batch denominated in USD specified in the Agreement (unit prices are subject to indexation based on future inflation). Under the Agreement, the parties have agreed on the volume and production schedule for each year in the period 2022–2025, based on which Mabion will manufacture the number of product batches required by Novavax. The production schedule has been set for the entire duration of the Agreement, but the parties may agree on modifications to the schedule and volume of deliveries.

The possibility of completing the agreed scope of work under the Agreement in the future years depends on the Company's available production capacity, therefore the Management Board's objective will be to expand the production capacity in late 2022 and early 2023 and equipping the facility with new bioreactors with accompanying equipment, which will result in the Company having four bioreactors in the years 2023–2025.

The Company's Management Board estimates that during the first two years of commercial manufacturing covered by the Agreement (i.e. 2022–2023), the Company may realise approximately 40% of the total value of the Agreement, and in the following two years, including as a result of increased production capacity, approximately 60% of the total value of the Agreement.

By the balance-sheet date, the Company received payments under the agreement that represent the first part of the consideration, of USD 530 thousand, and an advance payment on the purchase of materials and raw materials, of USD 500 thousand. Until the balance-sheet date, in accordance with the mutual agreement governing the scope of subsequent tasks, Novavax has made an advance payment, in the amount of USD 15,226 thousand, on future deliveries of materials and raw materials representing the raw material base for future commercial production, and further payments representing partial remuneration for the performance of the agreement of 3 March 2021 and the arrangement to cover expenditures for the refurbishment of the facility with additional necessary equipment and appliances for a total amount of USD 1,830 thousand.

After the balance-sheet date, the Company received further payments under agreements in progress in the amount of USD 5,371 thousand. Overall, payments received from Novavax up to the date of the financial statements amounted to USD 23,457 thousand. The Management Board underlines that as at the date of these statements, the Company is still in the initial phase of commercial production and that the number of batches produced for Novavax will steadily increase in the coming months.

To date, the Company has financed its operations with cash received from shareholder borrowings, capital issues, bank loans, grants and proceeds from MabionCD20 distribution partners. The agreement with Novavax has provided the opportunity to realise positive cash flows over the next 4 years until the end of 2025 and has become the main source of funding for ongoing operations and manufacturing capacity expansion. What is more, the Company does also exclude the use of other sources of financing such as external debt financing, grants, subsidies from EU funds, earmarked funds for the implementation of new projects, or other sources where a decision is taken to start implementing an investment aimed at a substantial increase in manufacturing capacity by constructing a new manufacturing facility with a research and development centre located next to the existing facility.

In consideration of a significant increase in manufacturing capacity, the Management Board of the Company analyses the existing possibilities to use funds under agreements in force, including a grant from the European Regional Development Fund (approx. PLN 63,000 thousand). Considering the specifics, duration and terms and conditions of the agreements described above, decisions on the possibility of obtaining funds from these sources will be taken in the foreseeable future, not later than on the date of publication of the financial statements for H1 2022.

The Management Board of the Company is also undertaking activities aimed at starting cooperation with other entities operating on the market, in the case of which such cooperation may bring profits to the Company in the area of development and production of biologics.

In addition to all the activities undertaken in 2021 as described above, the Management Board of the Company further informs that as at the date of these financial statements, the Company holds letters of support received from the key shareholders (Twiti Investments Limited, Glatton Sp. z o.o., Polfarmex S.A.), whose contents indicate that these shareholders are willing and able to continue their financial support for the Company's day-to-day operations in the near future covering a period of at least another 12 months from the date of signing of these financial statements, should the Company's financial situation so require, which, according to the Management Board's current knowledge, will not be the case.

Following the analysis, no significant uncertainties have been identified that may cast doubt on the Company's ability to continue as a going concern.

This report has been drawn up in accordance with the going concern principle, which provides that the Company will continue to operate in the foreseeable future – not shorter than 12 months as of the date of drawing up the financial statements. Therefore, no adjustments have been made to the financial statements which might be necessary should the going concern assumption be unjustified.

### Financial resource management in 2021

As at 31 December 2021, the Company's equity has a positive value of PLN 53,313 thousand, while the general debt due to long-term and short-term liabilities (supplies and services, and borrowings) amounts to PLN 130,924 thousand.

In evaluating its financing needs, the Company takes the following factors into account:

- > the extent of cooperation with the CDMO partner and the progress of the agreement implementation;
- > possibilities of obtaining financing for the expansion of manufacturing capacity at existing and planned production facilities;
- > current and planned level of cash generated from grants, subsidies, VAT refund and finance activities;
- > current structure of financing of non-current and current assets;
- > anticipated real investment level;
- > planned scale of core operations (research and development).
- > Modification of the registration strategy for MabionCD20 at the EMA.

### Further financing plans

The assumed payback of expenditures incurred to date involves ensuring the Company's liquidity in the development phase and our assumptions that the Company's key product MabionCD20 will obtain a marketing authorisation and that its sales will generate sufficient future cash flows.

In January 2021, a long-term financing strategy of the Company was adopted under which the financial resources for continued operations, including:

- > completion of R&D and registration of MabionCD20 in key markets;
- > launch of commercial scale production in the Scientific and Industrial Complex in Konstancin Łódzki;
- > design and preparatory work for the launch of construction of another production plant on the existing plot of land of Mabion in Konstancin Łódzki;
- > research and development work on further medicines developed by Mabion;

might be derived from:

- > granted EU assistance funds;
- > loans provided by banks;
- > funds obtained under leases;

- > performance of contracts for the provision of research and development services;
- > declared financial support of key shareholders;
- > future share issues.
- > joint ventures with industry and business partners;
- > expected distribution fees for MabionCD20 (milestone payments).

The actions taken to implement the financing strategy in 2021 are set out in section 2.9.1 of this report.

As at the date of this report, work is under way to update the medicinal product development strategy and project work schedule for MabionCD20, which also includes the financial area of the Company's operations and research and development activities. The above may affect decisions regarding the sources of financing of the Company's activities in the future, although it is not expected that such changes will significantly exceed the financing methods considered to date.

### 3.11 Assessment of the feasibility of investment plans

The Company's current investment ambitions include mainly the expansion of the manufacturing capacity of the existing facility by adding new bioreactors and the necessary equipment to ensure production for the purposes of the ongoing agreement in the CDMO formula and target production of medicines developed in-house.

The Company intends to raise funds for investment tasks from the sources indicated in point 3.10, while the Company is currently reviewing its financing strategy taking into account all work carried out as part of the Company's operations and research and development activities and the related demand.

The Company's liquidity may be adversely affected by:

- > interruptions in production material supply chains;
- > inability to carry out contract manufacturing at anticipated levels;
- > limitation of supply financing by the contracting partner;
- > lack of adequate financing to expand manufacturing capacity;
- > COVID-19 coronavirus pandemic and the resulting limitation of access to financing for the Company;
- > delays in the reimbursement of Value Added Tax (VAT);
- > a significant increase in the costs of planned work and expenditure on machinery;
- > the situation caused by the conflict in Ukraine and the inability to secure an adequate level of financing.

To date, the Company has financed its operations with cash received from shareholder borrowings, capital issues, bank loans, grants and proceeds from MabionCD20 distribution partners.

The agreement with Novavax has provided the opportunity to realise positive cash flows over the next 4 years until the end of 2025 and has become the main planned source of funding for ongoing operations and manufacturing capacity expansion, with support of debt financing.

The Company actively applies for grants, subsidies from EU funds, targeted funds for the implementation of new projects or other sources corresponding to the Company's business activities, with particular emphasis on research and development.

Having in mind the above mentioned sources of financing, the possibility of their diversification, as well as the ongoing process of acquiring a strategic investor, the Company's Management Board does not currently recognise any threat to the implementation of the investment plans and further development of the Company.

In April 2022, the Management Board received – from Polfarmex S.A., Glatton Sp. z o.o., and Twiti Investments Ltd. – the major (founding) shareholders ("Shareholders") of the Company – support documents pursuant to which the Shareholders declared their financial support for the Company for a period of at least 13 months from the date of the support document.

### 3.12 Dividend policy

In the financial year 2021, the Company did not pay out any dividend. The Company's Management Board adjusts its dividend policy to the Company's changing business situation, taking into account the scope of necessary investment expenditure. Currently, the Company is in the growth stage and it does not intend to pay any dividend.

### 3.13 Explanations of discrepancies between the actual financial results and the previously published forecasts

The Company has not published financial result forecasts for 2021.

## 4 PROSPECTS OF MABION S.A.

### 4.1 Development prospects

Since its incorporation, the Company has focused mainly on research and development work on biosimilars such as therapeutic monoclonal antibodies. The products developed by the Company are medicines which are more cost-effective in production than the manufacture of original products thanks to the technologies developed by the Company, including:

- > proprietary genetic, cellular and process engineering technologies, which enable achieving high productivity in medicine manufacturing;
- > fully integrated disposables technology, which enables the flexible use of manufacturing capacity and reducing fixed manufacturing costs;
- > industrial orbital shaking technology, which enables a cost-effective development of biofermentation processes.

The technology of manufacturing therapeutic monoclonal antibodies is a relatively new area of medical biotechnology explored by the largest global pharmaceutical concerns, an area which has been dynamically developing over the last 20 years. The process of manufacturing therapeutic preparations – one of the most eminent achievements of modern biotechnology, enables the manufacture of targeted medicines which selectively interfere with cancer cells, ensuring higher effectiveness and lower toxicity of therapies. Those medicines allowed departure from treatment of cancer based on surgery, radiotherapy and cytotoxic medicines which destroy not only neoplastic cells, but healthy tissue as well. The Company is a pioneer in the area of modern biotechnology, not only on a domestic scale, but also in the area of Central and Eastern Europe. The global supply of biosimilars is provided exclusively by large international pharmaceutical corporations.

Within several years Mabion S.A. acquired competencies to manufacture any biotechnological medicine, from the stage of designing, through the selection of the technological path, to manufacturing the finished medicine. Only a few companies in Europe have a relevant capability to carry out the comprehensive process of developing a biotechnological drug.

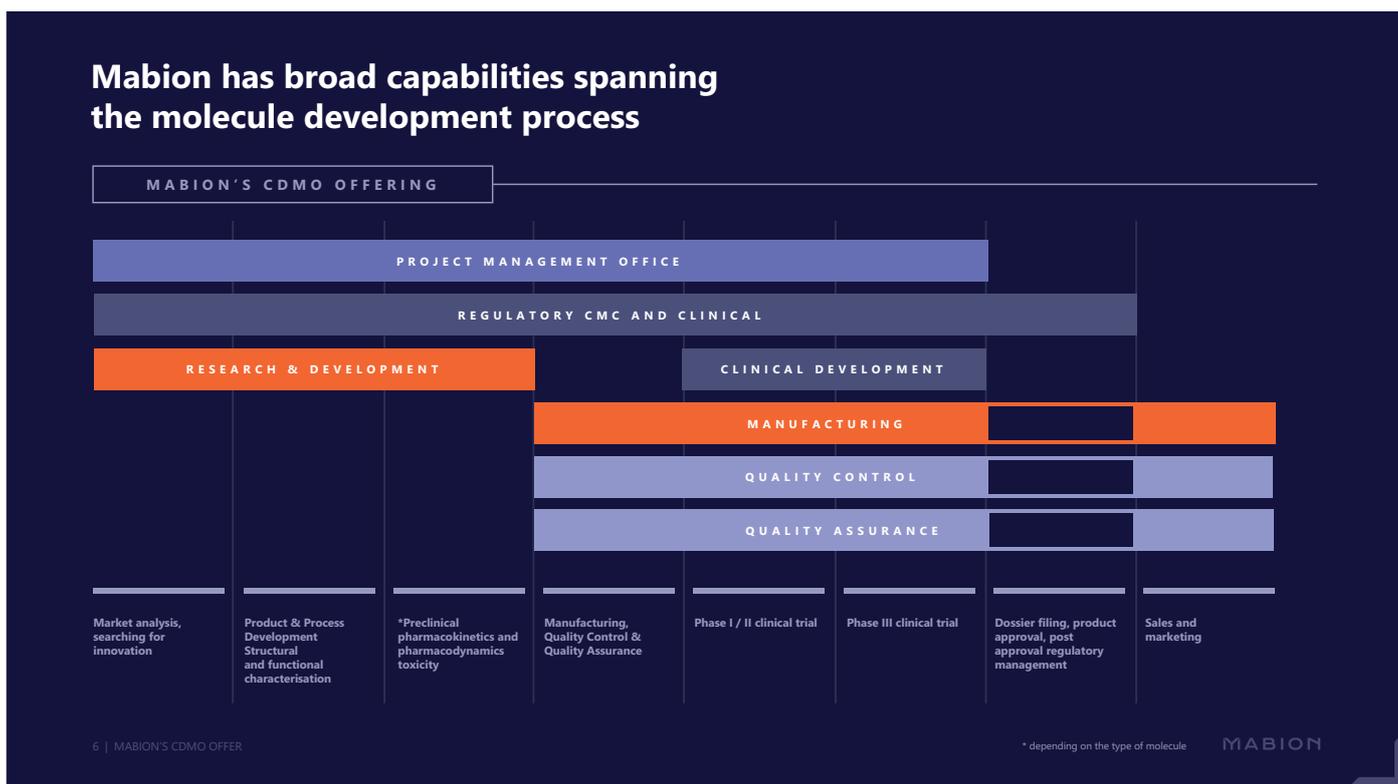
The selection of biosimilars in the form of therapeutic monoclonal antibodies used in oncology and immunology as the products developed by our company resulted from the dates of expiry of the patent protection of respective reference medicines and the high value of the reference medicines market for the products developed by Mabion S.A. referred to above. The said protection on the territory of the European Union expires over several years, beginning from 2014.

Independently or in cooperation with a prospective strategic investor, and aided by external consultants, the Company intends to carry out the registration process of a therapeutic monoclonal antibody according to the centralized procedure within the whole EU area, where the system for the registration of biosimilars is well regulated. The Company also has an important goal of introducing the medicine to the American market.

The work carried out to date on the MabionCD20 project has enabled the Company to acquire competencies unique on the Polish market in the development, clinical and regulatory development, and production of highly specialised protein drugs. As of 2021, this enabled the Company to diversify its business by offering services under the CDMO (Contract Development and Manufacturing Organization) model. Using its competences, the Company becomes a natural partner for other entities at all stages of the process of development and production of biological medicines.

As at the date of this report, the Company is in the process of developing a new business strategy to utilise the Company's existing and untapped manufacturing potential, among other things. The objective of the new development strategy for the Company is to continue its existing operations using additional capacity and in compliance with the GMP standards, and using the experience of the staff in the research and development, clinical and regulatory areas on the CDMO contract manufacturing market.

**Table 10. Key competences of Mabion S.A.<sup>32</sup>**



## 4.2 Development strategy and its implementation in the financial year

To 2021, the Company's primary objective was the development, manufacturing and marketing of biosimilars, i.e. biological medicines that are developed to be similar to the originator biotech medicines. From 2021 onwards, the Company also employs technologies it has developed not only to advance its own targeted therapy projects, but also to execute commercial orders for partners in the field of contract development and manufacturing (as a CDMO). In 2021, the Company has undertaken to start a transfer of technology related to the production of an antigen for the COVID-19 infection vaccine developed by Novavax Inc. As part of the work under the first agreement, the antigen manufacturing process was transferred at laboratory scale, and scaled up to commercial scale as a next step. At the same time, the Company transferred some of the analytical methods necessary for process evaluation as well as product evaluation. Also, a significant volume of documentation required to implement a number of new manuals and procedures related to new production and analytical processes in the Company's production facility and laboratories was drafted, and a range of documentation and procedures were created to enable the implementation and management of various processes in a single facility. The latter task has also involved transforming the Company's quality and work system to handle a wide variety of processes and products efficiently and safely, which is an asset to support continued growth of the CDMO business. All this work has been successfully completed

within the planned schedule, resulting in the commencement of implementation of a further agreement with Novavax for the regular commercial production and analysis of the vaccine antigen. The agreements with Novavax have been pivotal for the Company, both at an operational and financial level.

The current project pipeline of the Company in 2021 is reduced to three project groups: i.e. active projects, new projects, and partnership projects.

With the end of 2021, the Management Board of Mabion S.A. started to work on updating the Company's business and product strategy for the years to come. As at the date of this report, work to review and analyse the strategic areas is ongoing. The Company intends to adopt an updated development strategy in H1 2022.

### Active projects

This is a group of projects of high importance for the Company, as part of which the Company carries out work and invests funds. The group includes projects currently under way: MabionCD20, MabionMS, and MabionEGFR.

The Company's most advanced product is a biosimilar medicine, MabionCD20, a reference drug to MabThera/ Rituxan (Roche). As part of these projects, the Company allocates most of its human, organisational and financial resources to MabionCD20.

<sup>32</sup> Own study of the Company.

### Projects involving the development and marketing of new medicinal products

The projects for which the Company started research and development work in 2019 are three biosimilar drugs in the area of autoimmunity, metabolic diseases and oncology (denosumab and omalizumab antibodies).

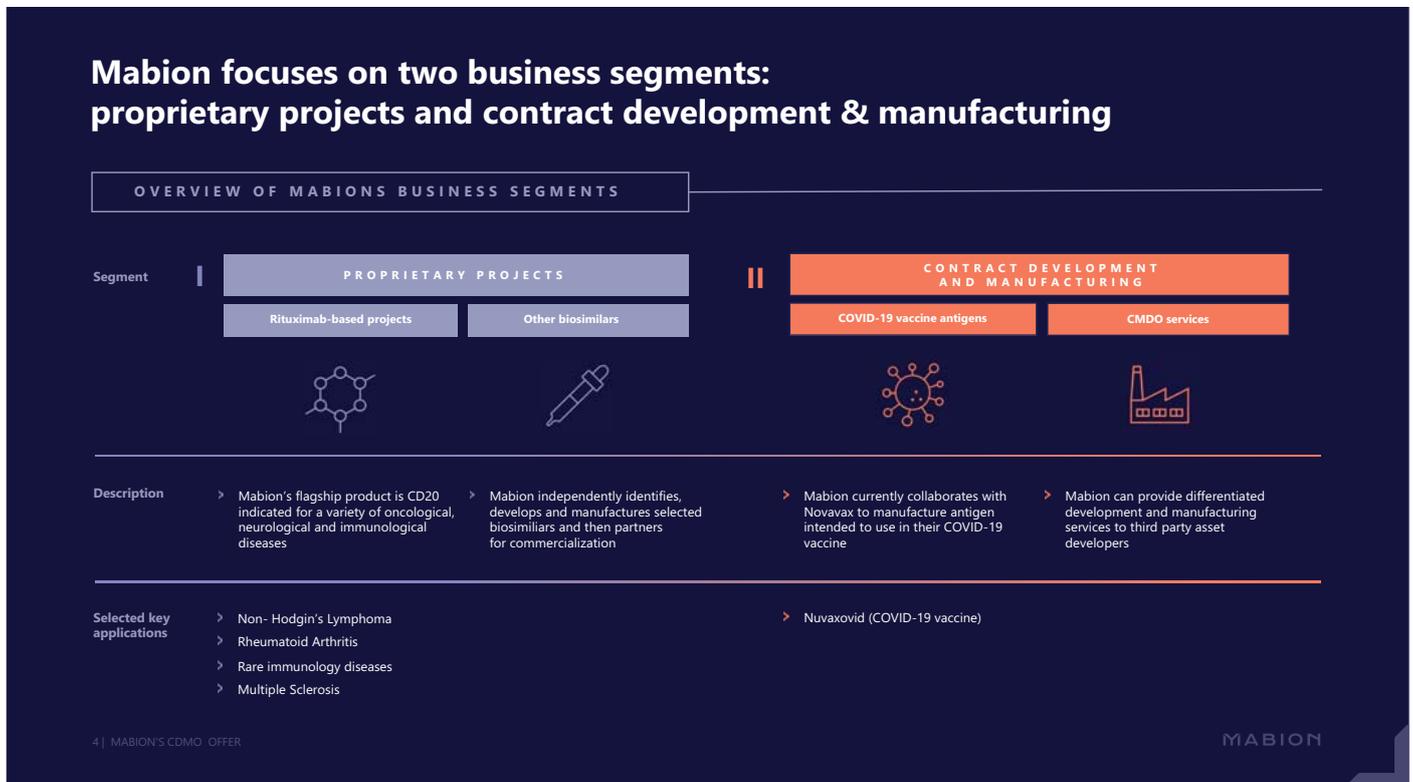
### Partnership projects

This group of projects includes all operations related to the development and marketing of new products (or therapies), as well as contract manufacturing. Contract manufacturing projects are those for which the Company is considering commencement of implementation in the medium to long term, under an order from an external partner.

The Company is currently implementing a long-term project related to the conclusion of a framework agreement (March 2021) and a commercial contract manufacturing agreement (October 2021) with Novavax, Inc. On their basis, the Company, with the participation of Novavax, carried out operations related to the transfer of the manufacturing process technology and antigen analytics of the vaccine against COVID-19 called Nuvaxovid® (previous working name: NVX-CoV2373) and conducted technical trial runs of the process on a commercial scale at the Company's facility.

Starting in December 2021, the Company commenced activities related to the commercial manufacturing of the above antigen for Novavax.

**Table 11: Preexisting product strategy of Mabion S.A. – a summary.<sup>33</sup>**



<sup>33</sup> Own study of the Company.

**Table 12. R&D project portfolio of Mabion S.A.<sup>34</sup>**

| Mabion's role   | Molecule/drug          | Clinical indication  | Characteristics                           | Status   | Commercialisation approach  | Partner                  |
|---|------------------------|--|---|--|-----------------------------|--------------------------|
| integrated partner for the development of technology, analytics, and manufacturing, medicine manufacturer | rituximab (MabionCD20) | oncology (NHL) and autoimmunology (RA)   | biosimilar medicine in approved therapies | at the registration stage in the EU and at the phase I clinical trial stage in the USA | active business development | partnering-capable asset |
| partner responsible for development and delivery of a product for trials and future therapy               | rituximab (MabionCD20) | rare diseases (autoimmunology)   | innovative therapy                        | product ready for the clinical stage   | memorandum of understanding | partnering-capable asset |
| <b>strategic co-developer / CMDO</b>  | <b>vaccine</b>         | <b>COVID-19</b>  | <b>innovative therapy</b>                 | <b>framework agreement and first order for contracted services signed</b>              | <b>partnering</b>           | <b>NOVAVAX<br/>USA</b>   |
| integrated partner for the development of technology, analytics, and manufacturing, medicine manufacturer | rituximab (MabionMS)   | CNS disease (multiple sclerosis)   | innovative therapy                        | product ready for the pre-clinical and clinical stage                                  | active business development | partnering-capable asset |
| integrated partner for the development of technology, analytics, and manufacturing, medicine manufacturer | cetuximab (MabionEGFR) | oncology (colorectal carcinoma, squamous cell carcinoma of the head and neck area) | biosimilar medicine in approved therapies | cell line optimisation   | pre-commercial stage        | partnering-capable asset |
| integrated partner for the development of technology, analytics, and manufacturing, medicine manufacturer | denosumab, omalizumab  | autoimmunological diseases, metabolic diseases and oncology                        | biosimilar medicine in approved therapies | active development of relevant cell lines  | pre-commercial stage        | partnering-capable asset |

### MabionCD20 project

The Company's most advanced project is MabionCD20, a proposed biosimilar to the reference drug MabThera/Rituxan (rituximab) (Roche). In 2018, the Company published the results of a clinical trial using the medicine originating from the 500L manufacturing process that confirmed the efficacy and safety of the therapy.

Currently, preparations are under way to initiate the stage a trial relating to patient treatment at clinical sites using the medicine originating from a target, commercial scale (5000L) In anticipation of this stage, the Company is carrying out laboratory work on an ongoing basis, as well as systematically drafting regulatory documents required to submit a marketing authorisation application for MabionCD20.

On 30 July 2021, following a round of interactions with the European regulatory agencies as part of the Scientific Advice procedure (two consulting sessions with the EMA and two consulting sessions with PEI) and with the FDA, the Company established a strategy for the co-development of MabionCD20 for registration in the European and US markets. The essential elements of the Company's regulatory strategy have not changed and include:

1. A three-arm bridging clinical trial in patients with rheumatoid arthritis ("RA");
2. A three-arm analytical bridging trial;
3. Implementation of the aforementioned tasks using MabionCD20 originating from the target, i.e. large, commercial production scale (5000L);
4. Including, in the registration procedure for the European market, the results of the already completed Phase III clinical trial with MabionCD20 originating from a small manufacturing scale (500L); the trial was carried out with 709 patients for the RA (rheumatoid arthritis) indication and 143 patients with NHL (non-Hodgkin's lymphoma).

The Company has simultaneously completed the reconciliation process and developed the final scope of data (including the scope of the bridging clinical trial) for the application for registration and marketing authorisation of MabionCD20 under the central procedure for the European market. The above mentioned three-arm clinical and analytical bridging trials include:

- (a) MabionCD20 originating from large-scale manufacturing,
- (b) MabThera as the European reference and
- (c) Rituxan, being the US reference, which is the basic assumption of the co-development strategy for MabionCD20.

<sup>34</sup> Own study of the Company.

At a further stage, the Company will clarify with the FDA the scope of additional trials (which may, as expected by the Company, include a clinical trial in an oncology indication as a required element of the registration application) required for MabionCD20 to be approved for the US market.

The three-arm bridging clinical trial in patients with RA referred to in item 1 above is expected to include a target population of 280 patients, which is in accordance with the Company's assumption that it is not necessary to carry out separate new Phase III clinical trials in order to register MabionCD20 on the European market. The primary endpoint of the trial is to analyse pharmacokinetic parameters for MabionCD20 originating from the target manufacturing scale, and for MabThera and Rituxan. Such a patient population will also allow assessment of treatment efficacy, which constitutes the secondary endpoint of the trial.

With respect to item 2, the Company has defined with the EMA and the PEI the target quality profile of MabionCD20 based on data obtained from validation batches of MabionCD20 produced at the target manufacturing scale and has established the scope of analytical trials for MabionCD20 produced on a commercial scale. The analytical trials are aimed at confirming analytical similarity to reference drugs and comparability to MabionCD20 originating from small-scale manufacturing, used in earlier clinical trials.

In the Company's opinion, the aforementioned trials and the scope of data (items 1.-4.) developed as part of the arrangements with the EMA and the PEI are sufficient for the submission of a registration application to the EMA. The above assumptions may be subject to change in the future (due to the fact that they are based on a number of factors that may affect the time-frame, including factors beyond the Company's control such as the speed of clinical trial recruitment). Moreover, the assumptions made and actions performed do not guarantee the registration of the product. In planning the scope and timing of the clinical trial, the foreseeable constraints of the COVID-19 pandemic were taken into account.

With respect to the bridging trial in rheumatoid arthritis, the Company has undertaken a number of activities to develop the internal quality systems required for the initiation of the clinical trial, including a number of procedures to allow for adequate control of the clinical trial, conducting a risk analysis taking into account both the potential risks specific to research in immunological diseases, observations from previous clinical work, as well as the current situation related to the coronavirus pandemic. The documents necessary for the launch of clinical trials were also drawn up, including the IMPD (Investigational Medicinal Product Dossier) and the IB (Investigator's Brochure), and the clinical trial protocol. In October 2020, a contract was signed with one of the most experienced CROs on the market, i.e. Parexel, which is to co-lead the clinical trial. In parallel, advanced work has been carried out leading to the development of a logistical plan for the clinical trial. The

Company has also qualified and positively identified over 35 clinical sites in Poland, Belgium, Ukraine, and Georgia for the planned clinical trial. However, Mabion does not exclude that a clinical trial will be conducted in other European countries. The suppliers of reference medicines for the trial (i.e. MabThera and Rituxan) were contracted and quality audits and qualification of the suppliers were carried out. Procurement of reference products has been continued to secure the availability of drugs for the clinical trial and analytical panels.

With respect to the ongoing activities aimed at the registration and marketing authorisation of MabionCD20, the Company – in order to commence the clinical bridging trial necessary for the authorisation of MabionCD20 in the EU in the first instance – has obtained approvals for the clinical trial from competent authorities and bioethics committees. These authorisations allow a clinical trial to be initiated in Poland, Georgia, Belgium, and Ukraine.

To sum up, in the research and development work on MabionCD20, in 2021 and until the date of publication of this report, the Company considers the following activities to be successfully carried out:

- > verification of the parameters of the antibody subjected to stability tests under routine and accelerated storage conditions for the validation batches;
- > development of analytical methods for qualitative and comparative analyses of MabionCD20, as well as clinical analytics as part of the characterisation of pharmacokinetics, pharmacodynamics and immunogenicity in MabionCD20-003RA clinical trial;
- > confirmation, during the scientific advice procedure with the EMA, of an optimised analytical panel for the assessment of biosimilarity of MabionCD20.

At the end of 2021, the Company started to work on updating the schedule of project work aimed at developing MabionCD20 for registration in the European and US markets. The update of the work plan for the next years is linked, among other things, to the current cooperation with Novavax based on contract manufacturing of the vaccine antigen, as well as the additional factor posed by the current situation in Ukraine. Consequently, the timetable for further work on the registration of MabionCD20 may be subject to change. The Company intends to adopt the updated schedule together with the Company's overall development strategy in H1 2022.

### MabionMS

With regard to the MabionMS (multiple sclerosis, MS) innovative therapy project, the Company has so far submitted the following patent applications in this therapeutic area:

- > In 2017 – European patent application (extended under PCT procedure in 2018) for legal protection for the invention called "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand". The subject of the patent

<sup>35</sup> Opracowanie własne Spółki.

application was an innovative therapy for the treatment of multiple sclerosis patients using the MabionCD20 antibody combined with other substances (MabionMS combination therapy project). In July 2020, the Company filed international patent applications for the above invention with selected patent offices, initiating a national and regional phase to obtain patent protection in dozens of countries. Based on statistics on multiple sclerosis in specific regions, as well as on the potential of specific markets, Mabion has filed patent applications with selected patent offices covering countries such as: USA, Canada, UK, EU and EFTA countries, Australia,

New Zealand, Israel, Turkey, Russia, and several others. The commencement of the national and regional patent application phase in each country is the next step on the path to obtaining legal protection for this innovative therapy.

- > In 2018, a European patent application (with the possibility of extension under the PCT procedure) in the area of application of MabionCD20 in the treatment of patients with multiple sclerosis, called "Low aggregate anti CD20 ligand formulation". This is the second patent application in the area of use of MabionCD20 for the treatment of multiple sclerosis, constituting an innovative indication for the molecule. This application concerns the use of MabionCD20 as a monotherapy.

Currently, the Company is looking for partners for further work related to the development of the above-mentioned therapy.

### MabionEGFR

The MabionEGFR project concerns the development of a medicine to treat patients with metastatic colorectal cancer expressing the epithelial growth factor receptor (EGFR), wild-type RAS genes, and patients with squamous cell carcinoma in the head and neck region. For this 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 was co-financed from EU funds. On 24 February 2022, the Company's Management Board decided to abandon further implementation of the project as part of the funding due to the fact that its further implementation was not justified.

Consequently, a final application for payment and Final Information on the Project implementation were submitted to the NCB. The documents are currently being evaluated by the NCB.

In 2021 and until the date of this report, the Company proceeded, as part of the project, with activities related to:

- > developing biological and physico-chemical analytical methods to characterise the protein obtained;
- > preliminary optimisation of cell culture and antibody purification conditions.

### Nuvaxovid® (formerly NVX-CoV2373)

On 3 March 2021, Mabion entered into a framework agreement with Novavax, Inc. based in the United States, pursuant to which the Company, with Novavax's participation, undertook activities related to the transfer of process technology for the production of a COVID-19 vaccine candidate antigen, together with the antigen analytics, called Nuvaxovid® (former NVX-CoV2373) and conduct technical trial runs of the process on a laboratory and commercial scale at the Company's facility.

With the conclusion of the framework agreement, the parties agreed on the scope and budget of the work contracted to the Company to carry out the technology transfer, analytics, and technical runs for the Nuvaxovid® protein antigen. These are standard activities when starting cooperation in the field of contract manufacturing. The scope of contracted work under the first order included technology transfer from Novavax to the Company. In addition, it included: the transfer and verification of analytical methods, together with implementation of the transferred methods and documentation related to the manufacturing process into the Company's quality system, completion of one technical run and one confirmatory run demonstrating the possibility of batch production in the facility.

The work under the first order was carried out in accordance with the commissioned scope, with positive results.

On 23 June 2021, the Company received a second order from Novavax under the framework agreement. The order was placed in conjunction with negotiations then in progress for a potential manufacturing agreement under which the Company could manufacture the active ingredient on a commercial scale for Novavax. To facilitate the Company's future production process, the parties signed an order allowing the Company to procure key raw materials for production in advance within a budget agreed by the parties and funded by Novavax. The order concerned the procurement of raw material volumes sufficient for the future commercial production of the active substance involving the Company's full production capacity by the end of the first half of 2022 (as estimated by the Company).

Immediately following the order, the Company started to procure materials and reagents necessary for the future possible commercial production of the active substance.

As a result of the successful implementation of the above, on 8 October 2021, the Company entered into a commercial contract manufacturing agreement with Novavax, together with Statement of Work #1 (SOW#1) under which the Company will commercially manufacture the Nuvaxovid® antigen, based on a-GMP standard, for Novavax.

On 19 November 2021, a quality agreement was concluded which marked an important step in the implementation of the manufacturing agreement, covering technical and regulatory arrangements for the production of Nuvaxovid® antigen, including relevant GMP standards. The agreement sets forth

the obligations and technical and regulatory arrangements required for the manufacture, testing, storage and shipment of the product. It also sets out the principles of cooperation between the departments involved in the implementation of the Agreement.

On the same day, the Company submitted a notification to the Chief Pharmaceutical Inspectorate (GIF) concerning the conclusion of the aforementioned agreement.

In December 2021, the Company also started, in line with the assumptions, the first manufacturing activities related to the preparation of the manufacturing facility, securing raw materials, approving raw materials for manufacturing in terms of quality, ensuring analytical capacity for process and product control, as well as commencing the implementation of the manufacturing schedule covering the period of 12.2021 - 12.2022, which, as previously announced, is cumulative in time, i.e. the initial batches are planned as a sequence, and over time the ratio of simultaneous batches per unit of time will increase. As at the date of the report, there was no indication of any deviation in the implementation of the schedule mentioned above.

In January 2022, under the existing Manufacturing Agreement, Mabion signed two further additional orders with Novavax in the form of:

- > Statement of Work #3 ("SOW#3") on 14 January 2022 for manufacturing of cell banks for Novavax in compliance with the GMP (Good Manufacturing Practice) standard. The resulting cell banks will be used as key biological material to form the basis for the production of vaccine antigens of the Nuvaxovid® product.
- > Statement of Work #2 ("SOW#2") on 18 January 2022, under which the Company will provide analytical services to Novavax for testing related to quality control of the Nuvaxovid® vaccine ("Product") not covered by previous contracts or orders and will transfer methods in accordance with Novavax specifications.

Both of the above orders are currently being implemented by the Company.

### **Business development: products based on MabionCD20 antibody**

On October 2020, the Company signed a Memorandum of Understanding with Taxon Therapeutics Ltd. regarding the parties' intention to work out the terms of a potential long-term collaboration for the research, development, and then worldwide commercialisation of medicinal products based on a monoclonal antibody recognising the CD20 receptor on human B lymphocytes ("Products") in specific clinical indications in the area of rare diseases. The memorandum was intentional and non-binding in nature. The parties have concluded their talks under the above memorandum and do not plan to continue them.

### **Additional equipment for the existing facility**

The current production capacity for the drug under the working name of MabionCD20 allows the Company to partially cover the estimated demand from customers in European Union countries. The implementation of long-term plans requires the Company to achieve adequate production capacity, which requires investment.

In addition, to deliver the agreed scope of work under the agreement with Novavax, the Company plans to expand its production capacity in late 2022 and early 2023 by equipping the existing facility with new bioreactors, bringing the Company to four bioreactors in subsequent years as of 2023. At the same time, the Company will refit the product purification line to optimally utilise the increased bioreactor capacities.

Moreover, as part of permit no. 301, the Company undertook to incur investment expenditure in the area of the Łódź Special Economic Zone in the amount of at least PLN 20,000 thousand (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 for conducting business activity in special economic zones), related to the increase of production capacity of the existing facility. The time limit for incurring these expenditures and completing the investment is 31 December 2024 (decision of 10 August 2021 by the Minister of Development, Labour, and Technology). Under permit no. 301, as at 21 April 2022, the Company made investment expenditures of PLN 2,803 thousand. The planned and contracted retrofitting of the existing facility will form a capital expenditure under this permit.

### **Extension of the existing facility**

In 2017, the Company started preparation activities connected with the expansion of the existing production facility (stage "MABION II"), with an aim to increase significantly the production as well as R&D capacity of the Company. A concept for the extension of the Scientific and Industrial Complex for Medical Biotechnology has been developed. In 2018, the Company selected an international consortium of architectural and technological companies, to which it entrusted the development of a technological and construction design.

In November 2018, the Company received the decision of the Pabianice Governor approving the construction design and granting a building permit for the aforementioned investment called "Technological and Scientific Centre for Advanced Medical Biotechnology of Mabion S.A." with the necessary infrastructure in Konstanyńów Łódzki.

In 2019 and 2020, work was under way to prepare detailed designs for all construction and installation sectors. Following the contractor's consideration of comments by the Company, the detailed design was completed and accepted by the Company in February 2021. Detailed specifications of user requirements were prepared for critical installations and main process lines.

In February 2020, the Company received the decision of the Pabianice Governor approving the change to the building permit, allowing to increase the cubic volume of the building to the target size necessary for the Company to implement the intended investment plans, including the increase of the Company's production and R&D capacity. The building permit allows for the commencement of works on the extension of the existing plant, however, the moment of their commencement depends on the Company's financial capabilities, including in particular the ability to obtain funding with the support of grants obtained and operating cash flows.

In June 2018, the Company signed a co-financing agreement with the Minister of Investment and Development for the project "Expansion of the Research and Development Centre of Mabion S.A. – research on the new generation of medicines" (Measure 2.1 Support for investment in R&D infrastructure of enterprises of the Operational Programme Smart Development 2014–2020 co-financed by the European Regional Development Fund). The objective of the project is to develop the Company's research and development facilities by preparing the necessary infrastructure: the building of the Research and Development Centre, and the purchase of research equipment to conduct research on innovative medicines. The planned Research and Development Centre will be used to develop and prepare for commercialisation the latest generation of biotechnology drugs: monoclonal antibodies. The total cost of the project was set at PLN 172,880 thousand, with a co-financing of PLN 63,250 thousand.

Currently, the Company is in the process of implementing the project in question, however, due to the planned extension of the substantive scope of the project and the issues related to the financing of its own contribution, the project work is delayed with respect to the originally assumed schedule, and its budget needs to be updated. Accordingly, the Company requested the Managing Authority (MA) to amend the project and extend its implementation until the end of 2023. On 19 April 2022, the Company concluded an annex to the Project funding agreement with the Ministry of Development Funds and Regional Policy. According to the annex, the period of expenditure eligibility for the Project was extended until 31 December 2023 (previously 31 December 2021). Moreover, due to the inclusion of an additional research area in the Company's activity, i.e. vaccine therapies, the objective and material and financial scope of the Project were changed to the extent enabling the introduction of the aforementioned research area to the Project.

### 4.3 Factors important for the development

#### Standards relating to studies

The research and development work of the Company is conducted within the pharmaceutical quality systems.

The medicines are manufactured according to the principles of Good Manufacturing Practice. This was confirmed by obtaining the GMP certificate from the Main Pharmaceutical Inspectorate:

- > in July 2019, for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstancinów Łódzki at ul. Gen. M. Langiewicza 60 (in the scope of production of active substance);
- > in August 2019, for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstancinów Łódzki at ul. Gen. M. Langiewicza 60 (in the area of medicinal product manufacturing);
- > in April 2021, for the Scientific and Industrial Complex for Medical Biotechnology of Mabion S.A. in Konstancinów Łódzki at ul. Gen. M. Langiewicza 60 (in the scope of investigational medicinal product manufacturing and import of the investigational medicinal product).

The analytics related to samples originating from clinical projects are carried out in accordance with Good Laboratory Practice (GLP) principles. This was confirmed by obtaining a GLP certificate in March 2014 from the Bureau for Chemical Substances (Biuro do spraw Substancji Chemicznych). Holding such a certificate indicates the top quality of the research and analyses conducted. Analyses in the scope of medicine quality parameters (pharmacokinetics, pharmacodynamics, immunogenetics) and clinical parameters provide unbiased, reliable results acceptable by medicine registration offices throughout the world. In March 2022, the laboratories of the Research and Development Centre in Łódź successfully underwent another GLP audit, as a result of which the validity of the certificate was extended. The activities related to planning, conducting, documenting and communicating the results of human clinical trials are performed in accordance with the principles of good clinical practice (GCP), i.e. the international ethical and scientific standards developed by the ICH (International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

#### Information on collective experience and knowledge of key technical personnel

During its existence, the Company has gathered a stable and experienced research personnel team. The team whose knowledge is of key importance to the results of research and development operations includes:

- > Ph.D. Sławomir Jaros, EMBA (Member of the Management Board, scientific director of the Company, graduate of the Warsaw University of Life Sciences, Inter-faculty Biotechnology Studies, doctor of biological sciences in the Institute of Parasitology of the Polish Academy of Sciences and graduate of Polish-American Studies Executive MBA (University of Maryland);
- > Anna Małecka, Regulatory Affairs Specialist, graduate of the Faculty of Biotechnology, Jagiellonian University (major: Biotechnology);
- > Ph.D. Dorota Jaros, Scientific Regulatory Specialist, graduate of the graduate of the Interdepartmental Study of

Biotechnology of the Warsaw University of Life Sciences, Doctor of Veterinary Sciences at the Warsaw University of Life Sciences

- > Marta Bednarek, Head of the Manufacturing Department, graduate of the Faculty of Biotechnology and Food Sciences at the Technical University of Łódź, MD student at the Faculty of Medicine of the Medical University of Łódź;
- > Dorota Owczarek-Hamrol, Head of the Quality Control Department, Qualified Person, graduate of the Faculty of Biology and Environmental Protection of the University of Łódź;
- > Julita Balcerek, Chief Operating and Scientific Officer, graduate of the Faculty of Biotechnology, University of Wrocław, MD student at the Faculty of Medicine, Medical University of Łódź, student of the Polish-American Executive MBA Program (PAM Center, Faculty of Management, University of Łódź);
- > Łukasz Waszak, Head of Quality Assurance Department, graduate of the Faculty of Biotechnology, University of Wrocław.

The company maintains close cooperation with the academic environment, implementing the provisions of cooperation agreements entered into with the Faculty of Biology and Environmental Protection of the University of Łódź and the Faculty of Biotechnology and Food Sciences at the Łódź University of Technology. In 2021, the Company, in consultation with the Medical University of Łódź, successfully applied to the Entrepreneur Service Center in Łódź for the funds to be used in the development of analytical methods. In addition, Mabion has been cooperating for years with universities (Medical University, Łódź University of Technology) in the implementation of didactic work, student internships and mentoring programmes (e.g. "Młodzi w Łodzi"). Owing to such programmes, students can learn about the special nature of research projects, benefit from the exceptional experience of Mabion's specialists, and work on best-in-class professional laboratory equipment.

Cooperation with Higher Education Career Offices, in particular at the Łódź University of Technology and the Medical University of Łódź, as well as the Wrocław University of Technology gives the Company an opportunity to prepare a team of young specialists for cooperation as part of scientific and commercial projects run by the Company.

The Company allocates significant funds for the participation of key employees in the most prestigious conferences and foreign trainings. It also supports their development by financing employee participation in post-graduate and doctoral studies.

## 4.4 Risk and threat factors

### 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, rapid changes in the legislative environment that have a negative impact on legal certainty.

Domestic and foreign laws and regulations which relate to the Company's operations require the Company to adapt its internal regulations and procedures to the requirements of the legislator. Failure to comply with the applicable regulations may result in the imposition of financial or other penalties on the Company. 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

If unforeseen events occur, such as wars or terrorist attacks or epidemics, adverse changes in economic conditions and the financial market may occur, which may adversely affect the Company's financial condition and/or the schedules of projects carried out by the Company. In addition, such random events as fires, floods and other extraordinary natural disasters may cause failures or destruction of material property belonging to Mabion S.A., as well as disruptions to the Company's operations, which may adversely affect the Company's financial results.

On 24 February 2022, Russia invaded Ukraine. At the time of drafting this report, the armed conflict in Ukraine, a country neighbouring Poland, is still continuing. The international community has imposed heavy sanctions on Russia, targeting specific entities and economic sectors. As for today, the sanctions and the armed conflict have not had a direct impact on the Company's business. Volatile exchange rates, interest rates, the potential for economic growth, the impact of higher immigration and the possibility of the proliferation of conflict, have increased the uncertainty of the environment in which the Company operates.

Therefore, as part of the work related to the update of the MabionCD20 project schedule indicated in section 4.2, the Company is currently analysing possible actions to mitigate the impact of the situation in Ukraine.

The ongoing economic situation in the East - due to the war in Ukraine - has caused the Management Board to closely monitor the regulations introduced by the Polish Government, the governments of other EU countries, and the United States. A protracted conflict may result in higher prices of, for example, energy, restrictions on free trade, or other business restrictions, including disruptions in the supply chain for goods and services.

The Company has analysed the impact of the Russian military invasion of Ukraine and its current and future possible consequences for the Company. The Management Board is of

the opinion that the invasion and its effects are post balance-sheet events that do not affect the measurement and classification of assets and liabilities in the financial statements as at 31 December 2021. The Management Board has assessed the possible impact on the Company and has included appropriate disclosures in the financial statements to describe both the existence of this event arising after the balance-sheet date and an assessment of its potential impact on the Company, including its financial performance in 2022 and beyond.

### **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;
  - > 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, restriction of freedom of trade and other business constraints;
  - > certain expenses, including travel, translation and insurance expenses;
  - > regulatory and compliance risks that relate to reliable information and control over sales and operations.
- for an unspecified period of time due to the possible or actual restrictions indicated below:
- > reduced staff availability (quarantine, childcare in case of school closures, risk of falling ill);
  - > limiting the mobility of the Company's employees – suspension of the participation of the Company's representatives in meetings and conferences, both foreign and domestic;
  - > suspension of meetings with external companies, including consultants;
  - > delays in deliveries resulting in the inability to conduct selected processes in the Company;
  - > delays in the acceptance and commissioning of the ordered equipment due to limited possibilities for external representatives to calibrate the equipment;
  - > problems with securing all the resources required for research as a result of the reduction in production and the depletion of stocks of external companies cooperating with the Company;
  - > the possibility of plant closure in order to limit the possibility of virus spread;
  - > the possibility of restrictions imposed by national government administrations hindering the launch of a clinical trial or affecting the modalities of its organisation and duration;
  - > potential impact on the conduct of the clinical trial, e.g. through prolonged recruitment time of patients with rheumatoid arthritis, potentially greater drop-out of patients from the clinical trial due to contracting COVID-19 or difficulties in contacting clinical sites, possible longer time to obtain clinical trial approvals from the competent authorities, possible logistical problems due to difficult access to specific materials, medicines, limitations in international transport, possible limited access to certain clinical sites and possibilities to organise monitoring visits or site meetings.

### **Risk related to the coronavirus (COVID-19) pandemic**

As regards the coronavirus (SARS-CoV-2) epidemic threat, which started to increase with the beginning of 2020, there was a risk of delays in the schedule of work or suspension of work

As at the date of this report, in the Company's opinion, it is not possible to exclude a possible impact of the pandemic on the Company's operations if further waves of cases occur. In order to prevent the aforementioned risk, the Management Board monitors the global situation on an ongoing basis, trying to adapt the Company's strategy to changes in the threats in the areas described above in advance. As regards the epidemic risk, the Management Board systematically implements measures aimed at significantly reducing the risk of infections among employees by, among other things, implementing solutions to protect their health. In the event of significant new circumstances related to SARS-CoV-2 coronavirus pandemic and affecting the Issuer's operations, the Company will introduce appropriate solutions, adapting to administrative decisions.

### 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 in particular those related to tax law, laws governing the operation of the social security system and publicly funded healthcare services, as well as pharmaceutical and intellectual property laws. 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, or 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

Some of the raw materials necessary for the production of the active substance are purchased in foreign currency (USD and EURO). In addition, the Company carries out significant investment purchases related to the retrofitting of the facility where the currency of the agreement is the euro.

Reimbursable advances for distribution rights (funds received from distribution partners) are denominated in foreign currencies, which leads to exposure to currency risk as long as

these funds are not used (i.e. reimbursed or reclassified to deferred income, depending on the outcome of uncertain future events). A significant portion of the advances for distribution rights as at the balance-sheet date have already been settled and the current risk in this regard can be considered limited.

Some of the laboratory equipment and reagents used for research and development are purchased by the Company with foreign currencies, mainly EUR and USD.

Unfavourable changes in exchange rates (depreciation of the Polish zloty against foreign currencies) may contribute to an increase in the level of the Company's capital outlays and increase research and development costs and current costs, which may have an adverse effect on the Company's financial results.

The Company has signed an agreement for the manufacture of an active substance denominated in USD, and therefore it is expected that the risk associated with currency fluctuations will be mitigated in the future owing to the sales and deliveries of the substance performed for Novavax.

The Company reviews the level of exchange rate risk and the possible impact of the above changes on the results of the period on an ongoing basis. At present, the Company's management does not deem it necessary to purchase instruments to mitigate the impact of changes resulting from temporary fluctuations in foreign exchange rates on its financial results and capital position.

### Bio-tech drug market risk

One of the main areas activity of the Company is development, manufacturing and marketing of biosimilars, i.e. biological medicines that are developed to be similar to the original biotech medicines (known as reference medicines). At present, the biotech medicines market is attractive, and in the coming years its value should increase even more significantly. 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.

### 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. Clinical development activities for oncological drugs are undertaken by more than a hundred of companies and the estimated expenditure will have a CAGR of 11–14% (until 2023).<sup>35</sup> In addition, there is a rapid development in

<sup>35</sup> Global Oncology Trends 2019, IQVIA Institute

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, it cannot be excluded 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. By the date of this report, biosimilars to MabThera/Rituxan have been marketed in the EU by Celltrion/Teva, Sandoz, and Pfizer, and in the USA – by Celltrion, Pfizer and Amgen/Allergan. Based on market analyses, it can be assumed that Amgen's product will still be authorised on the European market<sup>36</sup>.

The above mentioned activities of competitors do not affect Mabion's schedule. Even if the commercialisation of a biosimilar drug to MabThera/Rituxan is successful for several players, the analyses show that this market has a growth potential. For the sustainable development of the market for biosimilar medicines, it is essential that more manufacturers emerge. Even within the EU, where the market penetration of biosimilar medicines is the highest, some countries still have low access to biosimilar treatments. Currently, demand for medicines for oncology and autoimmune diseases exceeds the production capacity of suppliers and is limited by the financial capacity of national health systems. The market for biosimilar drugs is one with high entry barriers. These include very high requirements for clinical trials, particularly in the US and other developed countries, to prove that a medicine is biosimilar to the original medicine. This is supported by the fact that in November 2018, Sandoz abandoned its attempt to apply for marketing authorisation in the US for its biosimilar drug MabThera/Rituxan, after the regulator requested additional data<sup>37</sup>.

### Partnering risk

On 17 November 2021, the Company's cooperation with Mylan, which under an agreement entered into in 2016 held exclusive rights to sell the medicine with the working name of MabionCD20 in all European Union and Balkan countries, came to an end. In addition, under the agreement in question, Mylan provided support to the Company in the process of registration of MabionCD20 by the EMA. In April 2021, the Company signed an annex to the cooperation agreement with Mylan, under which the parties decided that Mylan will remain Company's non-exclusive distribution partner for MabionCD20 in selected countries in regions such as, in particular Australia, New Zealand, Mexico, Central America, South Africa, South East Asia, deciding at the same time that Mylan's exclusive right to sell MabionCD20 in the European Union and the Balkan countries, as well as Mylan's priority right to enter into a commercialization agreement for MabionCD20 in the United States (USA), shall expire.

As a result of the termination of the agreement with Mylan, Mabion now has full flexibility to commercialise MabionCD20 in all markets, which may have a positive influence on the Company's ability to obtain a strategic investor.

While the Company assumes that the sales plans will be implemented together with a partner, the process of acquisition of a partner is not actively pursued at the moment. In the Company's opinion, acquiring a partner will be more beneficial for the Company at the stage of registration of MabionCD20. At the same time, the Company does not exclude the possibility that the sales plans will be implemented with the support of a strategic partner chosen in the process carried out with the support of Rothschild & Co. and Plexus Ventures LLC.

### 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

<sup>36</sup> L.E.K. report prepared on request of the Company, published on 8 February 2022.

<sup>37</sup> [http://www.pharmatimes.com/news/sandoz\\_dumps\\_us\\_filing\\_for\\_biosimilar\\_rituximab\\_1258681](http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681)

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 8–10 years and costs between USD 100 and 200 million<sup>38</sup>. 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 ruled out that the actual costs of manufacturing and marketing of developed drugs (including MabionCD20) will be significantly higher than currently assumed. A significant increase in the costs of production and introduction of the developed drugs to the market may adversely affect 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, geopolitical situation, or new guidelines;
- > amendments to regulations concerning the scope of analyses needed to characterise 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 – MabionCD20**

Achieving the Company's objective which is to register and market MabionCD20 involves the implementation of a multi-stage, detailed work schedule. The possibility of pursuing this schedule depends on many various factors, both internal and external. Any changes at the strategic level or the occurrence of unforeseen delays in the implementation of the schedule may make it necessary to revise the assumptions adopted previously. The Management Board monitors all works related to the project in question and if necessary implements the required operating solutions to minimize the impact of unexpected events on adopted time schedules.

The Company is currently working on updating its strategy for the upcoming years, which may result in a change in the schedule of work on the registration of MabionCD20.

### **Risk related to the work schedule – NVX-CoV2373**

On 8 October 2021, the Company entered into a commercial contract manufacturing agreement (Manufacturing Agreement, Master Contract Manufacturing Agreement) with Novavax, together with a Statement of Work, pursuant to which the Company will manufacture on a commercial scale, on a GMP standard basis, an antigen for a COVID-19 vaccine called Nuvaxovid®. The parties agreed on the scope and budget of the work contracted to the Company as part of the production of engineered and commercial batches of the protein antigen Nuvaxovid®.

The risk that the planned timetable may change due to a number of factors of a technological and logistical nature at the level of supply of materials and substances necessary for the planned work, as well as those related to the COVID-19 pandemic of the present geopolitical situation, cannot be excluded. Due to a number of factors, there is a risk of delays in the implementation of the work and the need to postpone the originally adopted work schedule.

The Company has commenced the implementation of the agreement on schedule. However, it cannot be excluded that as a result of the ongoing work and discussions with the partner, the original assumptions relating to the manufacturing process or associated processes will change, which may also affect the work schedule.

To minimise the above risks, the Company's Management Board carries out ongoing monitoring of project work, participates in regular working group meetings and arrangements with the partner so as to counteract possible delays as far in advance as possible. The Company has specialised teams dedicated to the procurement of materials and equipment required for the project, as well as an extensive network of suppliers. A preliminary analysis of project risks (e.g. at the level of the quality system, technology, regulatory matters, technical installation) is also carried out and updated, and measures are taken to minimise

<sup>38</sup> <https://www.gabionline.net/reports/comparison-of-the-cost-of-development-of-biologicals-and-biosimilars>

possible risks. The team, dedicated to ongoing monitoring and risk analysis, undertakes ongoing activities to mitigate possible risks to the project.

As part of an expansion of the cooperation with Novavax product and an increase in the Company's production capacity, the preparatory work related to the conversion of the existing manufacturing plant and the implementation of the production capacity expansion project (Mabion II) is ongoing.

### **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 dedicated 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.

### **Risks related to the production process and quality control 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 (up-scaling). It is very important to ensure continuity, stability and purity of the entire production process. The Company's quality control laboratories are equipped with state-of-the-art equipment that ensures maximum accuracy and repeatability of the obtained results. A panel of validated analytical methods ensures maximum accuracy, precision, specificity and reproducibility of the results.

Designed in accordance with the regulator's guidance requirements, it enables reliable product inspection. A key parameter of analytical methods is their variability, which is influenced by a number of factors determined during validation. Continuous control of method variability over time is critical for research where results are collected over years (e.g. product stability, quality tests). The absence of a reliable analysis of method trends may adversely affect the final assessment of both production processes and the products themselves. The materials used in the production zone have appropriate certificates for use in the 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, batch loss, 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.

An extremely important factor in the Company's operations is maintaining appropriate conditions on the premises where the Company's products are being developed. Currently, Mabion holds all required approvals for the equipment and laboratory and manufacturing premises in both plants. 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 Manufacturing Practice (GMP), holds the necessary approvals and permits

(including a GMP Certificate for the Complex in Konstancinowa Łódzki, issued by the Main Pharmaceutical Inspector).

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

At present, it is difficult to accurately estimate demand for MabionCD20. Nevertheless, the plans to sell the medicine are connected with the need to increase production capacity above the level possible at the present plant in Konstancinowa Łódzki. The Company is aware of these needs and it seeks to erect another building in the same location, on the same plot. The new 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 the investment in question will depend mainly on two factors, such as the securing of funding for the construction of the new facility and the timing of the registration of MabionCD20.

The Company will implement the investment based on its own experience arising during the construction and operation of the plant in Konstancinowa Łódzki, as well as cooperating with 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.

The implementation of the agreement for the commercial contract manufacturing of vaccine antigen for Novavax requires the manufacturing capacity at the existing facility to be doubled. The Company has already begun ordering equipment so that the contracted product volume can be delivered by 2025. The implementation of the aforementioned investment constituting in an additional building would significantly improve the Company's ability to manufacture its own medicines and to execute external orders, and would reduce the risk of internal competition between projects within the Company for manufacturing resources.

### **Risk related to clinical trials**

One important preparation stage related to the registration and marketing of medicines are clinical trials. Conducting clinical trials involves risks that can be grouped as follows:

- > risks associated with inadequate design of the trial protocol, leading to inability to obtain sufficient data required by regulatory agencies, of defined statistical significance;
- > the risk of insufficient efficacy or safety of the investigational medicinal product;
- > risks associated with conducting the entire clinical trial in a manner inconsistent with GCP requirements;
- > risks related to the adverse impact of a pandemic, e.g. coronavirus, on a clinical trial;
- > risks associated with the war in Ukraine, which may delay or prevent the clinical trial in that country.

Being aware of the possible risk, the Company undertakes a number of activities leading to its minimisation. As part of these activities, all clinical trials planned by the Company, once an internal strategy has been established, are consulted with experienced, external, independent specialists and regulatory agencies in order to obtain a validated trial protocol designed to ensure the desired results with adequate statistical power. In addition, the product is evaluated with a broad panel of biological and physicochemical analyses before it is used in a clinical trial. These analyses are a more sensitive model for the characterisation of a medicinal product than a biological model in the form of a patient, and therefore the studies significantly reduce the risk of inadequate efficacy or safety of a Company's product used in a clinical trial.

In order to ensure that the clinical trial complies with the requirements of regulatory agencies, including GCP requirements, the Company has aligned its internal quality system with relevant guidelines. These procedures define both how to proceed in preparing for a trial and how to conduct a clinical trial. They also specify the requirements to be met by the CRO carrying out the trial and how the work will be verified.

When planning a clinical trial, the Company also takes into account the increased probability of events that may occur as a result of situations that are difficult to foresee, including the coronavirus pandemic, such as, for example, a decrease in the recruitment of patients for the clinical trial, a reduction in the availability of the reference drug and other resources necessary to implement the project, prolongation of the administrative processes necessary to carry out the trial, the potential closure of the borders of certain countries and, consequently, hindered transport of clinical samples. The Company's quality system entails a thorough risk analysis prior to the commencement of a clinical trial, defining the impact, ways to reduce the probability of occurrence and ways to mitigate the effects of adverse events. Based on the information about potential risks such as those mentioned above, the Company develops additional procedures and actions to ensure seamless execution of the project, e.g. selects appropriate countries and sites to guarantee the desired level of recruitment, qualifies a wider range of suppliers of a drug and other resources for the clinical trial, verifies the current administrative, legal and political situation in the countries intended as a place of the trial, or cooperates only with experienced partners guaranteeing the highest quality of work, or carries out studies and work to enable a further alternative country or service provider to be enrolled in a clinical trial even before the clinical phase of the project begins.

The risk analysis performed by the Company prior to the commencement of the project and the implementation of appropriate measures to minimise the probability of risk materialisation significantly increase the chance of successful completion of the clinical trial.

### **Risk related to drug registration**

One of the primary objectives of the Company is the introduction of the developed biosimilars to global markets, primarily the EU

and US markets, which involves the obligation to register such drugs with the EMA and Food and the FDA, respectively.

The Company has identified a number of risks that may affect the registration process and, consequently, the timing of MabionCD20's marketing in Europe. Such factors include regulatory issues (e.g. misinterpretation of guidelines), organisational issues (e.g. inability to respond to the regulator within a specific timeframe, lack of specific data and analytical or manufacturing results, etc.) or quality issues (failure to achieve specific quality parameters for the drug), and the COVID-19 pandemic. The ongoing monitoring and preventive actions undertaken by the Company were aimed at minimising the risk factors.

The scope and format of the MabionCD20 registration application concerning the large, target scale of production is being consulted with the representatives of the FDA, EMA, and national agencies (e.g. German Paul Ehrlich Institut) under the Scientific Advice procedures to align it with the Agency's expectations, which the Company believes should streamline the registration process.

Under the advisory procedures of the EMA, the German Paul Ehrlich Institut, and the FDA, an analytical and clinical programme fulfilling the anticipated requirements for the registration of MabionCD20 in the EU was developed and a clinical programme for the US was debated.

In February 2021, the Company received recommendations from the EMA as part of the Scientific Advice procedure on the details of the planned clinical trial under the Scientific Advice procedure, including primary and secondary endpoints, trial population, immunogenicity analysis and adaptation of trial parameters to pandemic conditions.

In April 2021, the Company held a Type 2 meeting with the FDA on the clinical trials required to obtain marketing authorisation for the biosimilar product in the United States. The design and important details of a three-arm clinical trial comparing MabionCD20 with EU and US reference drugs were agreed and the scope of the trial was discussed with regard to the oncology population.

In June 2021, the Company held consultations (under the national Scientific Advice procedure) with the German Paul-Ehrlich Institut (PEI), as part of which it presented analytical data for the current 5,000L batches, to receive approval of the registration strategy and to clarify the details of the necessary trials. At the same time, the Company further specified the scope of clinical data for registration, which includes studies using the product originating from the 500 L and 5,000 L scales. Some minor changes to the clinical trial design in response to EMA suggestions during the Scientific Advice procedure held in February 2021 were discussed and agreed with the PEI.

With the help of external regulatory experts, the Company analysed the documents received and adopted a preliminary framework for the scope and schedule of work required to submit a new marketing authorization application (MAA) for the product.

However, due to the specific responsibilities of the regulatory authorities, the content of the document is subject to interpretation, which poses some risk of discrepancies in interpretation.

As part of the Scientific Advice procedure held with the EMA in September 2021, the Company further specified the Regulator's expectations regarding the selected analytical methods as well as the full panel of tests for the physicochemical and biological properties of the MabionCD20 antibody as part of its characterisation, biosimilarity analyses in relation to the reference medicine, and the similarity of the product manufactured on the 5,000 L scale with that of the 500 L scale.

Nevertheless, although the registration process takes place in accordance with the adopted regulations and according to specific guidelines, the regulators (both the EMA and the FDA) have a number of tools at their disposal which provide them with considerable decision-making freedom and the possibility of individual adaptation of solutions to the needs that occur, in the regulator's assessment, in a given registration procedure. The process of registration and authorisation of a medicine is multi-stage, which the final position of the regulator being developed throughout the whole process. Even if the regulator provides guidance and guidelines on the shape and scope of the data currently required, it cannot be ruled out that additional requirements for product approval may arise in the future as part of the registration procedure for MabionCD20 manufactured on 5000L scale or independently of that procedure.

As part of its research, analysis, and planning, the Company consults on an ongoing basis with external regulatory, clinical, and analytical experts on the strategy and documentation required for registration.

### **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.

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.

### **Risks related to the employment level at the Company**

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. This is particularly relevant in relation to the Company's agreement for the production of vaccine antigen for Novavax, Inc. 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 the objectives of the Company's business strategy. The Company's performance will also depend, in part, on the future employment level, and on the Company's 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.

In order to counteract the above risk, the Company's Management Board pursues an active HR policy aimed at employing and 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. The Company's Management Board systematically monitors trends on the remuneration market, including the subject of non-wage benefits, implementing new solutions at Mabion on an ongoing basis.

In addition, the Company implements activities aimed at supporting the professional development of its employees, e.g. through their participation in internal and external training, support in undertaking doctoral studies, etc.

### 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 advisers 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 recombinant 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 thousand
  - Value of co-financing (contribution from the EU Funds): PLN 27,094 thousand
  - Project implementation period: 01.11.2016 – 29.12.2020.

In accordance with the assumed deadline (December 2020), the Company has completed all the tasks provided for in the aforementioned project and has submitted the relevant documentation to the NCBR. On 3 August 2021, the Company signed an annex to the co-financing agreement with the NCBR, providing for final settlement of both the project value (PLN 53,896 thousand) as well as the value of obtained co-financing (PLN 26,948 thousand). At present, the Company is anticipating the formal closure of the project, which includes the acceptance of the Final Report and the final payment request.

- > *"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 thousand
- Value of co-financing (contribution from the EU Funds): PLN 28,354 thousand
- Project implementation period: 01.08.2017 – 30.07.2022.

On 23 February 2022, a decision was taken to abandon further implementation of the Project due to the fact that, in the opinion of the Management Board, its further implementation is unjustified. Consequently, a final application for payment and Final Information on the Project implementation were submitted to the NCBR. The documents are currently being evaluated by the NCBR.

- > *"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 thousand
  - Value of European Regional Development Fund co-financing: PLN 63,247 thousand
  - Project implementation period: 20.01.2018 – 31.12.2021

The objective of the Project is to develop the Company's research and development facilities by preparing the necessary infrastructure: the building of the Research and Development Centre, and the purchase of research equipment to conduct research on innovative medicines. Currently, the Company is in the process of implementing the project in question, however, due to the planned extension of the scope of the project to include an additional R&D component, and the issues related to the financing of its own contribution, the project work is delayed with respect to the originally assumed schedule. Accordingly, the Company requested the Managing Authority (MA) to amend the project and extend its implementation until the end of 2023. On 19 April 2022, the Company concluded an annex to the Project funding agreement with the Ministry of Development Funds and Regional Policy. According to the annex, the period of expenditure eligibility for the Project was extended until 31 December 2023 (previously 31 December 2021). Moreover, due to the inclusion of an additional research area in the Company's activity, i.e. vaccine therapies, the objective and material and financial scope of the Project were changed to the extent enabling the introduction of the aforementioned research area to the Project.

- > *"Improvement of competitiveness of Mabion S.A. through implementation of a process innovation"*
  - Value of the project: PLN 1,082,400.00
  - Value of European Regional Development Fund co-financing: PLN 396,000.00
  - Project implementation period: 01.07.2021 – 01.11.2022.

On 14 December 2021, the Company entered into a co-financing agreement with the Entrepreneur Service Center in Łódź, which is an Intermediate Body under the Regional Operational Programme of the Łódzkie Voivodeship 2014–2020, for the implementation of the project in question. The main objective of the project is to deploy an innovation process at Mabion S.A., i.e. an innovation on the scale of the Łódzkie Voivodeship (and applied on a national scale for more than 3 years), consisting of the introduction of a validated method for determining critical parameters of a medicinal substance – the purity of

monoclonal antibodies, working in accordance with the requirements of the GMP-compliant environment, to regular use. The main objective of the project will be possible thanks to the use of a high-performance and reproducible electrophoretic method which will make it possible to analyse a larger number of samples compared to the traditional and often labour-intensive SDS-PAGE method.

All the above indicated co-financing agreements stipulate in detail the dates and scope of tasks which may be subsidized. There is a risk that if the Company fails to complete the planned work within the deadlines set by the Managing Institution/Intermediary Body, uses all or part of the subsidy contrary to its intended purpose or without complying with the applicable procedures, collects all or part of the subsidy in an undue or excessive manner, it will be obliged to reimburse part or the full amount of the subsidy plus interest. There is also a risk that the Managing Institution/Intermediary 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

In 2021, the Company generated proceeds from the implementation of agreements in force, and its operations were financed with funds raised from the issues of shares, shareholder borrowings, available lines of credit, public funding.

In January 2021, Mabion adopted a new long-term strategy for financing its operations. At the time of its adoption, the strategy included the overall capital needs of the Company that should be satisfied to carry out all activities necessary to complete the registration of MabionCD20 with the EMA and to commence sales of MabionCD20, which will allow the Company to generate positive cash flows. The adopted financial strategy consists of parallel processes: commencement of activities aimed at acquiring a strategic investor and two issues of the Company's shares. At the same time, as a result of the successful completion of the first issue (U shares) and the conclusion of the framework agreement with Novavax, Inc. for the COVID-19 vaccine programme in March 2021, the Company cancelled the Extraordinary General Meeting which was to pass a resolution on the second of the above-mentioned issues of the Company's shares.

The Company's management monitors current forecasts for the Company's liquid assets and liabilities based on projected cash flows.

The risk related to limited access to funding due to the global liquidity situation, the Company's financial position (with contract manufacturing taken into account), and the assessment of the potential for registration of the key medicine, MabionCD20, cannot be excluded. Here, it is important to highlight the risks associated with the lack of change in the terms and conditions of the existing financing agreements and the inability to use this financing, or the suspension of financing currently in use. In particular, the current situation resulting from the pandemic and the warfare in Ukraine, and their impact on capital markets should be borne in mind, as this may cause significant restrictions on sources of funding, including equity funding from share issues.

The Company is currently working on updating the Company's strategy for the next years, which may result in a change to the financing strategy adopted in January 2021.

### **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 (LSEZ). 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 LSEZ may become unfavourable and increase tax burden.

## **4.5 Risk management system**

The Management Board of the Company manages risk on a constant basis in all significant areas of the Company's operations. Due to the dynamic situation on the pharmaceutical market, the Company's Management Board monitors, audits and updates potential risks on an ongoing basis, through:

- > anticipating and identifying risk groups, in-depth understanding of the type of risk to enable its active prevention;
- > constant monitoring and controlling of existing risks;
- > avoiding risks – abandoning activities which expose the Company to high risk;
- > taking preventive actions – developing operating plans and appropriate procedures which may be immediately implemented in the event of a potential risk occurrence;
- > maintaining risk within predetermined limits or implementing plans to minimize the risks;
- > reporting on the risks identified and their nature.

## 5 STATEMENT ON CORPORATE GOVERNANCE

### 5.1 Applied corporate principles

In the period from 30 June 2021, the Company was governed by corporate governance principles specified in the document "Best Practices for GPW Listed Companies 2016" adopted by the Board of the GPW by a resolution of 13 October 2015, which entered into force on 1 January 2016 (the document is available on the website of the Warsaw Stock Exchange at the address: <https://www.gpw.pl/dobre-praktyki-spolpek-regulacje>).

On 29 March 2021, the WSE Board, by Resolution No. 13/1834/2021, adopted new corporate governance principles for companies listed on the WSE Main Market - "Best Practices for WSE Listed Companies 2021". Best Practices 2021 came into force on 1 July 2021.

As a result, as of 1 July 2021, the Company is subject to the principles of corporate governance set out in the "Best Practices of WSE Listed Companies 2021" (the document is available on the Warsaw Stock Exchange's website dedicated to corporate governance matters at: <https://www.gpw.pl/dobre-praktyki2021>).

### 5.2 Corporate governance principles and recommendations not applied

#### "Best Practices of WSE Listed Companies 2016"

Until 30 June 2021, the Company did not apply seven DPSN 2016 detailed principles: II.Z.2., III.Z.2., III.Z.3., III.Z.4., V.Z.6., VI.Z.1., VI.Z.2., and, in addition, the Company was not covered by 3 recommendations: I.R.2., IV.R.2., IV.R.3. as well as two detailed principles: I.Z.1.10., IV.Z.2.

Explanations relating to recommendations or detailed DPSN 2016 principles not applied or not applicable:

I.R.2. Where a company pursues sponsorship, charity or other similar activities, it should publish information about the relevant policy in its annual activity report.

This principle did not apply to the Company.

**The Company's comment:** The Company did not have a separate policy of sponsorship and charity or other similar activities. The Company was only able to engage in thematic biotech conferences to a limited extent as a partner or sponsor, having first analysed the compliance with the adopted communication strategy and adequacy of the costs incurred.

I.Z.1.10. A company operates a corporate website and publishes on it, in a legible form and in a separate section, in addition to information required under the legislation: financial projections, if the company has decided to publish them, published at least in the last 5 years, including information about the degree of their implementation.

This principle did not apply to the Company.

**The Company's comment:** The Company did not publish financial forecasts.

II.Z.2. A company's management board members may sit on the management board or supervisory board of companies other than members of its group subject to the approval of the supervisory board.

The principle was not applied.

**The Company's comment:** In accordance with the Company's Remuneration Policy for Members of the Management and Supervisory Boards of Mabion S.A., Members of the Company's Management Board must obtain the approval of the Supervisory Board to act as Members of the Supervisory Board in third-party companies. On the other hand, the Company's internal regulations and agreements with Members of the Management Board did not impose such restrictions in the case of serving as a member of the Management Board in third-party companies.

III.Z.2. Subject to principle III.Z.3, persons responsible for risk management, internal audit and compliance should report directly to the president or another member of the management board and should be allowed to report directly to the supervisory board or the audit committee.

The principle was not applied.

**The Company's comment:** There is no isolated unit responsible for risk management, internal audit and compliance in the Company's structure. Therefore, there was no person responsible for managing those areas, reporting directly to the President or another Management Board Member and also provided with the possibility of reporting directly to the Supervisory Board or the Audit Committee.

III.Z.3. The independence rules defined in the generally accepted international standards of the professional internal audit practice apply to the person heading the internal audit function and other persons responsible for such tasks.

The principle was not applied.

**The Company's comment:** There is no isolated unit responsible for internal audit in the Company's structure. Therefore, no one managed the internal audit function and no other people are responsible for the function to whom the independence principles specified in generally acceptable international professional internal audit practice standards could have applied.

III.Z.4. The person responsible for internal audit (if the function is separated in the company) and the management board

should report to the supervisory board at least once a year with their assessment of the efficiency of the systems and functions referred to in principle III.Z.1 and table a relevant report.

The principle was not applied.

**The Company's comment:** There is no isolated unit responsible for internal audit in the Company's structure. Therefore, there was no one managing the internal audit function and no other people were responsible for the internal audit function. The Company's Management Board presented to the Supervisory Board its own assessment of the efficiency of the systems and functions referred to in principle III.Z.1 and submits a relevant report.

IV.R.2. If justified by the structure of shareholders or expectations of shareholders notified to the company, and if the company is in a position to provide the technical infrastructure necessary for a general meeting to proceed efficiently using electronic means of communication, the company should enable its shareholders to participate in a general meeting using such means, in particular through:

- 1) real-life broadcast of the general meeting,
- 2) real-time bilateral communication where shareholders may take the floor during a general meeting from a location other than the general meeting,
- 3) exercise of the right to vote during a general meeting either in person or through a plenipotentiary.

This principle did not apply to the Company.

**The Company's comment:** Applying the adequacy principle to the Company's structure of shareholders, the Company did not enable its shareholders to participate in the General Meeting using means of electronic communication.

IV.R.3. Where securities issued by a company are traded in different countries (or in different markets) and in different legal systems, the company should strive to ensure that corporate events related to the acquisition of rights by shareholders take place on the same dates in all the countries where such securities are traded.

This principle did not apply to the Company.

**The Company's comment:** Securities issued by the Company have been and are only traded in Poland.

IV.Z.2. If justified by the structure of shareholders, companies should ensure publicly available real-time broadcasts of general meetings.

This principle did not apply to the Company.

**The Company's comment:** Applying the adequacy principle to the Company's structure of shareholders, the Company did not enable the shareholders to participate in publicly available broadcasts of the General Meeting in real-time.

V.Z.6. In its internal regulations, the company should define the criteria and circumstances under which a conflict of interest may arise in the company, as well as the rules of conduct where a conflict of interest has arisen or may arise. The company's internal regulations should, among other things, provide for ways of preventing, identifying and resolving conflicts of interest, as well as rules for excluding members of the management board or the supervisory board from participation in reviewing matters subject to a conflict of interest which has arisen or may arise.

The principle was not applied.

**The Company's comment:** The Company had no internal regulations defined in principle V.Z.6, which would determine the criteria and circumstances under which a conflict of interest may arise in the company, as well as rules of conduct where a conflict of interest has arisen or may arise, apart from indicating in the Supervisory Board Rules of Procedure the obligation of a member of the Supervisory Board to inform other members of the Supervisory Board and to refrain from voting on issues where a conflict of interests may arise.

VI.Z.1. Incentive schemes should be constructed in a way necessary among other things to tie the level of remuneration of members of the company's management board and key managers to the actual long-term financial standing of the company and long-term shareholder value creation as well as the company's stability.

The principle was not applied.

**The Company's comment:** The incentive scheme for Members of the Management Board of the Company and its key employees does not make the right to take up and exercise the rights from A and B series subscription warrants dependent on the parameters indicated in principle VI.Z.1., and therefore this principle was not applied by the Company. The rights to take up subscription warrants as part of the incentive scheme may be granted to eligible persons, i.e. persons of key importance for the Company indicated by the Supervisory Board, in the quantity indicated in a resolution of the Supervisory Board. The right to take up and exercise the rights attached to A series subscription warrants shall arise on condition that, among other things, the market objective of increasing the Company's share price on the Warsaw Stock Exchange is achieved, and for B series subscription warrants – regardless of whether the above objective is achieved.

VI.Z.2. To tie the remuneration of members of the management board and key managers to the company's long-term business and financial goals, the period between the allocation of options or other instruments linked to the company's shares under the incentive scheme and their exercisability should be no less than two years.

The principle was not applied.

**The Company's comment:** The Rules and Regulations of the Incentive Scheme for 2018-2021 of Mabion S.A. do not provide

for a minimum two-year period between the granting of the aforementioned financial instruments and the possibility of their realisation, therefore the above principle was not applied in the Company. In accordance with the Rules and Regulations of the Incentive Scheme for 2018-2021 of Mabion S.A., the exercise of rights carried by A and B series subscription warrants by an eligible person and the acquisition of R and S series shares of the Company requires submitting to the Company a declaration of commitment not to sell R and S series shares within one or three years, respectively, from submitting the declaration on taking up the shares.

### “Best Practices of WSE Listed Companies 2021”

In the period from 1 July 2021, the Company did not apply ten DPSN 2021 principles: 1.4., 2.1., 2.2., 3.3., 4.1., 4.8., 4.9.1., 6.2., 6.3., 6.4., and, in addition, the Company was not affected by the 2 DPSN 2021 principles: 3.2 and 3.7.

Explanations relating to DPSN 2021 principles not applied or not applicable:

1.4. To ensure quality communications with stakeholders, as a part of the business strategy, companies publish on their website information concerning the framework of the strategy, measurable goals, including in particular long-term goals, planned activities and their status, defined by measures, both financial and non-financial.

The principle is not applied.

**The Company's comment:** The Company's business strategy does not specify all the categories of information listed in principle 1.4. The Company will incorporate the criteria of principle 1.4 in its next business strategy and will publish them on the Company's website at that time.

2.1. Companies should have in place a diversity policy applicable to the management board and the supervisory board, approved by the supervisory board and the general meeting, respectively. The diversity policy defines diversity goals and criteria, among others including gender, education, expertise, age, professional experience, and specifies the target dates and the monitoring systems for such goals. With regard to gender diversity of corporate bodies, the participation of the minority group in each body should be at least 30%.

The principle is not applied.

**The Company's comment:** The Company does not have a diversity policy. However, at the stage of selection of the Management Board and the Supervisory Board, all applications are considered on the same basis, irrespective of gender, age, worldview, etc., and therefore there is no discrimination or unequal treatment of applications due to the above characteristics.

2.2. Decisions to elect members of the management board or the supervisory board of companies should ensure that the composition of those bodies is diverse by appointing persons

ensuring diversity, among others in order to achieve the target minimum participation of the minority group of at least 30% according to the goals of the established diversity policy referred to in principle 2.1.

The principle is not applied.

**The Company's comment:** The composition of the Company's bodies does not meet the diversity criteria indicated in principle 2.1. and 2.2. However, at the stage of selection of the Management Board and the Supervisory Board, all applications are considered on the same basis, irrespective of gender, age, worldview, etc., and therefore there is no discrimination or unequal treatment of applications due to the above characteristics.

3.2. Companies' organisation includes units responsible for the tasks of individual systems and functions unless it is not reasonable due to the size of the company or the type of its activity.

This principle does not apply to the Company.

**The Company's comment:** This principle does not apply to the Company due to the nature of the Company's business (research and development activities, and from Q4 2021 contract development and manufacturing services for the Company's first customer - Novavax, Inc.); development stage. Once the actual scale of the Company's business and its nature support a separation of units responsible for particular systems, the Company's Management Board will take action in this respect.

3.3. Companies participating in the WIG20, mWIG40 or sWIG80 index appoint an internal auditor to head the internal audit function in compliance with generally accepted international standards for the professional practice of internal auditing. In other companies which do not appoint an internal auditor who meets such requirements, the audit committee (or the supervisory board if it performs the functions of the audit committee) assesses on an annual basis whether such person should be appointed.

The principle is not applied.

**The Company's comment:** At present, the Company does not have an internal auditor – the function of internal audit is exercised by the Management Board of the Company. The Company's Management Board is keeping an eye on the possible appointment of an internal auditor and once the actual scale of the Company's business and its nature justify the existence of an internal auditor in the Company, the Company's Management Board will take steps to appoint such a person. Independently of the Company's Management Board, the Audit Committee assesses on an annual basis whether there is a need to appoint such a person.

3.7. Principles 3.4 to 3.6 apply also to members of the company's group which are material to its activity if they appoint persons to perform such tasks.

This principle does not apply to the Company.

**The Company's comment:** The Company does not belong to a capital group.

4.1. Companies should enable their shareholders to participate in a general meeting by means of electronic communication (e-meeting) if justified by the expectations of shareholders notified to the company, provided that the company is in a position to provide the technical infrastructure necessary for such general meeting to proceed.

The principle is not applied.

**The Company's comment:** The Company does not apply this principle in view of the lack of expectations reported to the Company by shareholders in this respect and the excessive legal risks, which, in the Company's opinion, arise from the organisation of the e-meeting.

4.8. Draft resolutions of the general meeting on matters put on the agenda of the general meeting should be tabled by shareholders no later than three days before the general meeting.

The principle is not applied.

**The Company's comment:** Bearing in mind the interests of the shareholders, in particular individual shareholders, the Company does not impose any restrictions on the possibility of proposing draft resolutions for the General Meeting beyond those provided for by law.

4.9.1. If the general meeting is to appoint members of the supervisory board or members of the supervisory board for a new term of office, candidates for members of the supervisory board should be nominated with a notice necessary for shareholders present at the general meeting to make an informed decision and in any case no later than three days before the general meeting; the names of candidates and all related documents should be immediately published on the company's website;

The principle is not applied.

**The Company's comment:** The Company does not apply any restrictions on the possibility to propose candidates for the Supervisory Board before the General Meeting. The candidate proposals are posted on the Company's website as soon as they are received, ensuring that shareholders have equal access to information in this respect.

6.2. Incentive schemes should be constructed in a way necessary among others to tie the level of remuneration of members of the company's management board and key managers to the actual long-term standing of the company measured by its financial and non-financial results as well as long-term shareholder value creation, sustainable development and the company's stability.

The principle is not applied.

**The Company's comment:** The existing incentive scheme for the Company's Management Board Members and key employees was established in 2018, with a duration defined for 4 years, i.e. for financial years 2018–2021. The scheme does not meet all the criteria set out in principle 6.2. The Company will incorporate these criteria into the design of its next incentive scheme.

6.3. If companies' incentive schemes include a stock option programme for managers, the implementation of the stock option programme should depend on the beneficiaries' achievement, over a period of at least three years, of pre-defined, realistic financial and non-financial targets and sustainable development goals adequate to the company, and the share price or option exercise price for the beneficiaries cannot differ from the value of the shares at the time when such programme was approved.

The principle is not applied.

**The Company's comment:** The existing incentive scheme for the Company's Management Board Members and key employees was established in 2018, with a duration defined for 4 years, i.e. for financial years 2018–2021. The scheme does not meet all the criteria set out in principle 6.3. The Company will incorporate these criteria into the design of its next incentive scheme.

6.4. As the supervisory board performs its responsibilities on a continuous basis, the remuneration of supervisory board members cannot depend on the number of meetings held. The remuneration of members of committees, in particular the audit committee, should take into account additional workload on the committee.

The principle is not applied.

**The Company's comment:** The current system of remuneration for members of the Company's Supervisory Board does not correspond to the guidelines of principle 6.4. The remuneration system results from the Policy on Remuneration of the Members of the Company's Management Board and Supervisory Board adopted by the Company's General Meeting.

## 6 INFORMATION ON SHARES AND SHAREHOLDING STRUCTURE OF MABION S.A.

### 6.1 The Company's share capital

As of 31 December 2021, the Company's share capital amounted to PLN 1,616,132.60 was divided into 16,161,326 shares with a nominal value of PLN 0.10 each, including:

- > 450,000 A series registered preference shares,
- > 450,000 B series registered preference shares,
- > 450,000 C series registered preference shares,
- > 450,000 D series ordinary bearer shares,
- > 100,000 E series registered preference shares,
- > 100,000 F series registered preference shares,
- > 20,000 G series registered preference shares,
- > 2,980,000 H series ordinary bearer shares,
- > 1,900,000 I series ordinary bearer shares,
- > 2,600,000 J series ordinary bearer shares,
- > 790,000 K series ordinary bearer shares,
- > 510,000 L series ordinary bearer shares,
- > 360,000 M series ordinary bearer shares,
- > 340,000 N series ordinary bearer shares,
- > 300,000 O series ordinary bearer shares,
- > 1,920,772 P series ordinary bearer shares,
- > 10,000 S series ordinary bearer shares,
- > 2,430,554 U series ordinary bearer shares.

Registered shares of A, B, C, E, F and G series are privileged in such a way that each of them entitles to two votes at the General Meeting, and accordingly the total number of votes attached to all issued Company's shares was 17,731,326.

In the financial year 2021 and up to the date of this report, there have been changes to the amount and structure of the Company's share capital relating to the issue of U shares and issues of S shares under the incentive scheme, as further described in this report in section 3.7. Issues of securities.

As of the date of submission of this report, the Company's share capital amounts to PLN 1,616,182.60 and is divided into 16,161,826 shares with a nominal value of PLN 0.10 each, including:

- > 450,000 A series registered preference shares,
- > 450,000 B series registered preference shares,
- > 450,000 C series registered preference shares,
- > 450,000 D series ordinary bearer shares,
- > 100,000 E series registered preference shares,
- > 100,000 F series registered preference shares,
- > 20,000 G series registered preference shares,
- > 2,980,000 H series ordinary bearer shares,
- > 1,900,000 I series ordinary bearer shares,
- > 2,600,000 J series ordinary bearer shares,
- > 790,000 K series ordinary bearer shares,
- > 510,000 L series ordinary bearer shares,
- > 360,000 M series ordinary bearer shares,
- > 340,000 N series ordinary bearer shares,
- > 300,000 O series ordinary bearer shares,
- > 1,920,772 P series ordinary bearer shares,
- > 10,500 S series ordinary bearer shares,
- > 2,430,554 U series ordinary bearer shares.

Registered shares of A, B, C, E, F and G series are privileged in such a way that each of them entitles to two votes at the General Meeting. The total number of votes resulting from all issued shares of the Company is 17,731,826 votes.

### 6.2 Shareholders of the Company holding significant blocks of shares

To the best knowledge of the Management Board of the Company, as at the date of approval of this report, i.e. 21 April 2022, the following shareholders held at least 5% of votes at the General Meeting of the Company.

**Table 13: Shareholding structure.**

| No. | Shareholder                           | Number of shares  | Number of votes   | Participation in the share capital | Share in the total number of votes |
|-----|---------------------------------------|-------------------|-------------------|------------------------------------|------------------------------------|
| 1.  | Twiti Investments Limited             | 2,674,617         | 3,268,917         | 16.55%                             | 18.44%                             |
| 2.  | Maciej Wiczorek through*:             | 1,717,485         | 2,210,335         | 10.63%                             | 12.47%                             |
|     | Glatton Sp. z o.o.                    | 1,097,135         | 1,097,135         | 6.79%                              | 6.19%                              |
|     | Celon Pharma S.A.                     | 620,350           | 1,113,200         | 3.84%                              | 6.28%                              |
| 3.  | Polfarmex S.A.                        | 1,474,346         | 1,957,196         | 9.12%                              | 11.04%                             |
| 4.  | Funds managed by Investors TFI S.A.** | 1,502,649         | 1,502,649         | 9.30%                              | 8.47%                              |
| 5.  | Other                                 | 8,792,229         | 8,792,229         | 54.40%                             | 49.59%                             |
|     | <b>Total</b>                          | <b>16,161,826</b> | <b>17,731,826</b> | <b>100%</b>                        | <b>100%</b>                        |

\* Mr Maciej Wiczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 58.84% of the share capital of Celon Pharma S.A. and 68.20% of the total number of votes in Celon Pharma S.A.

\*\* Based on the list of shareholders present at the Ordinary General Meeting of Mabion S.A. on 15 June 2020 and agreements on taking up the U shares of the Company concluded on 15 March 2021.

### 6.3 Ownership of the Company's shares and shares and stocks in related entities by managing and supervising persons

As at the date of publication of this report, i.e. 21 April 2022, Members of the Management Board and the Supervisory Board of Mabion S.A hold the quantities of the Company's shares listed below:

**Table 14. Number of shares held by managing and supervising persons as at the date of submitting the annual report (i.e. as at 21 April 2022).**

| Management Board      |  |
|-----------------------|--|
| Krzysztof Kaczmarczyk | holds directly 7,140 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.04% of the Company's share capital and entitling to 0.04% of votes at the General Meeting.  |
| Sławomir Jaros        | holds directly 5,295 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.03% of the Company's share capital and entitling to 0.03% of votes at the General Meeting.  |
| Adam Pietruszkiewicz  | holds directly 10,000 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.06% of the Company's share capital and entitling to 0.05% of votes at the General Meeting. |
| Grzegorz Grabowicz    | holds directly 700 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.004% of the Company's share capital and entitling to 0.004% of votes at the General Meeting.  |

As at the date of publication of this report, i.e. 21 April 2022, members of the Supervisory Board of Mabion S.A. do not hold any shares in the Company. Members of the Management Board and Supervisory Board of Mabion S.A. do not hold any shares in the Company's related entities.

### 6.4 Employee share ownership plan

By Resolution of the Ordinary General Meeting of the Company of 28 June 2018, an Incentive Scheme for the years 2018-2021 was adopted, addressed to persons of key importance for the Company indicated by the Supervisory Board (Eligible Persons), in the form of subscription warrants incorporating the right to acquire Company's shares within a conditional share capital increase up to the amount not higher than PLN 12,500. The objective of the Scheme was to ensure optimal conditions for the growth of the Company's financial results and long-term growth of the Company's value through continuous association of the persons participating in the Incentive Scheme with the Company and its objectives.

The Company does not have a separate control system for employee share programs. The decision on the form of exercising the rights is taken by the Supervisory Board of the Company after verification of the fulfilment of the criteria specified in the Incentive Scheme and on the basis of the recommendation of the Management Board. Detailed conditions for the Incentive Scheme are set out in the Incentive Scheme Rules and Regulations adopted by a Resolution of the Company's Supervisory Board. The Rules and Regulations are available at: <https://www.mabion.eu/dokumenty-korporacyjne/>.

The Incentive Scheme is implemented through the issue and allotment to the Eligible Persons of up to 114,000 A series registered subscription warrants and up to 11,000 B series registered subscription warrants entitling the holders to acquire

separately issued, within a conditional share capital increase, respectively, up to 125,000 R series ordinary bearer shares and 11,000 S series ordinary bearer shares of the Company. The subscription warrants are issued free of charge and are taken up by Eligible Persons in the quantity indicated for a specific year in a resolution of the Supervisory Board. Each A and B series subscription warrant entitles to subscribe, respectively for 1 R or 1 S series share. The issue price of shares for A series subscription warrants is PLN 91 per each R series share, and for B series subscription warrants, it is PLN 0.10 per each S series share. The rights attached to the subscription warrants may be exercised until 31 July 2022. R series shares and S series shares may be taken up only for cash contributions made in full before the shares are allotted. In addition, the Incentive Scheme allows for settlement in the form of an offer, extended by the Company to persons who have taken up the warrants, to purchase them against payment for the purpose of redemption. According to the Rules and Regulations of the Incentive Scheme, if the market goal is not met in a given year, subscription warrants of A series not granted for this reason may be granted together with warrants of series A for the year in which the market goal was met.

As regards the implementation of the Incentive Scheme for 2018, in February 2019 the Supervisory Board concluded that Eligible Persons are entitled to take up 28,500 A subscription warrants in total for 2018, while the market objective constituting one of the two conditions for the right to take up and exercise the rights attached to A series warrants to become applicable was not met. As regards B subscription warrants, the condition for the right to take up and exercise rights attached to B warrants was fulfilled, and thus the Supervisory Board granted the Eligible Persons the right to take up a total of 9,500 B series warrants for 2018. The above B series warrants were issued on 18 November 2019. On the same day, the Eligible Persons made statements on taking up the S series shares of

the Company to which they are entitled by exercising their rights under the warrants. 9,500 S shares were released (i.e. credited to the securities accounts) on 29 January 2020.

As regards the implementation of the Incentive Scheme for 2019, in February 2019 the Supervisory Board established that Eligible Persons are entitled to take up 28,500 A subscription warrants in total for 2019, and subsequently, in January 2020, it concluded following a review that the market objective in relation to the A warrants had not been met. As regards B subscription warrants, the condition for the right to take up and exercise rights attached to B warrants was fulfilled, and thus the Supervisory Board granted the Eligible Persons, in January 2020, the right to take up a total of 500 B subscription warrants for 2019. The above B series warrants were issued on 23 June 2020. On the same day, the Eligible Persons made statements on taking up the S series shares of the Company to which they are entitled by exercising their rights under the warrants. 500 S shares were released (i.e. credited to the securities accounts) on 18 February 2021.

As regards the implementation of the Incentive Scheme for 2020, in February 2020 the Supervisory Board established that Eligible Persons are entitled to take up 28,500 A subscription warrants in total for 2020, and subsequently, in January 2021, it concluded following a review that the market objective in relation to the A warrants had not been met. As regards B subscription warrants, the condition for the right to take up and exercise rights attached to B warrants was fulfilled, and thus the Supervisory Board granted the Eligible Persons, in January 2021, the right to take up a total of 500 B subscription warrants for 2020. The B series warrants were taken up by the Eligible Persons on 2 July 2021. Subsequently, by 15 December 2021, the Eligible Persons were submitting statements on taking up the S series shares of the Company to which they are entitled by exercising their rights under the warrants. 500 S shares were

released (i.e. credited to the securities accounts) on 28 January 2022 (an event after the balance-sheet date).

As regards the implementation of the Incentive Scheme for 2021, in April 2021 the Supervisory Board determined that the Eligible Persons are entitled to take up in total a maximum of 28,215 A series warrants for 2021 and then in January 2022, the Supervisory Board adjusted the number of A series warrants for 2021 to 27,645 due to the fact that the seniority criterion was not met by two Eligible Persons, and concluded as a result of verification that the market target with respect to A series subscription warrants was also not met. As regards B subscription warrants, the condition for the right to take up and exercise rights attached to B warrants was fulfilled, and thus the Supervisory Board granted the Eligible Persons, in January 2022, the right to take up a total of 500 B subscription warrants for 2021, including 213 B series subscription warrants to which Mr Sławomir Jaros – Member of the Management Board of the Company – was entitled. By the date of publication of this report, the B series subscription warrants for 2021 were not taken up by the eligible persons.

## 6.5 Purchase of own shares

In 2021, the Company did not acquire or dispose of its own shares.

## 6.6 Holders of securities with special control rights

Registered shares of A, B, C, E, F and G series are privileged in such a way that each of them entitles to two votes at the General Meeting. No other securities giving special control rights exist in the Company.

**Table 15. Holders of registered shares of Mabion S.A.**

| Series | Number of shares | Shareholder               | Number of series shares held by the shareholder as at 31 December 2021 |
|--------|------------------|---------------------------|--|
| A      | 450,000          | Celon Pharma S.A.         | 450,000  |
| B      | 450,000          | Polfarmex S.A.            | 450,000  |
| C      | 450,000          | Twiti Investments Limited | 450,000  |
| E      | 100,000          | Celon Pharma S.A.         | 32,850   |
|        |                  | Polfarmex S.A.            | 32,850   |
|        |                  | Twiti Investments Limited | 34,300   |
| F      | 100,000          | Celon Pharma S.A.         | 10,000   |
|        |                  | Twiti Investments Limited | 90,000   |
| G      | 20,000           | Twiti Investments Limited | 20,000   |

## **6.7 Restrictions on the exercise of voting rights**

The Company's Articles of Association do not provide for any restrictions as to the exercise of voting rights or any provisions according to which, in cooperation with the Company, capital rights attached to securities would be separated from the possession of securities. Restrictions on the exercise of voting rights may result, in the case of the Company, only from the generally applicable provisions of law.

## **6.8 Restrictions on the transfer of ownership of securities**

The Company's Articles of Association do not provide for restrictions on trading in the Company's ordinary bearer shares. A, B, C, E, F and G series shares of the Company are registered shares – the shareholders entitled under registered shares have the priority right and the pre-emption right to purchase registered shares intended for sale.

## **6.9 Agreements which may result in changes in the proportions of shares held by existing shareholders and bondholders**

To the best knowledge of the Company's Management Board, there are no arrangements which, if implemented in the future, could cause changes in the way the Company is controlled. The Articles of Association of the Company contain provisions related to the rules of disposal of privileged registered shares of A, B, C, E, F and G series (pre-emption right and priority right of purchase of registered shares for other owners of registered shares of the Company), on the basis of which a registered share can be disposed of to people other than shareholders entitled under the registered shares only on the condition that those entitled from the pre-emption right and from the priority right of purchase will not execute this right.

## 7 COMPANY'S BODIES

### 7.1 The Management Board

#### 7.1.1 Members of the Management Board, its changes and rules of appointing Members of the Management Board

The Management Board of Mabion S.A. consists of three to seven members. Members of the Management Board are appointed by the Supervisory Board for a joint term of office of 5 years. The first joint term of office of Members of the Management Board expires on the date of the Company's General Meeting approving the financial statements for the financial year 2021. Each Member of the Management Board may be suspended or dismissed by the Supervisory Board or the General Meeting.

As of 1 January 2021, the composition of the Company's Management Board was as follows:

- > Mr. Dirk Kreder – President of the Management Board,
- > Mr. Sławomir Jaros – Member of the Management Board,
- > Mr. Grzegorz Grabowicz – Member of the Management Board.

On 25 January 2021, the Company's Supervisory Board adopted resolution to delegate a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to act as Member of the Management Board of the Company. The period of delegation specified in the Supervisory Board's resolution was to last from 25 January 2021 to 25 April 2021. The Company informed about the event in Current Report no. 2/2021 of 25 January 2021.

On 3 March 2021, Mr. Adam Pietruszkiewicz tendered his resignation from the Company's Supervisory Board. At the same time, on 3 March 2021 the Supervisory Board of Mabion S.A. adopted a resolution to appoint Mr Adam Pietruszkiewicz as Member of the Management Board of the Company as of 3 March 2021. The Company informed about the event in Current Report no. 18/2021 of 3 March 2021.

On 13 May 2021, the Company's Supervisory Board adopted a resolution to dismiss Mr. Dirk Kreder from the position of President of the Company's Management Board. The resolution on the dismissal entered into force upon its adoption. At the same time, on 13 May 2021, Mr. Krzysztof Kaczmarczyk tendered his resignation from the position of Chairman and Member of the Supervisory Board of the Company, and the Company's Supervisory Board adopted a resolution to appoint Mr. Krzysztof Kaczmarczyk as President of the Management Board of the first joint term of office as of 14 May 2021. The Company informed about the event in Current Report no. 36/2021 of 13 May 2021.

As at 31 September 2021 and as the date of submitting this report, the composition of Mabion S.A.'s Management Board is as follows:

- > Mr. Krzysztof Kaczmarczyk – President of the Management Board,
- > Mr. Sławomir Jaros – Member of the Management Board,
- > Mr. Grzegorz Grabowicz – Member of the Management Board,
- > Mr. Adam Pietruszkiewicz – Member of the Management Board.

The distribution of key areas/tasks and responsibilities within the Company at the Management Board level is as follows:

- > Krzysztof Kaczmarczyk - President of the Management Board, CEO – manages the work of the Management Board and coordinates the work of other Management Board Members. The main duties of the President of the Management Board include the development of the Company's business strategy and investment policy and the acquisition of business and strategic partners for the Company. The President of the Management Board is also responsible for risk management, disclosure obligations and investor relations, and for overseeing the proper performance of the Company's operating and financial activities.
- > Sławomir Jaros – Member of the Management Board, COO and CSO – as a Member of the Management Board, he is responsible for supervising, managing, and integrating the following areas in the Company: medicine design, technology development and analytics, clinical trials area, and occupational safety and pharmaceutical risk control. His duties include cooperation with external partners in the field of technology, science and commerce, and the development of strategies for new products and technologies. He is also responsible for the area of manufacturing, quality control and quality assurance, and for implementing technological and analytical processes in the pharmaceutical environment, for scaling up processes, process quality, time and cost optimisation, as well as for supervising manufacturing processes and operational management.
- > Adam Pietruszkiewicz – Member of the Management Board, CCO – on the Management Board, Mr. Adam Pietruszkiewicz is responsible for business development of the Company in the CDMO area, for strategic projects, as well as for acquiring new partners - including cooperation with Novavax, Inc. (managing the vaccine antigen manufacturing project).
- > Grzegorz Grabowicz - Member of the Management Board, CFO - he is responsible for supervising and managing the Company's financial policy. His duties include raising of funds, negotiation of significant financial operations and business transactions of the Company, and development of the Company's financial plans, and its financial reporting.

### 7.1.2 Powers and description of the Management Board's activities

The Management Board exercises all rights to manage the Company with the exception of rights reserved by law or the Company's Articles of Association for decisions of the General Meeting and the Supervisory Board (§ 27 of the Company's Articles of Association). The right to take a decision on the issue or purchase of shares is vested in the General Assembly (§ 17 of

the Company's Articles of Association). Two Members of the Management Board acting jointly or one Member of the Management Board acting together with a proxy are authorised to make declarations of will on behalf of the Company. The Management Board is obliged to conduct the Company's affairs and manage its assets with due diligence required in business transactions, observe the law, provisions of the Company's Articles of Association and resolutions adopted by the General Meeting and the Supervisory Board.

### 7.1.3 Remuneration, bonuses and conditions of employment contracts of the Management Board Members

The table below presents the value of remuneration due and paid in 2021 to the Management Board Members for serving on the Company's Management Board.

**Table 16: Remuneration of Management Board Members.**

| Member of the Management Board | Gross fixed remuneration payable for 2021 | Gross additional remuneration payable for 2021 | Gross remuneration paid in 2021 |
|--------------------------------|---|--|---------------------------------|
| Adam Pietruszkiewicz           | PLN 472,903.23                            | PLN 1,156,800.00                               | PLN 1,640,670.00                |
| Krzysztof Kaczmarczyk          | PLN 535,705.60                            | PLN 809,760.00                                 | PLN 1,345,465.60                |
| Sławomir Jaros                 | PLN 545,236.80                            | PLN 462,720.00                                 | PLN 1,052,240.30                |
| Grzegorz Grabowicz             | PLN 550,368.80                            | PLN 462,720.00                                 | PLN 1,052,732.80                |
| Dirk Kreder                    | PLN 447,301.66                            | PLN 0.00                                       | PLN 447,301.66                  |

The Company does not have any subsidiaries, therefore the Members of the Management Board did not receive any remuneration from the Company's subsidiaries in 2021.

In 2021, additional remuneration was paid to the Members of the Management Board in relation to the signing of the agreement with Novavax, based on the additional agreements entered into between the Members of the Management Board and the Company (the figures are presented in the above table).

In 2018, the Company introduced an Incentive Scheme for persons of key importance to the Company, the principles of which are described in sections 6.4 and 8.1 of this Report. In accordance with the resolutions of the Company's Supervisory Board of the different years of the Scheme, the persons entitled to take up subscription warrants for different years in the period 2018–2020 include persons sitting on the Management Board of the Company in 2021:

- > Mr. Sławomir Jaros (Member of the Management Board) – for 2018: granted the right to take up a maximum of 5,644 A series warrants and granted and exercised 4,043 B series warrants; for 2019: granted the right to take up a maximum of 3,960 A series warrants and granted and exercised 213 B series warrants; for 2020: granted the right to take up a maximum of 6,099 A series warrants and granted and exercised 213 B series warrants; for 2021: granted the right to take up 213 B series warrants and a maximum of 6,099 A series warrants;
- > Mr. Grzegorz Grabowicz (Member of the Management Board) – for 2019: the right to take up a maximum of 3,300

A series warrants; for 2020: the right to take up a maximum of 5,101 A series warrants; for 2021: the right to take up a maximum of 5,101 A series warrants.

The A series warrants for the respective years in the period 2018–2021 were not granted due to non-fulfilment of the market target in these periods. The Eligible Persons have an immediate right to take up and exercise all rights attached to the Warrants granted as part of the Incentive Scheme, irrespective of reaching the Market Objective, if 50% of the total number of votes at the Company's General Meeting is reached or exceeded as a result of a call announced in accordance with the Act on Public Offering, Conditions Governing the Introduction of Financial Instruments to Organised Trading, and Public Companies of 29 July 2005 ("Act on Offering") by any entity acting directly or indirectly or under an agreement referred to in Article 87(1)(5) of the Act on Offering. The right under the Warrants to subscribe for Shares will be irrevocable and valid until 31 July 2022.

The B series subscription warrants for 2018, 2019 and 2020 have been granted and the rights thereunder have been exercised, resulting in an eligible person taking up the Company's S series shares to which they were entitled. On 18 November 2019, Mr. Sławomir Jaros took up, free of charge, 4,043 B series warrants and submitted a declaration on taking up 4,043 S series shares of the Company in the exercise of his rights carried by those warrants. Due to the fact that S series shares were issued as dematerialized shares and were subject to the application for admission to trading on the regulated market, the shares were released by recording them on securities accounts, which took place on 29 January 2020. Then,

on 23 June 2020, Mr. Sławomir Jaros took up, free of charge, 213 B series warrants for 2019 allocated to him and submitted a declaration on taking up 213 S series shares of the Company in the exercise of his rights carried by those warrants. The S shares were released similarly to the above by crediting the shares to the securities account, which took place on 18 February 2021. On 2 July 2021, Mr. Sławomir Jaros took up free of charge 213 B series warrants for 2020 and then made a statement on taking up 213 S series shares to which he was entitled under these warrants. The S shares were released by crediting them to the securities account, which occurred on 28 January 2022 (an event after the balance-sheet date).

B series subscription warrants for 2021 were granted under a resolution of the Supervisory Board of January 2022, but have not been issued as at the date of publication of this report.

### 7.1.4 Contracts with management members

No contracts have been entered into with members of management which would provide for compensation in the event of their resignation or removal from the position held without a valid reason, or in the event that the removal or lay-off is a result of a merger by acquisition.

## 7.2 Supervisory Board

### 7.2.1 Composition, changes in composition and principles of appointing Members of the Supervisory Board

The Supervisory Board of Mabion S.A. consists of five to nine members. Members of the Supervisory Board are elected for a joint term of office, which lasts 3 years. The second joint term of office of Members of the Supervisory Board expires on the date of the General Meeting of the Company approving the financial statements for financial year 2023. Members of the Supervisory Board are appointed and dismissed by the General Meeting.

As of 1 January 2021, the composition of the Company's Supervisory Board was as follows:

- > Krzysztof Kaczmarczyk – Chairman of the Supervisory Board (Independent Member);
- > Maciej Wieczorek – Deputy Chairman of the Supervisory Board;
- > Józef Banach – Member of the Supervisory Board (Independent Member);
- > Tadeusz Pietrucha – Member of the Supervisory Board (Independent Member);
- > Jacek Piotr Nowak – Member of the Supervisory Board;
- > David John James – Member of the Supervisory Board (Independent Member);
- > Robert Koński – Member of the Supervisory Board (Independent Member);
- > Adam Pietruszkiewicz – Member of the Supervisory Board.

On 25 January 2021, the Company's Supervisory Board adopted a resolution to delegate a Member of the Supervisory Board, Mr. Adam Pietruszkiewicz, to act as Member of the

Management Board of the Company. The period of delegation specified in the Supervisory Board's resolution was to last from 25 January 2021 to 25 April 2021. The Company informed about the event in Current Report no. 2/2021 of 25 January 2021.

On 9 February 2021, Mr. Tadeusz Pietrucha tendered his resignation as Member of the Company's Supervisory Board with effect as of 23 February 2021. The Company informed about the event in Current Report no. 7/2021 of 9 February 2021.

On 23 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the dismissal of Mr. Jacek Nowak from the Supervisory Board. Furthermore, on the same day, the Extraordinary General Meeting of the Company adopted resolutions on appointment of Mr. Wojciech Wośko and Mr. Sławomir Kościak to the Supervisory Board of the Company for the second joint term of office. The resolutions of the Extraordinary General Meeting of the Company came into force on the date of their adoption. The Company informed about the above events in Current Reports no. 12/2021 and 13/2021 of 23 February 2021.

On 3 March 2021, Mr. Adam Pietruszkiewicz tendered his resignation from the Company's Supervisory Board. At the same time, on 3 March 2021 the Supervisory Board of Mabion S.A. adopted a resolution to appoint Mr Adam Pietruszkiewicz as Member of the Management Board of the Company as of 3 March 2021. The Company informed about the event in Current Report no. 18/2021 of 3 March 2021.

On 13 May 2021, Mr. Krzysztof Kaczmarczyk tendered his resignation from the position of Chairman and Member of the Supervisory Board of the Company. At the same time, on 13 May 2021 the Supervisory Board of the Company adopted a resolution to appoint Mr. Krzysztof Kaczmarczyk as President of the Management Board for the first joint term of office in the Company as of 14 May 2021. Accordingly, on 13 May 2021, the Supervisory Board of the Company adopted a resolution to elect a Member of the Supervisory Board – Mr. Robert Koński as Chairman of the Supervisory Board of the Company. The Company informed about the event in Current Report no. 36/2021 of 13 May 2021.

On 22 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the appointment of Ms. Zofia Szewczuk as Member of the Supervisory Board for the second joint term of office. The resolution of the Company's Ordinary General Meeting came into force on the date of its adoption. The Company informed about the event in Current Reports no. 42/2021 and 43/2021 of 22 June 2021.

On 9 December 2021 Mr. Maciej Wieczorek tendered his resignation as a Member of the Supervisory Board of the Company as of 9 December 2021. The Company informed about the event in Current Report no. 65/2021 of 9 December 2021.

On 20 April 2022 (an event after the balance-sheet date), the Supervisory Board appointed Mr. Sławomir Kościak as Deputy Chairman of the Supervisory Board effective as of 20 April 2022.

As at 31 December 2021 and as at the date of publication of this report, the composition of the Company's Supervisory Board is as follows:

- > Robert Koński – Chairman of the Supervisory Board (Independent Member);
- > Sławomir Kościak – Member of the Supervisory Board as of 20 April 2022. Deputy Chairman of the Supervisory Board (Independent Member);
- > Józef Banach – Member of the Supervisory Board (Independent Member);
- > David John James – Member of the Supervisory Board (Independent Member);
- > Wojciech Wośko – Member of the Supervisory Board;
- > Zofia Szewczuk – Member of the Supervisory Board (Independent Member).

### 7.2.2 Powers of the Supervisory Board and description of its operations

Pursuant to § 22 of the Company's Articles of Association, the competences of the Supervisory Board of Mabion S.A. comprise actions reserved for it in the Commercial Companies Code, and moreover:

- a) passing resolutions on the purchase and sale of real estate, perpetual usufruct or share in real estate of a value exceeding PLN 250 thousand;
- b) appointing a statutory auditor to audit the Company's financial statements;
- c) appointing and dismissing the Company's Management Board Members;
- d) determining the amount of remuneration of Management Board Members;
- e) assessing Management Board motions as to distribution of profit or loss coverage;
- f) approval of the Rules of Procedure of the Management Board;
- g) giving opinions on the Company's multi-year strategic plans;
- h) passing the Rules of Procedure which determine the procedures of operation of the Supervisory Board;
- i) granting consent for the sale of Company's fixed assets the value of which exceeds 10% of the Company's equity;
- j) granting consent to pledging or granting usufruct in respect of registered shares
- k) granting consent for the Company to enter into a

significant agreement with a shareholder holding at least 5% of the total number of votes in the Company or an entity related to the Company, except for typical transactions concluded on arm's length as part of the Company's operating activity with entities belonging to the Company's capital group.

In addition to the activities listed above, the Supervisory Board should:

- a) once a year, prepare and present to the General Meeting a concise assessment of the internal control system and risk management system material to the Company;
- b) examine and give opinions on issues that are to be subject General Meeting's resolutions.

The Supervisory Board appoints the Audit Committee responsible for supervising the Company's financial affairs. The Audit Committee comprises at least three persons elected by the Supervisory Board from among its Members. The majority of the Members of the Audit Committee, including its Chairman, should be independent from the Company within the meaning of the Act of 11 May 2017 on statutory auditors, audit firms and public oversight. At least one member of the Audit Committee should have knowledge and skills in accounting or auditing of financial statements. At least one member of the Audit Committee should have knowledge and skills in the industry in which the Company operates.

Moreover, the Supervisory Board may appoint the Nomination and Remuneration Committee responsible for preparing assessments of candidates for Members of the Management Board and determining the remuneration principles and amounts of remuneration of Members of the Management Board. The Remuneration Committee comprises at least three Members appointed by the Supervisory Board from among its Members, where at least one of the Members of the Remuneration Committee should be an independent Member of the Supervisory Board within the meaning of the provisions of § 21 of the Company's Articles of Association.

### 7.2.3 Remuneration, bonuses and terms and conditions of employment contracts of Members of the Supervisory Board

The value of the remuneration due for performing functions on the Company's Supervisory Board and paid in respect of the year 2021 was as follows:

**Table 17. Remuneration of the Supervisory Board Members**

| <b>Supervisory Board Member</b> | <b>Remuneration due for 2021, gross*</b> | <b>Remuneration paid for 2021, gross**</b> |
|---------------------------------|--|--|
| Józef Banach                    | PLN 84,508.38                            | PLN 88,583.38                              |
| David James                     | PLN 101,000.00                           | PLN 109,000.00                             |
| Krzysztof Kaczmarczyk           | PLN 38,354.84                            | PLN 46,354.84                              |
| Robert Koński                   | PLN 84,377.42                            | PLN 88,452.42                              |
| Zofia Szewczuk                  | PLN 19,881.45                            | PLN 19,881.45                              |
| Jacek Nowak                     | PLN 7,262.86                             | PLN 11,322.86                              |
| Wojciech Wośko                  | PLN 36,266.67                            | PLN 36,266.67                              |
| Tadeusz Pietrucha               | PLN 1,000.00                             | PLN 1,000.00                               |
| Sławomir Kościak                | PLN 36,581.67                            | PLN 36,581.67                              |
| Adam Pietruszkiewicz            | PLN 4,096.77                             | PLN 5,903.22                               |
| Maciej Wieczorek                | PLN 48,851.29                            | PLN 52,911.29                              |

\* The amount stated above is inclusive of the remuneration due in respect of the year 2021 for performing the function of Member of the Supervisory Board.

\*\* The amount stated above is inclusive of the remuneration paid in the year 2021, with amounts due for 2020 included, paid as part of "remuneration transfer".

The Company does not have any subordinated entities, therefore, Members of the Supervisory Board did not receive any remuneration from the Company's subordinated entities in 2021.

In 2021, no bonuses, benefits or remuneration were paid out to Members of the Supervisory Board based on plans for bonus schemes or participation in profits. The Company's corporate regulations do not provide for the Members of the Supervisory Board to receive remuneration in the form of bonus schemes or participation in profits.

In 2021, no remuneration was paid to Members of the Supervisory Board in the form of share options. The Company's corporate regulations do not provide for the Members of the Supervisory Board to receive remuneration in the form of share options.

In 2021, the Company did not grant any in-kind benefits to Members of its Supervisory Board.

In accordance with the Resolution of the Extraordinary General Meeting of the Company dated 16 February (no. 26/II/2017), remunerations of the Supervisory Board Members were as follows:

- > Members of the Supervisory Board are entitled to remuneration of PLN 1,000 gross for participating in a Supervisory Board meeting;
- > Members of the Supervisory Board appointed to Supervisory Board Committees are entitled to monthly remuneration of PLN 4,000 gross.

The above-mentioned resolution on remunerating Members of the Supervisory Board became binding upon entering amendments to the Company's Articles of Association by the Registration Court in the Register of Entrepreneurs of the National Court Register on 23 March 2017, introduced by paragraph 10 of Resolution of the Extraordinary General Meeting No. 7/II/2017 dated 16 February 2017.

In 2021, Members of the Supervisory Board did not receive any remuneration for services provided in any capacity except for additional remuneration for membership of the Audit Committee and the Nomination and Remuneration Committee, which was shown in the table above and remuneration for participating in the Supervisory Board's meeting.

#### **7.2.4 Appointed Committees**

The Company has an Audit Committee and an Appointment and Remuneration Committee of the Supervisory Board.

##### **1. Audit Committee**

As of 1 January 2021, the composition of the Company's Audit Committee was as follows:

- > Mr. David John James – Chairman of the Audit Committee;
- > Mr. Jacek Piotr Nowak – Member of the Audit Committee;
- > Mr. Krzysztof Kaczmarczyk – Member of the Audit Committee;
- > Mr. Józef Banach – Member of the Audit Committee.

On 23 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the dismissal of Mr. Jacek Nowak from the Supervisory Board.

Accordingly, on 29 April 2021, pursuant to a resolution of the Company's Supervisory Board, Mr. Sławomir Kościak was appointed to the Audit Committee.

On 13 May 2021, Mr. Krzysztof Kaczmarczyk tendered his resignation from the position of Chairman and Member of the Supervisory Board of the Company.

Accordingly, on 13 May 2021, pursuant to a resolution of the Company's Supervisory Board, Mr. Robert Koński was appointed to the Audit Committee.

On 18 August 2021, pursuant to a resolution of the Company's Supervisory Board, Ms. Zofia Szewczuk was appointed to the Audit Committee of the Company's Supervisory Board.

As at 31 December 2021 and as at the date of this report, the composition of the Audit Committee is as follows:

- > Mr. David John James – Chairman of the Audit Committee,
- > Mr. Józef Banach – Member of the Audit Committee,
- > Mr. Robert Koński – Member of the Audit Committee,
- > Mr. Sławomir Kościak – Member of the Audit Committee,
- > Ms. Zofia Szewczuk – Member of the Audit Committee.

The Audit Committee operates in accordance with the provisions of the Act of 11 May 2017 on Statutory Auditors,

Audit Firms and Public Supervision (hereinafter referred to in point 7.2.4 as "Act"), and its organisation and operation are specified in the rules of procedure adopted by the Supervisory Board.

In 2021, the Audit Committee held 2 meetings.

The criteria of independence within the meaning of the Act in the composition of the Audit Committee in 2021 were fulfilled by David James, Krzysztof Kaczmarczyk, Józef Banach, Robert Koński, Sławomir Kościak and Zofia Szewczuk. These persons also met the independence criteria within the meaning of the Best Practice of WSE Listed Companies 2016 and the Best Practice of WSE Listed Companies 2021.

**Table 18. Responsibilities and powers of the members of the Audit Committee<sup>39</sup>.**

**Members of the Audit Committee have declared that they had knowledge and skills in the field of:**

| accounting or audit of financial statements:  | Skills in the industry in which Mabion S.A. operates:   |
|---|---|
| <ul style="list-style-type: none"> <li>&gt; David John James</li> <li>&gt; Krzysztof Kaczmarczyk (until 13 May 2021)</li> <li>&gt; Jacek Nowak (until 23 February 2021)</li> <li>&gt; Józef Banach</li> <li>&gt; Zofia Szewczuk</li> <li>&gt; Sławomir Kościak</li> </ul> | <ul style="list-style-type: none"> <li>&gt; Krzysztof Kaczmarczyk (until 13 May 2021)</li> <li>&gt; Jacek Nowak (until 23 February 2021)</li> <li>&gt; Józef Banach</li> <li>&gt; Sławomir Kościak</li> </ul> |

▪ **David John James  
– Chairman of the Audit Committee**

Graduate of the University of Cambridge, certified auditor at the Polish Chamber of Chartered Accountants and ICAEW (Institute of Chartered Accountants in England and Wales). Currently International Liaison Partner, Grupa Strategia, Poland. He has 32 years of experience in audit and internal control. Member of the management boards of many companies and a start-up advisor in the CEE region for nearly fifty companies. Partner responsible for auditing the financial statements of over 100 companies and groups of companies from multiple sectors of the economy, both listed companies, private equity funds and family businesses. His portfolio includes over 80 due diligence analyses, he dealt with statutory, internal and forensic financial audits and provided business advisory services to many clients. He has worked in Poland, UK, Germany, Czech Republic, Slovakia and Russia. He is fluent in eight languages and speaks twelve others. David James spent four years mentoring about 100 teams of young entrepreneurs participating in the Cambridge Python Project. As part of this project, organised under the aegis of the British Embassy and the University of Cambridge, David James trained students from all over Poland in creating modern business plans and budgeting. David James is the creator of an original method of foreign language learning.

▪ **Krzysztof Kaczmarczyk (until 13 May 2021)**

Graduate of the Warsaw School of Economics with specialization in finance and accounting. He is also a former student of the University of Warsaw, faculty of International Relations. In 1999-2008, he worked for Deutsche Bank in Poland, where he held a position, among others, of Deputy Director of the Stock Market Analysis Department and Stock Market Analyst for Central and Eastern Europe. In the period of 2008-2010, he held various managerial positions in the TP S.A. Group, including Director of the Strategy and Development Division. In 2010-2011, he worked for a Swiss investment bank, Credit Suisse, in Poland. In 2012-2015, he held a position of Vice-President of the Management Board for Strategy and Development at Emitel, a leading operator of the terrestrial radio and television network in Poland. In 2016-2018, Advisor to the Management Board of KGHM Polska Miedź S.A. Thereafter, professionally independent member of supervisory boards of companies listed on the Warsaw Stock Exchange. His almost 15 years of supervisory experience were gained by sitting on more than 30 supervisory boards, of companies listed on the Warsaw Stock Exchange and non-listed companies, including: Action, Alta, Arteria, Braster, BEST, BSC Drukarnia, Celon Pharma, Duon, Emitel, TP Edukacja i Wypoczynek, Warsaw Stock Exchange, Graal, Integer, InPost, KGHM Polska Miedź, KGHM International, KGHM TFI, Develia

<sup>39</sup> Based on statements by members of the Audit Committee.

(former LC Corp), Magellan, PolimexMostostal, Polish Energy Partners, Robyng, SARE, TIM, Vigo System, Wirtualna Polska, Work Service, 4fun Media. Krzysztof Kaczmarczyk has knowledge and skills in the industry in which the Company operates, acquired owing to 11 years of work at Deutsche Bank and Credit Suisse, where he held managerial positions, and was responsible for market analyses of many market sectors, including the market segment in which the Company operates. At the same time, prior to his appointment to the Supervisory Board of the Company, he previously held the position of Member of the Supervisory Boards of Braster S.A. and Celon Pharma S.A., owing to which he acquired knowledge in the area in which the Company operates.

#### ▪ **Józef Banach**

Graduate of the Faculty of Law at the Jagiellonian University in Cracow. Legal Counsel. Managing Partner at Ontilo Banach Szczypiński Partnerzy. He started his career in the Ministry of Finance, and then for a number of years worked at PricewaterhouseCoopers sp. z o.o., most recently as a leader of the Proceedings and International Tax Law team. Member of a number of supervisory boards of capital companies, including the position of Chairman of the Supervisory Board of Poczta Polska SA and Chairman of the Supervisory Board and Chairman of the Audit Committee of PHN SA. A long-term expert of the Tax Council at PKPP Lewiatan, including the acting head of the Tax Council. He has many years of experience in advising companies from the pharmaceutical industry, including Genexo Sp. z o.o. since its inception. Author of numerous publications in the field of law, including the commentary "Polish Agreements on Avoidance of Double Taxation" by CH Beck. Repeated proxy of the parties in proceedings before administrative authorities and administrative and common courts which ended with a success of the client.

#### ▪ **Jacek Nowak (until 23 February 2021)**

Graduate of Accounting and Financial Management at the University of Łódź. Additionally, he completed postgraduate studies at the French Institute of Management in Warsaw and postgraduate studies in Pharmacoeconomics, Marketing and Pharmaceutical Law at the Warsaw University of Technology Business School. Member of the ACCA since 2012. Since 2001, he has been working for the pharmaceutical company Polfarmex S.A. and since 2005, he has been holding the position of CFO at Biofana.

#### ▪ **Sławomir Kościak**

Licensed Investment Advisor with license number 303 and holder of the CFA (Chartered Financial Analyst) title. Graduate of the Warsaw School of Economics with a major in Finance and Banking, he also studied at the Aarhus School of Business in Denmark and Universität zu Köln in Germany, and completed the Community of European Management Schools – Master's in International Management (CEMS MIM) management programme. Scholarship holder of the Educational Enterprise Foundation. He lectured at courses for

stockbrokers (Association of Brokers and Advisors, ZMiD) and for investment advisers (PERK). He has more than 10 years of experience in asset management. He worked, among others, at the European Investment Fund in Luxembourg and the Morgan Stanley real estate fund in Frankfurt. In 2009-2020, he managed a number of different funds and investment strategies within TFI PZU, both with the PZU Group's own funds and those entrusted by external clients, equity, mixed and absolute return funds. The investment portfolio included companies listed on the WSE as well as those listed on stock exchanges in the EU and the USA. Member of the investment committee, AUM of over PLN 20 billion. From 2014, a Medical Sector Director at TFI PZU responsible for investments in companies from the healthcare sector.

#### ▪ **Zofia Szewczuk**

Graduate of ESCP-EAP Europe and Poznań University of Economics and Business with titles of Master of Science in Finance and Accounting for Business and Master of Science in Management. She has over 12 years of experience in the private equity industry, gained by working for leading funds in Poland and abroad. Since 2016, she has been associated with Polski Fundusz Rozwoju S.A., where she currently acts as Head of Office in the Investment Department of PFR S.A. and President of the Management Board of PFR Life Science Sp. z o.o., a company specialising in investments in the field of biotechnology. Her previous experience includes Mid Europa (2011–2015) and 3i (2009–2011). In that time, she has participated in numerous transactions in sectors such as industry, new technologies, services, manufacturing, health, and tourism. Ms. Zofia Szewczuk has extensive ownership and supervisory experience, gained when representing the investor side. Her work entails regular cooperation with the management boards of companies in, among other things, the implementation of development and recovery initiatives and performance monitoring. At present, she is a member of the supervisory boards of Mabion S.A., Polskie Kolei Linowe S.A. and serves as an observer on the supervisory board of Proteon Pharmaceuticals S.A.

## 2. **Appointment and Remuneration Committee**

The Appointment and Remuneration Committee is an advisory body to the Supervisory Board. Members of the Committee exercise powers set out in the Rules of Procedure of the Appointment and Remuneration Committee adopted by the Company's Supervisory Board, pursuant to Article 390 of the Commercial Companies Code.

As of 1 January 2021, the composition of the Company's Appointment and Remuneration Committee was as follows:

- > Mr. Robert Koński – Chairman of the Appointment and Remuneration Committee,
- > Mr. Maciej Wiczorek – Member of the Appointment and Remuneration Committee,
- > Mr. Krzysztof Kaczmarczyk – Member of the Appointment and Remuneration Committee,

- > Mr. David John James – Member of the Appointment and Remuneration Committee,
- > Mr. Adam Pietruszkiewicz – Member of the Appointment and Remuneration Committee.

On 3 March 2021, Mr. Adam Pietruszkiewicz tendered his resignation from the function of Member of the Company's Supervisory Board.

On 13 May 2021, Mr. Krzysztof Kaczmarczyk tendered his resignation from the position of Chairman and Member of the Supervisory Board of the Company.

On 29 April 2021, by way of a resolution of the Company's Supervisory Board, Mr. Wojciech Wośko was appointed to the Appointment and Remuneration Committee.

On 13 May 2021, by way of a resolution of the Company's Supervisory Board, Mr. Józef Banach was appointed to the Appointment and Remuneration Committee.

On 9 December 2021, Mr. Maciej Wieczorek tendered his resignation as Member of the Supervisory Board of the Company.

As at 31 December 2021 and as at the date of this report, the composition of the Appointment and Remuneration Committee is as follows:

- > Mr. Robert Koński – Chairman of the Appointment and Remuneration Committee,
- > Mr. David John James – Member of the Appointment and Remuneration Committee,
- > Mr. Józef Banach – Member of the Appointment and Remuneration Committee,
- > Mr. Wojciech Wośko – Member of the Appointment and Remuneration Committee.

## 7.2.5 Procedures related to the selection and services of an audit firm

### Audit firm selection policy and policy for the provision of permitted non-audit services

Pursuant to § 22(1)(b) of the Company's Articles of Association, the Company's Supervisory Board selects a statutory auditor to audit the Company's financial statements. When selecting an audit firm, the Supervisory Board acts on the basis of the indicated criteria and the recommendation of the Audit Committee.

The policy and procedure for selecting an audit firm to conduct the audit and the Policy for the provision of permitted non-audit services were adopted by resolutions of the Audit Committee on 20 October 2017 (updated on 21 April 2020 following amendments in law provisions).

**The main assumptions of the implemented policy for the selection of an audit firm and the policy for the provision of permitted non-audit services are as follows:**

The audit firm is selected in appropriate advance so that the contract for statutory audit of financial statements can be signed in time to allow the audit firm to participate in the stocktaking of significant assets.

The selection is made taking into account the principles of impartiality and independence of the audit firm and taking into account the principle of rotation of the audit firm and the key statutory auditor. The first audit agreement is entered into with an audit firm for a period of not less than two years with the possibility of extension for further periods of at least two years.

It is forbidden to include contractual clauses in agreements entered into by the Company, as invalid by virtue law, which would limit the possibility of selecting an audit firm by the Supervisory Board of the Company, for the purpose of carrying out the statutory audit of the Company's financial statements, to certain categories or lists of audit firms.

The Audit Committee, acting as part of the Supervisory Board of the Company, takes a decision on a recommendation to extend or not to extend the agreement with an audit firm, of which it informs the Supervisory Board of the Company.

If the Supervisory Board of the Company decides not to extend the agreement with the audit firm for a subsequent period and if the extension of the agreement for a subsequent period is not permissible in line with the rotation principle, the procedure for the selection of the audit firm shall apply.

The Tender Committee appointed by the Company's Management Board is responsible for organizing the selection procedure for the statutory audit of the Company's financial statements, including for drawing up tender documentation.

The request for proposals for the selection of an audit firm for the purposes of the statutory audit of the Company's financial statements is prepared by the Tender Committee in consultation with the Audit Committee and is subject to publication on the website [www.mabion.eu](http://www.mabion.eu) and is sent to selected audit firms within a specified period of time.

Collected offers of audit firms together with a report containing conclusions from the selection procedure are submitted to the Audit Committee for approval.

The Audit Committee decides on the approval of the report containing the conclusions of the selection procedure and submits a recommendation to the Supervisory Board, which includes at least two options for selecting an audit firm with a justification and an indication of the Audit Committee's reasonable preference for one of them.

If the Supervisory Board's decision to appoint an audit firm deviates from the recommendations of the Audit Committee, the Supervisory Board justifies the reasons for non-compliance with the recommendations of the Audit Committee and communicates such justification to the General Meeting.

In accordance with Article 5(1) of Regulation (EU) No 537/14 of the European Parliament and of the Council of 16 April 2014, a

statutory auditor or an audit firm carrying out the statutory audit of a public-interest entity, or any member of the network to which the statutory auditor or the audit firm belongs, shall not directly or indirectly provide to the audited entity, to its parent undertaking or to its controlled undertakings within the Union any prohibited non-audit services in:

- a) the period between the beginning of the period audited and the issuing of the audit report; and
- b) the financial year immediately preceding the period referred to in point (a) in relation to the services listed in Article 5(1), second paragraph, point e) of the above mentioned Regulation.

Services prohibited under Article 136.1 of the Act include also other services which are not financial audit activities. Where a statutory auditor or an audit firm provides the said services to the Company, its parent undertaking or entities controlled by it for a period of at least three consecutive financial years, the total remuneration for such services shall be limited to a maximum of 70 % of the average remuneration paid in the last three consecutive financial years for the statutory audit(s) of the Company and, where applicable, its parent undertaking, entities controlled by it, and the consolidated financial statements of that group of undertakings. For the purposes of the limitations set out in the first sentence, non-audit services other than those referred to in the preceding paragraph and in this paragraph which are required to be provided under EU or national legislation shall be excluded.

The services indicated in Article 136(2) of the Act are not Prohibited services. The provision of these services is possible only to the extent not related to the tax policy of the audited entity, after the Audit Committee has carried out an assessment of threats to and safeguards of independence referred to in Articles 69–73 of the Act and after the Audit Committee has given its consent.

### Audit firm

The Company's financial statements for 2021 was audited by PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp. k. with its registered office in Warsaw ("PwC"). PwC also performed a review of the financial statements for the semi-annual period ended on 30 June 2021. The audit firm was selected by the Supervisory Board by resolution no. 2/V/2020 dated 7 May 2020 on the basis of the authorisation provided for in the Company's Articles of Association. The audit firm was selected on the basis of recommendations of the Audit Committee. The recommendation of the Audit Committee met the applicable conditions and was drawn up as a result of the procedure for selecting an audit firm meeting the applicable criteria, organised by the Company.

In 2021, PwC provided permitted non-audit certification services to the Company in the form of a review of the condensed semi-annual financial statements of the Company for the period from 1 January 2021 to 30 June 2021, as well as services concerning the assessment of the accuracy and

reliability of the written report of the Company's Management Board drawn up for the purpose of offsetting pecuniary receivables arising from the obligation of subscribers to pay the issue price due on account of the new U series shares, and services concerning the audit of the report on the remuneration of the Members of the Company's Management Board and Supervisory Board for 2019 and 2020.

The services listed above have been given a prior positive recommendation by the Audit Committee of the Company's Supervisory Board regarding the auditor's independence assessment. The Company's Supervisory Board has agreed to the provision of the above services.

For more information on the audit firm, please refer to point 8.4.

## 7.3 General Meeting

### 7.3.1 Operating principles of the General Meeting

The General Meeting acts based on the Commercial Companies Code and the Rules of Procedure of General Meetings of Mabion S.A.

### 7.3.2 Essential powers of the General Meeting

The competence of the General Meeting includes issues reserved for it by the Commercial Companies Code, while the purchase and sale of real estate, perpetual usufruct or share in real estate or perpetual usufruct do not require the adoption of a resolution by the General Meeting (§ 17(2) of the Company's Articles of Association).

The following, in particular, require a resolution by the General Meeting:

- > appointing and dismissing Members of the Supervisory Board;
- > suspending or dismissing Members of the Management Board;
- > method of distributing the Company's net profit;
- > determining the dividend date.

To be valid, a resolution on the merger or division of the Company requires a majority of 3/4 of the votes cast.

Subject to the provisions below, to be valid, a resolution on removing items included in the General Meeting's agenda requires a majority of 3/4 of the votes cast in the presence of shareholders representing at least 50% of the Company's share capital, with the consent of the shareholders filing a justified motion to abandon investigating an item included on the agenda. In the event that a motion for removing an item from the agenda is filed by the Management Board, the resolution of the General Meeting requires an absolute majority of votes cast. Removing items included in the General Meeting's agenda on the motion filed, based on Article 401 of the Commercial Companies Code, by a shareholder representing at least 1/20 of the Company's share capital requires the consent of the shareholder who made the motion.

### 7.3.3 Rights of shareholders and the manner of their execution

Rights and obligations related to the Company's shares are determined in the provisions of the Commercial Companies Code (CCC), in the Articles of Association, and in other legal regulations.

#### Property rights attached to the Company's shares resulting from the Articles of Association

The Company's shareholders have the following property rights following from specific provisions of the Articles of Association:

- 1) Right of first refusal in the purchase of registered shares by the then holders of registered shares in proportion to the shares held (§ 13 of the Company's Articles of Association)
- 2) Right to redeem the shares held (§ 12 of the Company's Articles of Association).

Corporate rights vested in the Company's shareholders in connection with participation in the Company:

- 1) Right to participate in the General Meeting in person or through a proxy (Article 412 of the CCC) and right to vote at the General Meeting (Article 411 § 1 of the CCC).

Voting rights from the existing Company shares are as follows:

- a. two votes at the General Meeting are attached to each of the A, B, C, E, F, G series shares;
  - b. one vote at the General Meeting is attached to each of the D, H, I, J, K, L, M, N, O, P, S, U series shares.
- 2) The right to convene the Extraordinary General Meeting by shareholders representing at least one-half of the share capital or at least one-half of the votes in the Company (Article 399 § 3 of the CCC).
  - 3) The right of shareholders with at least one-twentieth of the Company's share capital to request that the Extraordinary General Meeting be convened and to request that certain items be put on the agenda (Article 400 § 1 of the CCC). If within two weeks of the date of presenting the request to the Management Board the Extraordinary General Meeting is not convened, the registration court may authorise the shareholders who requested the Meeting to convene it (Article 400 § 3 of the CCC).
  - 4) The right of shareholders with at least one-twentieth of the Company's share capital to request that certain matters be put on the agenda of the next General Meeting (Article 401 § 1 of the CCC). The request should contain at least a justification or draft resolution relating to the proposed item on the agenda (Article 401 § 1 of the CCC).
  - 5) The right to appeal against General Meeting resolutions pursuant to the rules specified in Articles 422–427 of the CCC.
  - 6) The right to request appointing the Supervisory Board in separate groups. Pursuant to Article 385 § 3 of the CCC, on motions from shareholders representing at least one-fifth of the share capital. The Supervisory Board should be then appointed by the next General Meeting by voting in separate groups.

- 7) The right to request that a specific item related to the incorporation of a public company or running it be audited by a statutory auditor (an auditor for special issues). The respective resolution should be adopted by the General Meeting upon a motion by a shareholder or shareholders holding at least 5% of the total voting rights at the General Meeting (Article 84 of the Act on Public Offering). For this purpose, the shareholders may request that the Extraordinary General Meeting be convened or that the passing of such a resolution be included in the agenda of the next General Meeting. If the General Meeting dismisses the motion for appointing an auditor for special issues, the motioners may request that such an auditor be appointed by the Registration Court within 14 days of passing the resolution (Article 85 of the Act on Public Offering).
- 8) The right to obtain information about the Company in the scope and manner specified by the law, in particular pursuant to Article 428 of the CCC. During a General Meeting, at the request of a shareholder the Management Board has to provide information relating to the Company, if this is justified for assessing an item on the agenda; a shareholder who is refused such information during a General Meeting and who reports his/her objection to the minutes of the Meeting may file a motion with the Registration Court to oblige the Management Board to provide such information (Article 429 of the CCC).
- 9) The right to request copies of the Directors' Report of the Company, copies of the Company's financial statements, and of the statutory auditor's opinion fifteen days before the General Meeting at the latest (Article 395 § 4 of the CCC).
- 10) The right to inspect, on the premises of the Management Board, the list of shareholders entitled to participate in the General Meeting and to request a copy of such a list, subject to payment of the costs of its preparation, and to request that the list be sent free of charge to an electronic delivery address or by e-mail (Article 407 § 1–11 of the CCC).
- 11) The right to request copies of motions regarding items on the agenda, within a week preceding the date of the General Meeting (Article 407 § 2 of the CCC).
- 12) The right to file a motion for checking the list of attendees to the General Meeting by a specially appointed committee comprising at least three persons. The motion may be filed by shareholders holding one-tenth of the share capital represented at such a General Meeting. The motioners are entitled to appoint one of the members of the committee (Article 410 § 2 of the CCC).
- 13) The right to inspect the book of minutes and request that copies of resolutions certified by the Management Board be issued (Article 421 § 3 of the CCC).
- 14) The right to file a claim for repairing damage caused to the Company according to the principles specified in Article 486 and 487 of the CCC, if the Company does not file a lawsuit for damages within a year of the date of disclosing the action which caused the damage.
- 15) The right to inspect documents and request that the copies of documents referred to in Article 505 § 1 of the CCC (in the event of a merger of the Company), in Article 540 § 1 of the CCC (in the event of a division of the Company) and in

Article 561 § 1 of the CCC (in the event of the Company's transformation) be made available on the Company's premises free of charge.

- 16) The right to request that a commercial company which is a Company's shareholder provide information whether it is the parent or subsidiary of a given commercial company or co-operative which is a Company's shareholder, or whether it ceased to be such a parent or subsidiary. A shareholder may also request that the number of shares or votes be disclosed, or the number of shares or votes that the commercial company holds, including as a pledgee, user or based on agreements with other persons. The demand for information should be filed in writing (Article 6 § 4 and 6 of the CCC).

#### **7.4 Principles for amending the Company's Articles of Association**

The principles for amending the Company's Articles of Association are regulated by the Commercial Companies Code. Amendments to the Articles of Association require a resolution of the General Meeting and entry into the National Court Register. The General Meeting may authorise the Supervisory Board to set the consolidated text of the Company's amended Articles of Association or to make other editorial changes as specified in the resolution of the Meeting.

#### **7.5 Main features of internal control and risk management systems**

The Company does not have an institutionalised, formalized internal control system or a financial risk management system in respect of the process of drawing up the financial statements. Data for the purpose of financial statements and the financial statements themselves are prepared by the Company's finance department. A Management Board Member for Financial Matters supervises the preparation of the financial statements.

## 8 SUPPLEMENTARY INFORMATION

### 8.1 Remuneration policy

On 15 June 2020, the Ordinary General Meeting of the Company adopted a resolution on the adoption of the Remuneration Policy for the Members of the Management Board and Supervisory Board of Mabion S.A. ("Remuneration Policy"). Then, on 22 June 2021, the Ordinary General Meeting of the Company adopted a resolution on the adoption of amendments to the Remuneration Policy for the Members of the Management Board and Supervisory Board of Mabion S.A.

The Remuneration Policy is available on the Company's website at: <https://www.mabion.eu/dokumenty-korporacyjne/>.

The Remuneration Policy contains the framework and general principles for the remuneration of the Management Board and the Supervisory Board Members, to be followed by the Supervisory Board and the General Meeting when determining the remuneration of individual members of the company's bodies in accordance with statutory requirements. The objective of these principles is to lay the foundations for the implementation of the Company's strategy and its stable development, to ensure effective and smooth management of the Company, to increase the long-term value for investors, to ensure the Management Board's loyalty to investors, to build motivation of members of the Management Board to take actions conducive to long-term development of the Company and innovation, without taking excessive risk, to create a framework to manage potential conflicts of interest and to take into account the interests of employees and respect for the environment.

The terms and conditions, and amounts of remuneration for 2021 separately for individual Members of the Company's Management Board, and non-financial elements of remuneration for which they are eligible in 2020 are presented in sections 7.1.3 and 7.2.3 of this Report.

### 8.2 Liabilities under pensions and similar obligations

In 2021, the Company did not have any liabilities for pensions or similar benefits towards former members of its managing or supervisory bodies, or any liabilities incurred in connection with such pensions.

### 8.3 Lawsuits

In 2021, the Company was not a party to any proceedings before a court, an arbitration authority or a public

administration authority which in the opinion of the Management Board of the Company could have a material adverse effect on the financial situation, operations or cash flows of the Company.

### 8.4 Information about the audit firm

The financial statements for 2021 were audited by PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k. with its registered office in Warsaw, ul. Polna 11, entered on the list of audit firms maintained by the National Council of Statutory Auditors ("PwC"). The audit firm was selected by the Supervisory Board by resolution no. 2/V/2020 dated 7 May 2020 on the basis of the authorisation provided for in the Company's Articles of Association. The agreement with PwC was entered into on 20 July 2020 for a period of 2 years and includes the audit of interim financial statements and the audit of annual financial statements for 2020 and 2021. The total remuneration for the performance of the aforementioned services covered by the agreement was set at PLN 465,000 net.

In previous years, Mabion S.A. used the services of PwC in the following scope:

- > audit of the annual financial statements for 2015, 2016, 2017, 2018, 2019 and 2020, review of the interim condensed financial statements for the period from 1 January to 30 June of 2015, 2016, 2017, 2018 and 2019, and audit of the remuneration policy report for 2019 and 2020;
- > services related to the planned issue of the Company's shares on a stock exchange outside the territory of the Republic of Poland (on the territory of Europe or the United States), i.e. support for the Company in the preparation for the conversion of the financial statements for 2016 and 2015 prepared in accordance with PAS into IFRS-compliant statements, audit of the Company's financial statements for 2016 and 2015 prepared in accordance with the IFRS, preparation of comfort letters in connection with the planned listing of the Company's shares on the aforementioned stock exchange, support and other services related to the preparation of issue documents necessary for the implementation of the share issue on the aforementioned stock exchange;

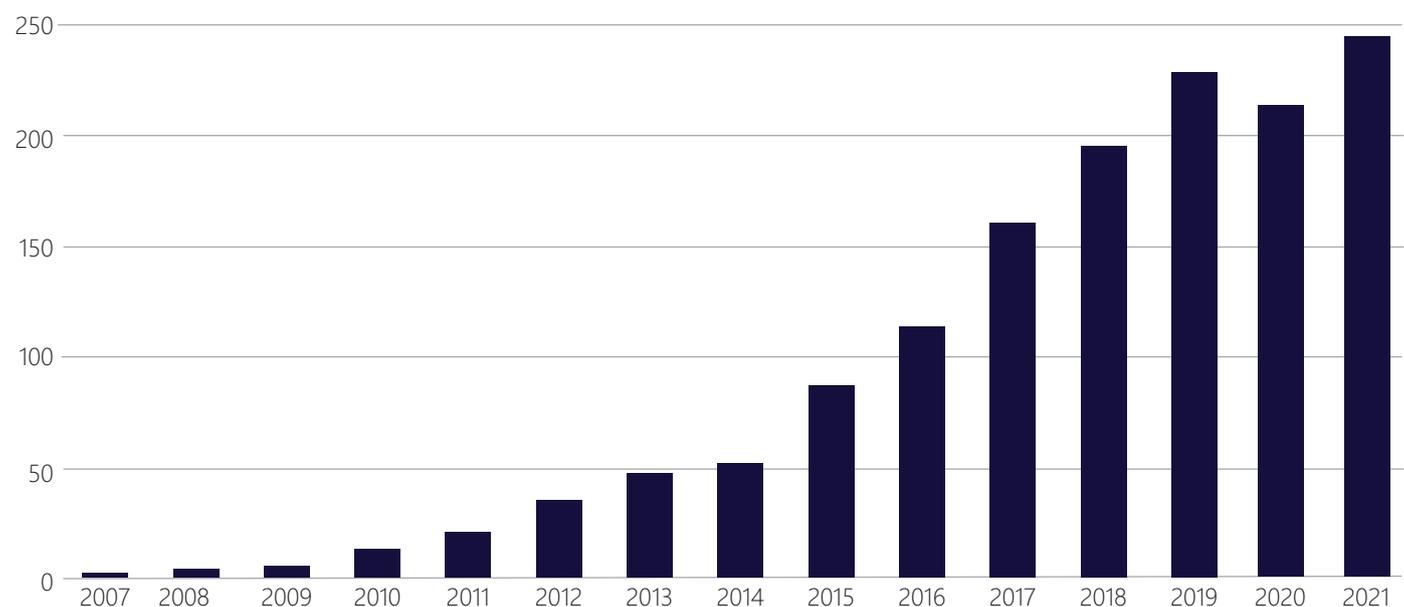
Remuneration due to PwC for services provided in 2020 and 2021 is presented in the table below.

**Table 19. PwC's fee in 2020–2021**

|  | 2021    | 2020    |
|--|---------|---------|
| Audit of the annual financial statements                               | 185,000 | 160,000 |
| Other assurance services, including the review of financial statements | 60,000  | 60,000  |
| Tax consultancy services   | 0       | 0       |
| Other services   | 52,500  | 61,300  |

## 8.5 Employment

As at 31 December 2021, the Company employed 244 people, while the average employment in 2021 was 225.75 full-time equivalents.

**Table 20. Employment at Mabion S.A. in 2007 – 2021.**

## 8.6 Major research and development achievements

Mabion focuses on the development and manufacture of originator medicines using the recombinant protein technology which is currently a prerequisite for the development of advanced products to fight the most serious diseases, for example in the field of oncology, neurology, or autoimmunity, as well as on using the technologies the Company has developed to execute commercial orders for its partners.

The Company's experience in the research and development area and its assets enabled it to deliver on an order from Novavax Inc. as part of which a vaccine antigen manufacturing process was successfully transferred to the Company's laboratories and the process was subsequently scaled up to its intended commercial level. The process in the set-up accepted by the customer was handed over to the Manufacturing Department for commercial implementation. Likewise, analytical methods for process control and quality control of the resulting product have been transferred. The analytical processes in the set-up accepted by the customer were handed over to the Quality Control Department for commercial implementation.

As regards the Company's own projects, work focused primarily on MabionCD20, a proposed biosimilar to the reference drugs MabThera/Rituxan (Roche). To date, the Company has completed most of the work within the project (development of technology, analytical tools, Phase III clinical trials, scaling up production to commercial scale with validation). The remaining tasks include a clinical bridging trial in a limited patient population to demonstrate the equivalence of the commercially manufactured medicine with the product previously tested in the Phase III trial and originating from the clinical manufacturing scale, as well as an analytical studies. In 2021, the Research and Development Department carried out work related to analytical studies, as well as the preparatory work for the bridging clinical trial described in the report.

## 8.7 Environment protection

Issues related to environmental protection, but also to ensuring safe working conditions and improving energy efficiency are a very important aspect of the Company's operations, which, acting on the basis of current regulations, guidelines and legislation in these areas, pursues the Company's strategic objectives guided by the principle of sustainable development.

An important aspect of the Company's operations is to conduct the processes at the plant in a manner that minimises negative impact on the environment.

Considering the above, the Company has made every effort to implement and maintain an Integrated Management System in accordance with ISO 14001:2015, 45001:2018 and 50001:2018 standards, which contributes to the improvement of its operations in the management of the EP, OHS, and energy areas.

The Company has implemented all planned measures to ensure that the plant's operations and processes comply with all guidelines arising from ISO standards and legislation relating to the areas of EP, OHS, and energy.

In November 2020, the Company completed a two-stage certification process, which was conducted by independent auditors from an accredited certification body. The scope of certification covered the main and ancillary processes that comprise research and development activities enabling the development and subsequent implementation of new product of biological origin and biotech medicines, including biosimilar medicines, and activities related to the manufacture of biological preparations and biosimilars.

The audit team reported that the organisation has established and maintains its management system in accordance with the requirements of the standards and demonstrates the ability to meet in a systematic manner the agreed requirements for products and services in accordance with the organisation's scope of certification, objectives and policy.

The certificates obtained confirm the successful implementation and certification of IMS, which are valid for the period of three years. In order to maintain the validity of the certificates, the Company underwent a supervisory audit carried out in November 2021 by the aforementioned independent certification body. The supervisory audit of the integrated management system was completed with a positive recommendation from the audit team, confirming the continuous improvement of the Company's activities in the area of environmental, energy, and occupational health and safety management.

The basic assumption of the Integrated Management System Policy in the area of environmental protection, occupational health and safety and energy efficiency is to raise the awareness of all employees with regard to the systems in force, which translates into effective implementation of the Policy, as well as to build a sense of responsibility for its implementation with regard to:

- > the provision by Senior Management of safe and healthy working conditions;
- > the commitment of Senior Management to the promotion of IMS;
- > continuous improvement in the areas of environmental protection, occupational health and safety, and energy efficiency;
- > elimination of hazards and mitigation of risks;

- > prevention of injuries and health problems;
- > environmental protection and pollution prevention;
- > improving energy performance;
- > compliance with the requirements of PN-EN ISO 45001:2018, PN-EN ISO 14001:2015, PN-EN ISO 50001:2018 standards, and with legal and other requirements in the area of environmental protection, occupational health and safety and energy use and consumption, binding upon the Company;
- > consultation and participation of employees in building an effective system;
- > the availability of information and resources necessary to achieve the objectives and targets;
- > taking into account environmental, occupational health and safety, and energy efficiency issues in investment processes and procurement plans.

With a view to meeting these assumptions of the integrated management system and mobilising employees to make it work effectively, the Company has organised an internal competition entitled "Let's make work safer, protect the environment and save energy - share your idea and win a prize!" The underlying idea behind the competition was to motivate employees to propose their own initiatives for improving the integrated management system. During the competition, employees submitted a total of 131 ideas for improving the safety of working conditions, energy efficiency, and environmental performance. Two winners were chosen from among the participants – the person who submitted the highest number of proposals and the employee who proposed the most effective action.

Simultaneously, the Company implements a project related to environmental education of employees, as part of which, in 2020, the following campaigns were organised:

- > "Battery Day" collection;
- > collection of waste electronic equipment, confirmed by the "Responsible Entrepreneur" certificate issued by GreenGo and Moby;
- > cooperation with the "RECAL" Foundation through active participation in the "Every Can Counts" project – selective collection of aluminium cans;
- > planting trees twice in cooperation with the Grotniki Forestry Board;
- > employee competition to mark International Green Transport Day, promoting zero-emission transport and cycling to work;
- > cleaning up the world together with the "Our Earth" Foundation.

Due to the ongoing epidemic and the resulting restrictions, the Company was obliged to suspend its environmental education project for the benefit of the local community.

The Company has analysed energy efficiency, use and consumption based on current data and information to detect significant consumption points and identify opportunities to improve energy performance. The summary of these activities is included in a document titled "Energy Review".

These actions are intended to make every effort to improve energy efficiency, increase the level of waste segregation and reduce the consumption of natural resources, while implementing optimal production processes.

The company has two business locations. The Company's registered office is located in Konstanyń Łódzki, at ul. gen. Mariana Langiewicza 60. The office of the Management Board is also located at this address.

The Research and Development Centre for Biotechnological Medicinal Products is located at ul. Fabryczna 17 in Łódź.

The Company has complied with the formal regulations for obtaining administrative decisions and holds the permits and notifications listed below:

1. Decision of the Marshal of the Łódź Region of 29.07.2016 on the integrated permit (reference: RŚVI.7222.190.2015.KK) – for the location of the Company in Konstanyń Łódzki.
2. Decision of the Państwowe Gospodarstwo Wodne Wody Polskie, the Regional Water Management Board in Poznań of 08 March 2019 (reference: PO.RUZ.421.456.5.2018.ML) on granting the water-legal permit covering the special use of waters consisting in injection of industrial sewage containing substances particularly harmful to the aquatic environment (total phosphorus) into the sewage system of another entity – for the Company's location in Konstanyń Łódzki.
3. Notification of the fuel combustion installation to the District Office in Pabianice – confirmation of the notification receipt of 3 April 2018 (reference: OŚ.6221.2.2018) – for the Company's location in Konstanyń Łódzki.
4. Notification to the Marshal of Łódź Region of the operation of an installation in the scope of the emission of gases and dust into the air, concerning the test operation for the manufacture of medicinal products or pharmaceutical raw materials, for which the maximum time of emission of substances into the air will amount to 120 hours per year of 30.09.2021 (reference: SRIV.7223.1.2.2021.MO) – for the Company's in Konstanyń Łódzki.
5. Decision No. 65/Op/15 of the Mayor of Łódź of 28 April 2015 on the award of a waste generation permit (reference: DSSOŚR-IV.6221.5.2015) – for the Company's location in Łódź.

The Company also has internal system documents (procedures and instructions of a Good Laboratory Practice and a Good Manufacturing Practice system), regulating issues related to the conduct of rational, environmentally safe waste management at the plant, in accordance with the provisions of law.

The following agreements were in force in 2021 in Mabion S.A. as part of the waste management:

1. With EGOLIT Sp. z o. o. of 21.08.2015 along with Annex 5 to the Agreement, entered into on 31.12.2020. The Agreement concerns the collection, disposal or recovery of hazardous and non-hazardous industrial waste.

2. With ECO-ABC, of 15.05.2018, No. 37/JN/2018. The agreement concerns the collection and neutralization of solid medical waste. On 28 June 2019, ECO-ABC Sp. z o. o. terminated part of agreement No. 37/JN/2018 in the field of disposal and neutralization of liquid waste, due to the fact that the technology used to neutralize medical waste does not have sufficient power to burn liquid waste in a pyrolytic furnace.

In 2021, Annex No. 01/2021 amending the financial terms and conditions of cooperation, effective as of 01.11.2021, was signed with REMONDIS Sp. z o. o. dated 20.07.2020, together with a letter amending the terms and conditions of cooperation of 15.11.2021. The agreement applies to the collection of municipal waste and selectively collected waste.

3. Remondis is providing services from 01.09.2020.
4. With REMONDIS Sp. z o. o. of 15.06.2021 for collection and management of industrial and production waste.

The Company has been entered on the register of entities introducing products, products in packaging and managing waste (waste database) for installation and non-installation waste generation. In October 2020, the Company updated its entry in the register with regard to the activities resulting from the Act of 13 June 2013 on Packaging and Packaging Waste Management.

In order to fulfil the obligation under the aforementioned Act, on 30 December 2019 the Company also signed, with INTERSEROH Organizacja Odzysku Opakowań S.A., agreement no. UM/2019/1244 with annex no. UM/2021/1374 of 22 September 2020 on the takeover and fulfilment of the entrepreneur's obligation to ensure recovery and recycling of packaging waste.

Under the agreement, the Organization undertakes to perform the following activities for and on behalf of the Company:

- > collecting packaging waste,
- > recovering and recycling packaging waste,
- > preparing and submitting an annual report on packaging and packaging waste management to the competent public administration,
- > conducting public education campaigns.

The Company has complied with all obligations relating to environmental reporting, which includes the collection and processing of data and information and the production of reports reflecting the environmental performance of the plant. Reports have been submitted to the relevant environmental authorities, on official forms in force. The Company have submitted the following reports:

- > List containing a summary of information on the use of the environment and the amount of fees due for the introduction of gases and dusts into the air. The emission sources are: HCl dosing and disinfection of equipment and surfaces, both for basic installation (installation for the production of medicinal products or pharmaceutical raw

materials) and auxiliary installation (research and development laboratories, quality control laboratories); fuel combustion installations; combustion of fuels in internal combustion engines.

- > The report of the National Centre for Pollution Control and Balancing (KOBiZE) containing information on the amount of greenhouse gas emissions to the atmosphere, the source of which is: HCl dosing in the basic and auxiliary installation; disinfection of equipment and surfaces; fuel combustion installations; combustion of fuels in internal combustion engines.
- > Annual report on waste generated and on waste management.
- > Annual report containing information necessary for the establishment of the National Pollutant Release and Transfer Register (PRTR) for the transfer of hazardous waste across the country.
- > Annual information on the types and quantities of category 2 drug precursors used at the Mabion's facility.
- > Annual report on products, packaging, and waste management.

Pursuant to Article 28 of the Environmental Protection Law, entities using the environment are obliged by law and by virtue of decisions held by them to measure the level of substances or energy in the environment and the amount of emissions.

Such measurements shall be carried out in a periodically repeatable manner. The results of the monitoring shall be recorded and reported or made available for inspection to the relevant environmental protection authorities. The Company fulfils this obligation by carrying out:

- > measurements of noise emissions from installations and forwarding test results to the relevant environmental authorities;
- > quality tests of industrial wastewater and mixed industrial and household wastewater. The results of the tests have been forwarded to the relevant environmental protection authorities;
- > quantitative monitoring of: water intake, industrial wastewater discharge, electricity consumption, network heat consumption, fuel use;
- > control of the technical condition and operational inspection of the oil-derivative separator.

In order to monitor the amount of waste generated, the Company keeps full records of generated waste using documents specified in waste management regulations for that purpose and makes entries in the Database on Products, Packaging, and Waste Management.

Fulfilling the obligations specified in the Integrated Permit, the Company also carries out ongoing technological monitoring, which includes measurements of parameters characterising specific technological processes, i.e. consumption of materials, substances, products, and production volume.

The Company measures key non-financial indicators in the area of environmental protection based on ESG guidelines:

- > water consumption [m<sup>3</sup>];
- > electricity consumption [MWh];

- > quantity of waste generated [kg], divided into hazardous and non-hazardous waste.

## 8.8 Social responsibility policy

### 1. EQUAL OPPORTUNITIES POLICY

Mabion pursues a policy of equal opportunities for all employees, in terms of:

- > gender;
- > race;
- > ethnic origin;
- > religion;
- > views;
- > disability;
- > age;
- > sexual orientation.

Both the scope of responsibilities and the level of remuneration are not differentiated depending on any of the above factors. The basis for the assessment of employees is competence, knowledge and regular evaluation of the results achieved. The Company actively pursues a policy of protection of pregnant women and women on maternity leave, granting them several special rights. Where necessary, female employees who are pregnant, have recently given birth to a child or who are breastfeeding are transferred to positions which do not pose risks to their health.

We also draw attention to the fact that the Company respects parental rights of female and male employees alike, i.e. the right to additional childcare leave (Article 188 of the Labour Code).

The Company employs people of all ages from the age of majority. Religion does not affect employment either, as religious issues are not discussed during the recruitment process or employment. Mabion has been pursuing an equal employment opportunity policy on the various dimensions of its operation since its incorporation. The Company's policy is rooted in the European Union's Directives (including, among other things, Council Regulation (EC) No. 1083/2006).

### 2. ETHICS

Each employee of the Company may learn about his/her rights and obligations and values embedded in our corporate culture, which translates into clarity and transparency of mutual expectations and rules of conduct in everyday work. Mabion aspires to creating a work environment based on respect and mutual trust. Every person working for the Company is subject to the following rules:

- > knows his or her duties;
- > may engage in an open and constructive dialogue about his or her work performance;
- > may count on professional development assistance;
- > is recognised and rewarded based on merit (basic pay system, plus performance bonuses and motivational trips);

- > may talk openly and improve the performance of the whole team;
- > is treated fairly and respectfully;
- > is not discriminated against (see point 1);
- > feels supported in pursuing his or her personal priorities.

### 3. RECRUITMENT

Mabion's recruitment policy ensures equal opportunities for all those interested in getting a job with the Company. In particular, the following rules apply to recruitment:

- > equal treatment - the same procedures and criteria apply to all candidates;
- > unchanging requirements for candidates – before the recruitment process begins, the requirements and criteria for candidates are defined which do not change during the recruitment and selection process;
- > impartiality – each Mabion representative participating in the recruitment process acts in a way that eliminates any form of favouritism or discrimination against candidates;
- > professionalism – people who take part in a recruitment process are properly prepared for it and keep the official tone of the conversation;
- > transparency – the recruitment process is clear and documented, allowing candidates to receive reliable feedback on their application;
- > respect for privacy – interviewers avoid questions about candidates' private life, family status and plans to start a family;
- > respect for individuality – interviewers tolerate that candidates show other attitudes, behaviour, physical and mental characteristics than their own;
- > easy access to job offers – advertisements are published in several ways (industry portals, Mabion website, recruitment portals, social media, presence at universities and cooperation with research clubs) allowing a wider group of candidates to apply for a position of their choice.

### 4. PERSONAL AND PROFESSIONAL DEVELOPMENT

Mabion builds a culture based on values common to everybody. Key values supporting the vision, mission and strategy of the company include: orientation on quality and effect of work, work culture, responsibility, communication and cooperation. The performance management model takes into account not only the achievement of business goals, but also the development of competencies based on these values.

The summary of work results is a manifestation of caring for the smooth functioning of the organization and contributes to shaping good interpersonal relations. Mutual feedback serves to build the organisational culture and cooperation of all employees. The development summary and planning have a far-reaching influence on the personal and professional development of employees and on the functioning of the organization as a whole.

The Company's activities in the aspect of human capital development are visible in the increasing amounts of training investments dedicated to our employees.

Mabion offers specialist training and a series of development training for the managerial staff.

In addition to professional competence development, the company provides employees with access to meetings and development workshops in the areas of personal development, personal resources management, and building own brand.

In 2020, a programme called "Mabion Ambassador" was developed and implemented. It is addressed to all employees of the Company and its aim is to motivate, support the development of soft and hard competencies, and to recognise the best employees. In 2021, a "Leadership Academy" was launched to support the development of leaders and strengthen them in their role.

### 5. WORK-LIFE BALANCE

Mabion believes that acquisition and retention of good employees requires more than just competitive remuneration and a stimulating work environment. The Company also focuses on work-life balance aspects. Therefore, the Company promises to be fully open to employees' work-life balance initiatives.

Projects are managed in equal measure by men and women, depending on their qualifications and competition results. While treating all of its employees equally, the Company promotes a culture of diversity, which should be understood as respect for values and religions, opinions, experiences and rights of each employee to his or her own opinion.

Continued efforts to train employees are yet another dimension. Relevant departments are a starting point for the training programme. Away training days and one-on-one training are managed by relevant business units. Each employee has equal access to the professional education programme and agrees with his/her supervisor on the type and pace of promotion. The high score of the employee's appraisals and the degree of experience obtained in his/her work (laboratory, process, or administrative) predispose him/her to participate in the promotion procedure organised by the heads of departments.

The promotion procedure envisages professional development in terms of substantive or functional positions. The guidelines for the promotion procedure are established in a clear and transparent manner that takes into account all positions in the Company. The promotion procedure concludes with the employee writing a test, completing an assignment or preparing a multimedia presentation based on the material presented to the employee prior to the procedure.

The Company makes it possible for employees to continually improve their qualifications by supporting training initiatives and assisting employees in taking and completing PhD

courses. This policy ensures that employees are fully committed to the Company and their jobs..

The above policy of the Company is being continually developed as the Management Board of Mabion uses its best efforts for Mabion to remain an attractive and competitive employer.

## 8.9 Promotional and charitable activities

In 2021, the Company did not incur any expenses on supporting culture, sports, charities, media, social organisations, or trade unions.

## 8.10 Investor relations

In 2021, similarly to previous years, the Company carried out active communication activities, reaching out to a wide audience of stakeholders. Due to the SARS-Cov-2 virus pandemic, the Company focused its activity online, organising webinars for investors and other stakeholders.

Communication activities, including in the area of investor relations, included:

- > participation in national and international fairs and conferences;
- > meetings (mainly online) with institutional and individual investors, analysts from brokerage houses, and the media;
- > educational activities among investors and the media;
- > preparation and distribution of information and press materials for, among others, the media, institutional and individual investors, and analysts at brokerage houses;
- > expert statements and comments of the Company's officials in Polish and international media (news media, media from capital market related sectors and specialised industry media dedicated to biotechnology), online interviews and teleconferences involving the Company's Management Board;
- > as a result of commencing cooperation with Novavax in the area of production of COVID-19 protein vaccine elements, educational activities conducted by representatives of the Company and invited experts as part of social responsibility activities aimed at promoting vaccination against COVID-19;
- > participation in initiatives organised by universities and other institutions (e.g. "Młodzi w Łodzi" initiative);
- > CSR activities (pandemic health care support, charity actions, education and environmental activities).
- > Company's involvement in the initiative aimed at establishing the Union of Biotechnology Companies to develop the innovative biotechnology industry in Poland, through, among other things, consultation in shaping laws, building awareness and knowledge of representatives of public authorities on the role and importance of the biotechnology industry, and mutual support in the process of registration, production of biotechnology products in the European Union.

The purpose of Mabion's investor relations activities is to create value for the Company's Shareholders. The key objective is to have an regular, effective, two-way communication channel with the investors, and to ensure the Company's transparency through full compliance with disclosure obligations and corporate governance principles contained in the Best Practice of of WSE Listed Companies 2021.

The Company communicates with investors via its website which contains a separate section for investors and another separate one – for the media, with the materials available in Polish and English. In 2021, the adaptation of the Company's investor relations website to the recommendations set out in the Best Practices of WSE Listed Companies 2021 and the DPSN 2021 Guidelines took place. The IR site includes, among other things:

- > Information about the Company and its bodies (bodies, shareholders, current share price, strategy, corporate documents, general meetings, corporate governance, financial information, capital structure);
- > Current and interim reports;
- > Current share quotation of the Company and analysts writing about the Company;
- > Calendar of corporate events;
- > Investor relations contact details;
- > Materials for investors – presentations and recordings of speeches by Company's representatives;
- > Press releases and image bank (in the media section).

The Company regularly informs about the most important events through current reports published via the ESPI system, as well as through press releases in key daily newspapers, on financial and business portals. The Management Board representatives give interviews to key media covering biotechnology and finance. The Company responds to enquiries from investors, shareholders, and other stakeholders on an ongoing basis.

The main topics communicated by the Company in 2021 were:

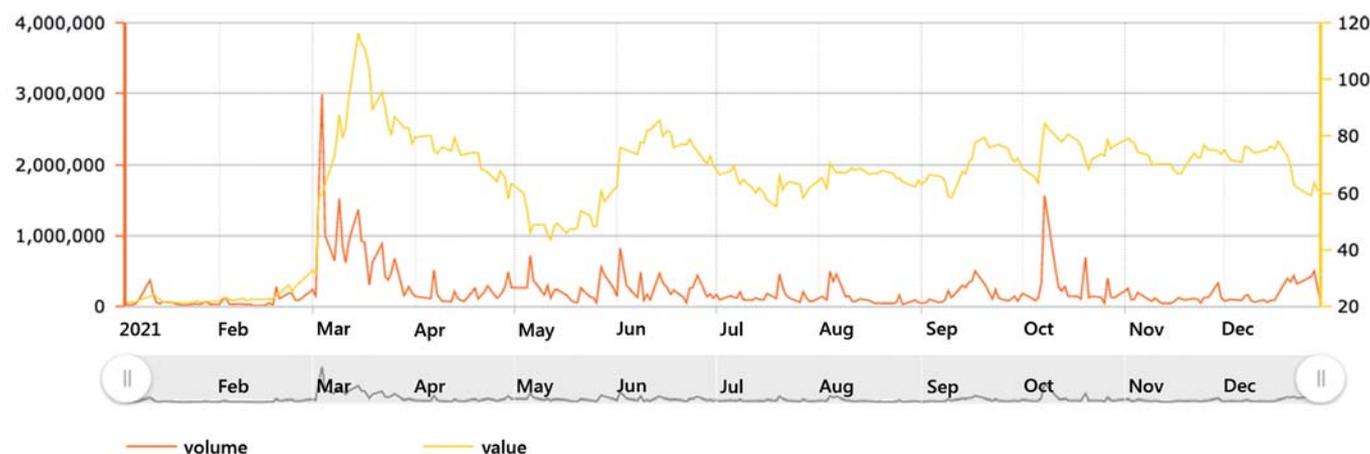
- > update of the Company's financing strategy, commencement of the process of securing a strategic investor, and the successful completion of a capital raising transactions in March 2021;
- > establishing crucial cooperation with Novavax and concluding a framework agreement regarding the production of antigen for COVID-19 protein vaccine by Mabion, and subsequently updating this information as regards, among others, additional orders, the technology transfer process;
- > conclusion of a manufacturing agreement with Novavax for the GMP-compliant commercial production of the antigen for COVID-19 vaccine;
- > conclusion of an annex and termination of the collaboration agreement of 2016 with Mylan Ireland resulting in the Company regaining the full rights to the MabionCD20 project, enabling the commencement of a new collaboration in the field of distribution of MabionCD20;

- > update of the development strategy for MabionCD20 in terms of plans for a bridging clinical trial, including the clinical trial budget, and product registration in the European and US markets, as well as information on preparations for the clinical trial (approvals for the trial in additional markets).

Contact for investors: [relacjeinwestorskie@mabion.eu](mailto:relacjeinwestorskie@mabion.eu).

## 8.11 The Company's stock performance on the Warsaw Stock Exchange

**Table 21. Mabion S.A. stock quotes on the Warsaw Stock Exchange (04.01.2021 – 30.12.2021) – chart.**



Source: <https://www.gpw.pl/spolka?isin=PLMBION00016>

**Table 22. Mabion S.A. stock quotes on the Warsaw Stock Exchange (04.01.2021 – 30.12.2021) – a summary.**

|                   |                        |
|-------------------|------------------------|
| Start date:       | 2021-01-04             |
| End date:         | 2021-12-30             |
| Reference price:  | PLN 20.75 (30.12.2020) |
| End price:        | PLN 61.10 (2021-12-30) |
| Change:           | 194.46%                |
| Change:           | PLN 40.35              |
| Minimum:          | PLN 19.90 (21-01-28)   |
| Maximum:          | PLN 126.20 (21-03-15)  |
| Average:          | PLN 62.53              |
| Trading volume:   | 57,070,163 pcs.        |
| Average volume:   | 227,407 pcs.           |
| Turnover:         | 4,076.057 million      |
| Average turnover: | 16.239 million         |

## Management Board

**Krzysztof Kaczmarczyk**

President of the Management Board

**Sławomir Jaros**

Member  
of the Management Board

**Grzegorz Grabowicz**

Member  
of the Management Board

**Adam Pietruszkiewicz**

Member  
of the Management Board

Konstantynów Łódzki, 21 April 2022

# MABION

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