MABION

Mabion S.A.
Directors' Report
for the first half of 2022

Konstantynów Łódzki, 29 September 2022

Contents

1. SELECTED FINANCIAL DATA

	in PLN thousand		in EUR thousand	
Selected financial data	**from 01.01.2022 to 30.06.2022**	**from 01.01.2021 to 30.06.2021**	**from 01.01.2022 to 30.06.2022**	**from 01.01.2021 to 30.06.2021**
Net income from sales of products, commodities, and materials	82,553	1,590	17,781	350
Operating profit (loss)	10,197	-18,510	2,196	-4,071
Gross profit (loss)	12,560	-19,572	2,705	-4,304
Net profit (loss)	12,560	-19,572	2,705	-4,304
Weighted average number of shares (in pcs)	16,161,751	16,161,326	16,161,751	16,161,326
Profit (loss) per ordinary share (in PLN/EUR)	0.78	-1.21	0.17	-0.27
Diluted profit (loss) per ordinary share (in PLN/EUR)	0.78	-1.21	0.17	-0.27
Net cash flows from operating activities	-21,594	-29,397	-4,651	-6,465
Net cash flows from investing activities	-3,027	-7,977	-652	-1,754
Net cash flows from financing activities	-1787	112,280	385	24,692
Total net cash flows	-26,408	74,906	-5,688	16,473
	30.06.2022	**31.12.2021**	**30.06.2022**	**31.12.2021**
Total assets	154,458	184,237	33,000	40,057
Liabilities and provisions for liabilities	88,583	130,924	18,926	28,465
Long-term liabilities	36,195	34,787	7,733	7,563
Current liabilities	52,388	96,137	11,193	20,902
Equity	65,876	53,313	14,074	11,591
Share capital	1,616	1,616	345	351
Number of shares (in pcs)	16,161,826	16,161,326	16,161,826	16,161,326
Book value per share (in PLN/EUR) *	9.56	11.40	2.04	2.48
Diluted book value per share (in PLN/EUR)	9.56	11.40	2.04	2.48
Dividend declared or paid per share (in PLN/EUR)	0	0	0	0

* Net assets/Weighted average number of shares

Selected balance-sheet items presented in EUR have been translated according to the average EUR exchange rate announced by the National Bank of Poland on 30 June 2022 (4.6806 PLN/EUR) and on 31 December 2021 (4.5994 PLN/EUR). Selected items of the income statement and cash flow statement have been converted into EUR at the exchange rate announced by the National Bank of Poland and being the arithmetic average of the average exchange rates for the euro effective as at the last day of each ended month in the period of six months ended 30 June 2022 and the period of six months ended 30 June 2021 (respectively: 4.6427 PLN/EUR and 4.5472 PLN/EUR).

2. INFORMATION ON MABION S.A.

2.1. Introduction

Mabion S.A. ("Mabion" or "Company") was established on 30 May 2007 as a limited liability company with its registered office in Kutno. In 2009, the legal form of the Company changed as a result of the transformation of the limited liability company into a joint-stock company. Currently, Mabion S.A. is entered on the Register of Entrepreneurs of the National Court Register kept by the District Court for Łódź Śródmieście in Łódź, 20th Commercial Department of the National Court Register under KRS number 0000340462. The Company was assigned tax identification number NIP 7752561383 and statistical identification number REGON 100343056. The Company's shares are listed on the regulated market of the Warsaw Stock Exchange (Giełda Papierów Wartościowych w Warszawie S.A.).The Company's registered office is located at ul. gen. Mariana Langiewicza 60 in Konstantynów Łódzki.

Mabion S.A. 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 in the field of manufacturing, analytics, and development of biopharmaceuticals.

The Company's experience in the development, analytical, and regulatory areas made it possible for it to complete a commercial order for its partner, Novavax Inc. ("Novavax"), 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 (Good Manufacturing Practice) production capacity, enabled the Company to sign and commence implementation of another agreement with Novavax for the contractual commercial manufacturing of and analytics for the Nuvaxovid® vaccine antigen ("Manufacturing Agreement, "MCMA" – Master Contract Manufacturing Agreement). At present, the agreement provides for cooperation between the parties until 2026.

As for 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 studies.

In relation to the signing of an annex to the manufacturing agreement and an annex to the Statement of Work #1 ("Statement of Work #1" or "SOW#1") with Novavax on 22 September 2022 (an event after the balance-sheet date), which significantly extend the scope and duration of the parties' cooperation, as at the date of publication of this report work is underway to review and analyse both the Company's ongoing and planned projects, while preparatory work has commenced for the implementation of a further contract service consisting in the manufacture of antigen for the Omicron variant vaccine for Novavax. The work schedules are being updated so that the structure of activities in the context of the implementation of Company's own projects and commercial orders would enable optimum use of its resources and future financial results. Upon completion of all necessary work and arrangements, the Company will announce an updated schedule, together with the Company's overall development strategy.

Management Board of Mabion S.A.

In the period of H1 2022 and as at the date of submission of this report, the composition of the Company'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.

Changes in the composition of the Company's Management Board in H1 2022 and after the balance-sheet date:

On 25 May 2022, due to the expiry of the first joint term of office of Members of the Company's Management Board, the Supervisory Board of Mabion S.A. adopted resolutions to appoint the existing Members of the Management Board to the Management Board of the Company for the second joint term of office: Krzysztof Kaczmarczyk, Sławomir Jaros, Adam Pietruszkiewicz and Grzegorz Grabowicz. The Supervisory Board's resolutions will become effective on the day following the date of the Ordinary General Meeting of the Company approving the financial statements for the financial year ended 31 December 2022, i.e. as of 22 June 2022. In line with the Company's Articles of Association, members of the Management Board are appointed for a joint term of office of 5 years. The Company informed about the event in Current Report no. 16/2022 of 25 May 2022.

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,

is responsible for developing the Company's business strategy, risk management, the area of disclosure obligations and investor relations, and the process of acquisition of a strategic investor,
- Sławomir Jaros – Member of the Management Board for Operations and Scientific Matters, COO, CSO – responsible for medicines design, technology development, the area of clinical research, the area of pharmaceutical risk control and for supervision of manufacturing processes and operational management,
- Adam Pietruszkiewicz – Member of the Management Board, CCO – responsible for cooperation with Novavax, business development of the Company, strategic projects management and acquisition of new partners,
- Grzegorz Grabowicz – Member of the Management Board for Financial Matters, CFO – 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.

2.2. Supervisory Board of Mabion S.A.

In the period of H1 2022 and as at the date of submission 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 – Deputy Chairman of the Supervisory Board (Independent Member; until 20.04.2022 Member of the Board),
- Józef Banach – Independent Member of the Supervisory Board,
- David John James – Independent Member of the Supervisory Board,
- Wojciech Wośko – Member of the Supervisory Board,
- Zofia Szewczuk – Independent Member of the Supervisory Board.

Changes in the composition of the Company's Supervisory Board in H1 2022 and after the balance-sheet date:

In H1 2022 and after the balance-sheet date, there were no changes in the composition of the Company's Supervisory Board. On 20 April 2022, the Company's Supervisory Board appointed its Member, Mr. Sławomir Kościak as Deputy Chairman of the Supervisory Board of the Company.

2.3. Entities subject to consolidation

Mabion S.A. does not hold any shares in other entities. There are also no other situations which could lead to the conclusion that the Company is a dominant company within the meaning of Article 4 §1(4) of the Commercial Companies Code. In H1 2022, Mabion S.A. did not form a capital group and did not draw up consolidated financial statements.

3. OPERATIONS OF MABION S.A.

3.1. Object of activity

The Company's core business includes:

- the development, analytics and manufacture of its own medicine candidates;
- contract operations as a CDMO (Contract Development and Manufacturing Organisation) – in 2021, the Company undertook to commence the transfer of technology relating to the production of the antigen for the COVID-19 vaccine by Novavax Inc. and subsequently entered into a commercial manufacturing agreement for 2022–2025. On 22 September 2022, annexes were entered into with Novavax (an annex to the manufacturing agreement and an annex to SOW#1) extending the term of the agreement until the end of 2026.

So far, the Company's project catalogue, as per classification adopted in 2019, amounts to three project groups: 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 a result of the signing of the aforementioned annexes with Novavax on 22 September 2022, as at the date of publication of this report work is underway to review and analyse both the Company's ongoing and planned projects. Upon completion of all necessary work and arrangements, the Company will announce an updated schedule, together with the Company's overall development strategy.

Active projects

In line with the classification adopted in 2019, this is a group of projects of high importance for the Company, as part of which the Company carries out work and invests funds. At present, this group mainly includes the ongoing project concerning the biosimilar medicine, MabionCD20, for which MabThera/Rituxan (rituximab) (Roche) are reference products. Moreover, in line with the previous classification, this group also includes the MabionMS and MabionEGFR projects, for which the Company is not currently incurring capital expenditure, as they are at the standby stage, awaiting continuation as part of a partnership model.

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

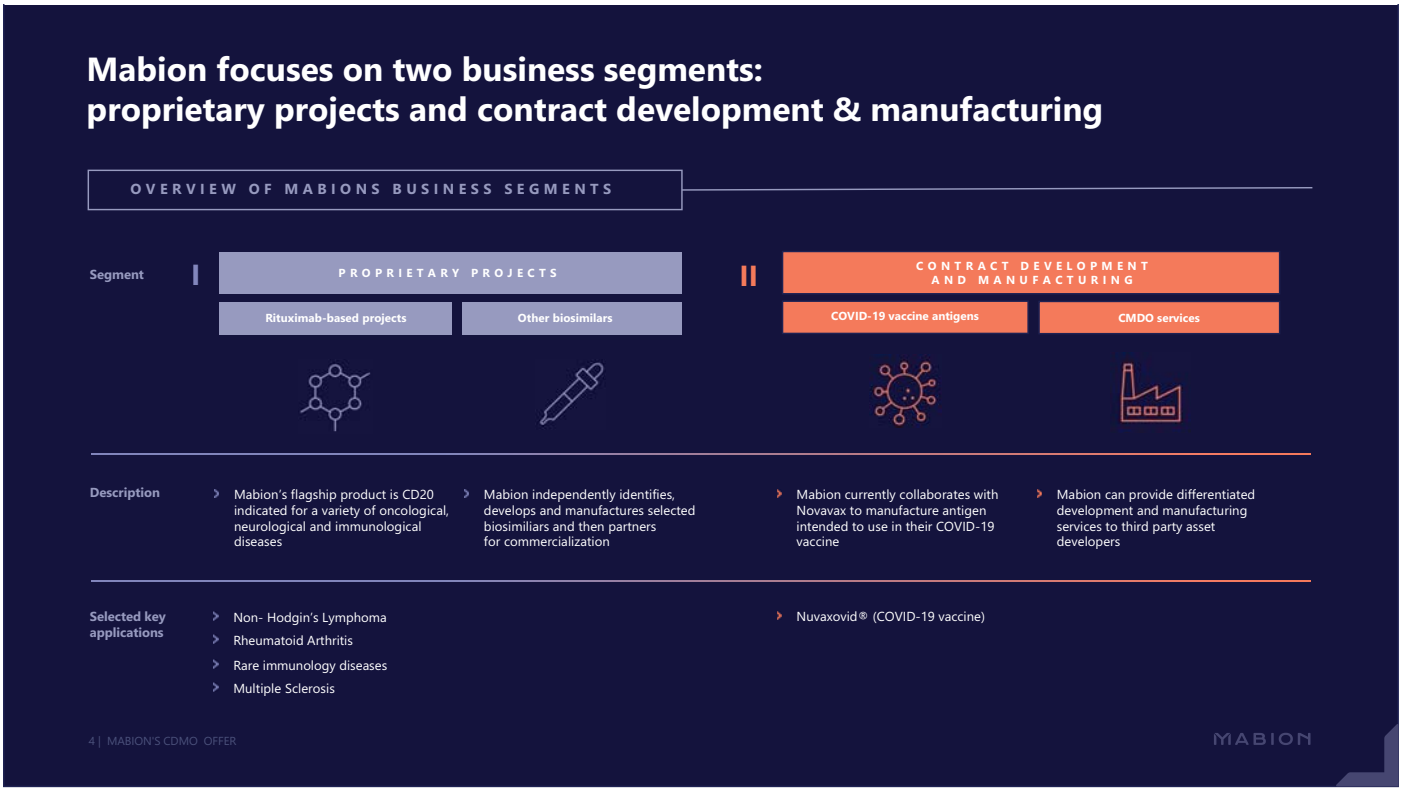
area of autoimmunity, metabolic diseases and oncology (denosumab and omalizumab antibodies).

Partnership projects

This group of projects includes all operations carried out with external partners and related to the development and marketing of new products (or therapies), as well as contract manufacturing.

At present, the Company is pursuing a long-term project with Novavax, Inc.

Table 1: Pre-existing product strategy of Mabion S.A. – a summary.[1]



[1] Own study of the Company.

Table 2. R&D project portfolio of Mabion S.A.[2]

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
strategic co-developer / CMDO	**vaccine**	**COVID-19**	**innovative therapy**	**framework agreement and first order for contracted services signed**	**CDMO**	**NOVAVAX USA**
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

The Company's most significant activities in H1 2022 were related to the Nuvaxovid® and MabionCD20:

Nuvaxovid® (former NVX-CoV2373)

In 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 manufacturing process together with the antigen analytics for the purposes of production of the COVID-19 vaccine antigen, called Nuvaxovid® (former NVX-CoV2373) and conduct technical trial runs of the process on a laboratory and commercial scale at the Company's facility.

As a result of the successful implementation of the above activities, in October 2021 the Company entered into a commercial contract manufacturing agreement (Manufacturing Agreement) together with SOW#1 with Novavax, under which the Company carries out commercial manufacturing of the Nuvaxovid® antigen, based on the GMP standard, for Novavax.

In 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 agreement date, the Company submitted a notification to the Chief Pharmaceutical Inspectorate (GIF) concerning the fact of concluding 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 quality control, as well as commencing the implementation of the annual manufacturing schedule which 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 this report, the Company is carrying out the work as agreed with Novavax. After the balance-sheet date and up to the date of these statements, the parties have agreed to changes to the original manufacturing schedule until the new arrangements are finalised and the schedule updated. In the annex – to the agreement in force as at the balance-sheet date – signed after the balance-sheet date (referred to in more detail below), the agreement was supplemented by, among other things, a provision concerning access to the Company's manufacturing capacity in the form of reserved manufacturing slots against payment.

[2] Own study of the Company.

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") covering the manufacture of cell banks for Novavax in compliance with the GMP standards. 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. The work on cell banks preparation has been completed.
- Statement of Work #2 ("SOW#2") involving the provision by the Company of analytical services to Novavax for the purposes of tests related to the quality control of the Nuvaxovid® vaccine, not covered by previous agreements or orders, and the transfer of methods in line with Novavax's specifications. The order is currently being executed by the Company.

On 27 May 2022, the scope of services under the Manufacturing Agreement was extended in the form of Statement of Work #4 (SOW#4). The extended scope of cooperation includes the quality test to be carried out by the Company, which is one of the most important analyses of the finished product. The Company has become an entity involved in the processes of release of finished products to the market. SOW#4 is currently being executed by the Company.

On 7 June 2022, the scope of services under the Manufacturing Agreement was extended in the form of Statement of Work #5 (SOW#5). The scope of SOW#5 covers the stability testing of intermediates and buffers manufactured and used in the production of the SARS CoV-2 rS active substance of the Nuvaxovid® vaccine.The tests are being conducted in line with the agreed schedule and are expected to be completed in the last quarter of 2022.

On 6 July 2022, the scope of services under the Manufacturing Agreement was extended in the form of Statement of Work #6 (SOW#6). The scope of SOW#6 covers the stability testing of stationary phases used in the production of the active substance of the Nuvaxovid® vaccine. The tests are carried out in the production area, in a GMP-compliant environment. SOW#6 is currently being executed by the Company.

On 20 July 2022, the scope of services under the Manufacturing Agreement was extended in the form of Statement of Work #7 (SOW#7). The scope of SOW#7 entails the Company's generation of cell banks carrying genetic structures that will be used for the manufacturing processes of the active substance of one of Novavax's formulations. The banks will be manufactured in a GMP-compliant environment. The resulting material will then be subjected to the relevant analytical tests, after which it will be transferred to Novavax. SOW#7 is currently being executed by the Company.

On 2 August 2022, the scope of services under the Manufacturing Agreement was extended in the form of Statement of Work #8 (SOW#8). The scope of SOW#8 entails the Company conducting stability tests on the SARS CoV-2 rS active substance. The tests will be conducted in a GMP-compliant environment, for the batches produced at the Company's facility and indicated by Novavax. The order is long-term and will be executed over a period of three years for each batch subjected to the test. Preparation for the work covered by SOW#8 commenced immediately after the order was signed.

On 22 September 2022, the Company entered into an annex to the manufacturing agreement with Novavax and an annex to SOW#1. On the basis of the aforementioned annexes, the Manufacturing Agreement's duration has been extended to the end of 2026. The parties agreed on a guaranteed volume of manufacturing capacity for Novavax until Q2 2024, while the scope of cooperation was defined for each year between 2022 and 2026. In addition, the parties have also agreed on the principles of remuneration for the Company, as further discussed in section 3.2 of this report. Under the annex, Novavax also undertook to take actions to immediately commission the Company to use its manufacturing capacity guaranteed to Novavax to produce the batches of the COVID-19 vaccine antigen, Omicron variant ("Omicron Product", agreed upon by the parties, including to carry out the transfer of technology. To this end, the parties will take suitable steps to enter into a further annex to SOW#1, covering the detailed scope of the Omicron Product manufacturing rules. The current manufacturing capability of the Company allows it to commence production of the Omicron Product.

MabionCD20 project

The Company's most advanced own 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 forMabionCD20.

In order to initiate the clinical bridging trial, the Company has obtained authorisations from the relevant authorities and bioethics committees. These authorisations allow a clinical trial to be initiated in Poland, Georgia, Belgium, and Ukraine.

Regarding the research and development work on MabionCD20, carried out in H1 2022 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;
- further testing of the reference drug batches (MabThera and Rituxan) to determine analytical ranges for individual protein attributes;

- continued development, and qualification and validation of 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, dedicated to patients with rheumatoid arthritis (RA).

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 was initially linked, among other things, to the cooperation commenced with Novavax based on contract manufacturing of the vaccine antigen, as well as the additional factor posed by the current situation in Ukraine.

As a result of the annexes entered into with Novavax on 22 September 2022, the Company continues to work on updating the work schedule for the years to come, taking into account at the moment also the the current format of cooperation with Novavax and the expansion of the Company's contract activities as a CDMO. Consequently, in the Management Board's view the schedule for further work on the registration of MabionCD20 will be subject to change. The Company will announce an updated schedule, together with the Company's overall development strategy, upon completion of all necessary work and arrangements.

3.2. Major events affecting Mabion S.A. in the first half of 2022 and up to the date of this report

Mabion receives an order to manufacture cell banks under the manufacturing agreement with Novavax, Inc. – SOW#3

On 14 January 2022, as part of an agreement entered into by the Company with Novavax, Inc. on 8 October 2021 and concerning commercial contract manufacturing ("Master Contract Manufacturing Agreement"), the parties signed an additional order in the form of 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. 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 on receiving SOW#3 in Current Report no. 2/2022 of 14 January 2022.

Mabion receives an order for product quality control analytical services under the manufacturing agreement with Novavax, Inc. – SOW#2

On 18 January 2022, as part of the Company's Manufacturing Agreement with Novavax, the parties signed an additional order in the form of Statement of Work #2 ("SOW#2"), pursuant to which the Company provides additional analytical testing services to Novavax related to the 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 carried out the transfer of methods in accordance with Novavax's specifications. The above work commenced in January 2022 and the transfer was completed as planned in the Q3 2022. The Company will perform the tests using the aforesaid analytical methods on the Product samples indicated by Novavax throughout the duration of the Manufacturing Agreement. Pursuant to SOW#2, the testing may cover 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 on receiving SOW#2 in Current Report no. 3/2022 of 18 January 2022.

Decision to abandon further implementation of the research project concerning the development of MabionEGFR

On 24 February 2022, the Company's Management Board decided to abandon further implementation of the research project concerning the development of MabionEGFR, entitled

"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", due to the fact that, in the opinion of the Management Board, it was not reasonable to continue with the project.

The implementation of the project was covered by a co-financing agreement entered into in October 2017 with the National Centre for Research and Development (NCBR) as part of the sectoral programme: InnoNeuroPharm (competition 2/1.2/2017/POIR, Measures 1.2: "Sectoral R&D Programmes"), funded by the SGOP 2014–2020. Following this decision and in accordance with the provisions of the co-financing agreement, the Company has submitted an application for payment together with final information on the project implementation. Under the agreement, the value of co-financing amounted to approx. PLN 28 million, of which until the date on which further agreement implementation was abandoned the Company had submitted payment applications to NCBR for approx. PLN 4 million. The final amount of funding received will be determined by NCBR after evaluation of the documents submitted by the Company, including those indicated above.

The Company informed about the decision in Current Report no. 7/2022 of 24 February 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 concluded, with the Ministry of Development Funds and Regional Policy, an annex to the agreement of 11 June 2018 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, it was 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 annex was concluded at the request of the Company due to circumstances affecting the project in previous years, i.e. first issues related to the funding of the own contribution and then the COVID-19 pandemic and the need to accommodate the area of vaccine therapies.

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

Registration of the Company as a manufacturer of the SARS-CoV-2 rS active substance in the Register of the Chief Pharmaceutical Inspectorate

On 19 April 2022, 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 (GIF).

From the operational side of the implementation of the Manufacturing Agreement with Novavax, obtaining the entry was a neutral event, i.e. it was not related to the tasks and settlements carried out to date, nor did it affect the tasks planned for subsequent periods, the settlements between the parties, or the timetable for the production of vaccine antigen. All these elements are governed by the Manufacturing Agreement, which the Company implements as planned. The event was significant for the Company from a regulatory perspective. It represented the final regulatory element for which the Company, as the manufacturing operator, was responsible as part of its cooperation with Novavax, i.e. having the relevant up-to-date GMP certificate and achieving registration as a manufacturer of the SARS-CoV-2 rS active substance in the Register of the Chief Pharmaceutical Inspectorate as the competent authority for the Company. The remaining regulatory activities, namely those related to updating the regulatory dossier on the product side, rest with Novavax. Thanks to the registration, all batches of the product, i.e. the vaccine antigen for COVID-19 bearing the name of Nuvaxovid®, Novavax, will be marketable once the formalities have been completed by Novavax. The Company is remunerated on an ongoing basis upon completion of production and quality control of the respective batch.

The Company informed about the entry in Current Report no. 11/2022 of 19 April 2022.

Extension of the scope of services under the manufacturing agreement with Novavax, Inc. – SOW#4

On 27 May 2022, the Company received an extension to the scope of services under the Manufacturing Agreement, signed by Novavax, in the form of Statement of Work #4 (SOW#4). The extended scope of cooperation includes the quality test to be carried out by the Company, which is one of the most important analyses of the finished product. Therefore, the Company becomes an entity involved in the processes of release of finished products to the market.

The scope of SOW#4 includes, in the first instance, an assessment of feasibility to be carried out by the Company with regard to the analytical method ("feasibility" stage) and transferring, by the Company, the aforementioned method to the Company's quality system. The Company has completed the "feasibility" stage and is now working to start the transfer of the aforementioned method. Both parties expect that the transfer and the incorporation of the method into the Company's quality system will be completed no later than the end of 2022. Then, during the term of the Manufacturing Agreement, i.e. in 2022–2026, (in accordance with the annex of 22 September 2022 to the Agreement) under SOW#4, the Company will, on behalf of Novavax, perform sample analyses of the Novavax finished product (final product in the form of Nuvaxovid® vaccine manufactured outside the Company) using the aforementioned GMP-compliant method, together with preparation of a certificate confirming the analysis performed.

The value of SOW#4 depends on the number of analytical tests performed by the Company in each year, with the maximum annual budget currently agreed at USD 1.8 million. In view of the Management Board, signing of SOW#4 is important for the Company primarily due to the next step in the process of expanding the cooperation with Novavax allowing the Company to further develop its Contract Development and Manufacturing Organization (CDMO) activities.

The Company informed about receiving SOW#4 in Current Report no. 17/2022 of 28 May 2022.

Extension of cooperation with Novavax, Inc. – SOW#5

On 7 June 2022, the Company received a further extension to the scope of services under the Manufacturing Agreement, signed by Novavax, in the form of Statement of Work #5 (SOW#5).

The scope of SOW#5 covers the stability testing of intermediates and buffers manufactured and used in the production of the SARS CoV-2 rS active substance of the Nuvaxovid® vaccine. The work covered by SOW#5 started immediately after the signing the statement and will be completed in 2022. In the opinion of the Management Board, SOW#5 is important for the Company primarily due to the further extension of cooperation with Novavax, and the tests covered by the current additional order will facilitate the management of the manufacturing process carried out in the Company under the Manufacturing Agreement.

The Company informed about receiving SOW#5 in Current Report no. 18/2022 of 8 June 2022.

Extension of cooperation with Novavax, Inc. – SOW#6

On 6 July 2022 (an event after the balance-sheet date), the Company signed another extension to the scope of services under the Manufacturing Agreement with Novavax, in the form of Statement of Work #6 (SOW#6). The scope of SOW#6 covers the stability testing of stationary phases used in the production of the active substance of the vaccine produced for Novavax. The tests are carried out in the production area, in a GMP-compliant environment. The Company immediately commenced the work covered by SOW#6 and assumes that it should be completed in Q4 2022. In the opinion of the Management Board, SOW#6 is important for the Company first and foremost due to the further expansion of cooperation with Novavax.

The Company informed about the conclusion of SOW#6 in Current Report no. 21/2022 of 6 July 2022.

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

On 12 July 2022 (an event after the balance-sheet date), the Company entered into Annex No. 3 to an agreement of 15 July 2020 for a borrowing of PLN 15 million with Glatton Sp. z o.o. (Borrower). Under the annex, it was agreed that the Borrowing will be repaid in two tranches: the first tranche of PLN 5 million was repaid on 28 September 2022, while the second tranche of PLN 10 million will be repaid by 31 December 2022 (the existing one-off repayment date was 12 July 2022). The other significant terms and conditions of the borrowing agreement remain unchanged.

The Company informed about concluding the Annex in Current Report no. 22/2022 of 12 July 2022.

Extension of cooperation with Novavax, Inc. – SOW#7

On 20 July 2022 (an event after the balance-sheet date), the Company signed another extension to the scope of services under the Manufacturing Agreement with Novavax, in the form of Statement of Work #7 (SOW#7). The scope of SOW#7 entails the Company's generation of cell banks carrying genetic structures that will be used for the manufacturing processes of the active substance of one of Novavax's formulations. The banks will be manufactured in a GMP-compliant environment. The resulting material will then be subjected to the relevant analytical tests, after which it will be transferred to Novavax. Immediately after signing SOW#7, preparations for the implementation of the tasks thereunder commenced.

The Company informed about concluding SOW#7 in Current Report no. 25/2022 of 20 July 2022.

Extension of cooperation with Novavax, Inc. – SOW#8

On 2 August 2022 (an event after the balance-sheet date), the Company signed another extension to the scope of services under the Manufacturing Agreement with Novavax, in the form of Statement of Work #8 (SOW#8).

The scope of SOW#8 entails the Company conducting stability tests on the SARS CoV-2 rS active substance. The tests will be conducted in a GMP-compliant environment, for the batches produced at the Company's facility and indicated by Novavax. The order is long-term and will be executed over a period of three years for each batch subjected to the test.

The Company informed about the conclusion of SOW#8 in Current Report no. 26/2022 of 2 August 2022.

Extension of cooperation with Novavax, Inc. – Omicron variant

On 22 September 2022 (an event after the balance-sheet date), the Company entered into an annex to the Manufacturing Agreement and an annex to Statement of Work No. 1 – SOW#1 (hereinafter: "Annex", jointly: "Annexes") with Novavax regarding the manufacture of the COVID-19 vaccine antigen ("Product") under the name of Nuvaxovid®, in compliance with the GMP standard and at a commercial scale.

The Manufacturing Agreement's duration has been extended to the end of 2026.

As a result of the annex, based on the schedule agreed between the parties, the Company will either receive remuneration "per batch" of the Product manufactured or remuneration for the readiness to manufacture the Product ("Manufacturing Slot Fee") based on the production capacity guaranteed to Novavax ("Manufacturing Slot").

As a result of the annexes, the price for the manufactured batches of the Product will remain unchanged from the one originally specified in the Manufacturing Agreement. The amount of the Manufacturing Slot Fee will represent an equivalent of the unit price per manufactured batch, adjusted for the value of the materials to produce the Product batch in question. Including prepayments and other exceptions as indicated in the schedule, the Manufacturing Slot Fee will be payable on a regular basis – monthly.

Starting from January 2023, the fixed unit price per batch and per Manufacturing Slot will be subject to annual indexation until the end of the Manufacturing Agreement.

The total value of the Manufacturing Agreement during its term remains unchanged from its original value (i.e. an estimate value of USD 372 million based on a theoretical assumption of future zero inflation over the Manufacturing Agreement's term).

The schedule, in the form of reserved slots, has been defined for each year in the period between 2022 and 2026. Under the Manufacturing Agreement, the parties have agreed a guaranteed capacity volume for Novavax until Q2 2024. Novavax is not entitled to reduce the capacity volume reserved until Q2 2024.

According to the schedule current as at the date of the annexes, it is assumed that the Company should realise more than 15% of the total value of the Manufacturing Agreement between the onset of the Agreement and the end of 2023. In the period from the beginning of 2024 to the end of 2025, the Company should achieve approximately 55% of the total value of the Manufacturing Agreement (Current Report no. 31/2022 mistakenly indicated the period from the beginning of mid-2024). In 2026, the Company should achieve approximately 30% of the total value of the Manufacturing Agreement (this does not include indexation of Agreement terms based on the inflation rate).

Under the annex, Novavax also undertook to take actions to immediately commission the Company to use the Manufacturing Slot to produce the batches of the COVID-19 vaccine antigen, Omicron variant ("Omicron Product"), agreed upon by the parties, including to carry out the transfer of technology. To this end, the parties will take suitable steps to enter into a further annex to SOW#1, covering the detailed scope of the Omicron Product manufacturing rules. The current manufacturing capability of the Company allows it to commence production of the Omicron Product.

Entering into the annexes does not deprive the Company of its ability to carry out contracting activities as a CDMO for other counterparties, excluding those engaged in activities competitive to Novavax, as defined in detail in the Manufacturing Agreement.

As a result of the annexes, the Company resumed ongoing work related to the updating the schedule of project work aimed at developing MabionCD20 for registration in the European and US markets. The work plan for the next few years will be updated with account taken of the current format of cooperation with Novavax and the development of contract activities as a CDMO. Consequently, in the Management Board's view the schedule for further work on the registration of MabionCD20 will be subject to change. The Company will announce an updated schedule, together with the Company's overall development strategy, upon completion of all necessary work and arrangements.

The Company informed about the event in Current Report no. 31/2022 of 22 September 2022.

3.3. Transactions with related parties

In the period of H1 2022, the Company did not enter into transactions with related parties on terms other than arm's length.

3.4. Guarantees and sureties granted for a loan or borrowing

In the period of H1 2022, the Company did not provide any loan or borrowing sureties or guarantees in aggregate to any one entity or its subsidiary where the total value of the existing sureties or guarantees would be significant for the Company.

3.5. Description of the main threats and risks for Mabion S.A.

1) Risks directly related to the Company's business

Risk related to the work schedule – Nuvaxovid®

In 2021, the Company into a Manufacturing Agreement, together with a Statement of Work, with Novavax 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 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.

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

Despite the remedies in place, the Company did not rule out that as a result of the ongoing work and discussions with the partner, the original assumptions relating to the manufacturing process or associated processes would change, which may also affect the work schedule. An additional factor likely to generate changes in the adopted schedules is the volatility of the pandemic situation (periods of increased COVID-19 incidence interlaced with periods of low incidence), which affects market demand for vaccines, including the Novavax's vaccine.

The Company has undertaken measures to mitigate the aforementioned risks, which resulted in the annexes entered into with Novavax on 22 September 2022. Based on the schedule agreed between the Parties, the Company will either receive remuneration "per batch" of the Product manufactured or remuneration for the readiness to manufacture the Product ("Manufacturing Slot Fee") based on the production capacity guaranteed to Novavax ("Manufacturing Slot"). The scope of cooperation, indicated in the appendixes to the annexes signed, has been specified for each year in the period between 2022 and 2026. Under the Agreement, the parties have agreed a guaranteed capacity volume for Novavax until Q2 2024. Novavax is not entitled to reduce the capacity volume reserved until Q2 2024.

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 Company's 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.

As a result of the annexes to the agreement entered into with Novavax on 22 September 2022, the Company resumes the work on updating the schedule of project work aimed at developing MabionCD20 for registration in the European and US markets. The work plan for the next few years will be updated with account taken of the current format of cooperation with Novavax and the development of contract activities as a CDMO. Consequently, in the Management Board's view the schedule for further work on the registration of MabionCD20 will be subject to change. The Company will announce an updated schedule, together with the Company's overall development strategy, upon completion of all necessary work and arrangements.

Risks related to contract manufacturing of medicines (CDMO)

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 and other services in biopharmaceutical processes – as a CDMO (Contract Development and Manufacturing Organisation) – in order to effectively use its available capacities and competences.

Mabion's competence as an integrated biopharmaceutical company spans over the entire medicine development chain of the recombinant protein biologics, providing the Company with a good chance of winning contracts on the CDMO market despite the existing 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. In the last year, the value of the global CDMO market was estimated at around EUR 70 billion, of which the CDMO market for biologics stood at EUR 22 billion with an expected average annual growth rate of 5.9% from 2020 to 2022[1].

However, it should be taken into account that acquiring a client is a prolonged process, preceded by a multi-stage due-diligence procedure and complex negotiations (or a tender procedure). The entity to act as the contract manufacturer is selected only after a number of analytical tasks, followed by tasks related to the transfer of technology. Furthermore, adaptation to client's requirements often requires additional investment on the part of the Company (equipment, technology, additional personnel) and involves the need to meet certain formal and legal requirements.

Last but not least, the contract manufacturing process itself involves a number of technological, process, and quality risks outlined in the other risk areas in this section of the report. Subject to the business model adopted for such cooperation, the Company may or may not provide similar services to other entities. Cooperating with several clients creates operational risks due to the need to reconcile different projects within a certain timeframe and the challenge of planning optimal schedules in the face of limited resources. Additionally, there is a risk related to the protection of confidential, business-secret data of the entity in question, where several parties are involved and their representatives can be present at the production processes. Any legal restrictions may hinder the development of the Company's own products and limit the ability to establish new partnerships. Involvement in contract projects can monopolise the Company's manufacturing and human resource capacity, reducing its own R&D activities.

In addition, the CDMO business presents risks related to the possibility of a party failing to comply with the provisions of the agreement, which could pose a risk of financial loss and possible legal disputes for the Company.

[1] 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

The Company's Management Board recognizes the aforementioned risks and takes measures to mitigate the impact of the above factors on current and future agreements.

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 attractiv, 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 Company's 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)[2]. In addition, there is a rapid development in 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 Company's 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[3].

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[4].

Partnering risk

In November 2021, the Company's cooperation with Mylan, which under an agreement entered into in 2016 (until its annexation in April 2021) held exclusive rights to sell MabionCD20 in all European Union and Balkan countries, and priority rights to conclude a commercialisation agreement for MabionCD20 in the USA, came to an end. Mylan provided support to the Company also in the process of registration of MabionCD20 with the EMA.

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 not be implemented with the support of a strategic partner chosen in the process carried out in cooperation with Rothschild & Co. and Plexus Ventures LLC.

[2] Global Oncology Trends 2019, IQVIA Institute
[3] Raport L.E.K opracowany na zlecenie Spółki, publikowany 8 lutego 2022 r
[4] http://www.pharmatimes.com/news/sandoz_dumps_us_filing_for_biosimilar_rituximab_1258681

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 opinion of the Company's Management Board, significantly reduce the risk of not achieving ultimate success. In addition, the Company's Management Board constantly monitors the progress of research and development, and implements some operational and procedural solutions to ensure a high efficiency of the process.

Risk of underestimating the costs of MabionCD20 manufacture and launch

According to assumptions very generally adopted by the biotechnological industry, the development and production of a single biosimilar which meets global standards lasts about 8–10 years and costs between USD 100 and 200 million[5]. 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 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

[5] https://www.gabionline.net/reports/comparison-of-the-cost-of-development-of-biologicals-and-biosimilars

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 Konstantynów 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 Konstantynów 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 Konstantynów 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 in the period of 2022–2026 requires the manufacturing capacity at the existing facility to be doubled. The Company has procured equipment supplies so that the contracted product volume can be delivered by 2026. The extension of the existing facility with an additional building would 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, or the need to change the trial protocol;
- 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 (Good Clinical Practice) 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 and can affect clinical activities in the other selected countries.

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. The work in progress, as well as the procedures and action plans in place, are also reviewed by external specialists, including experts in GCP operations.

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 Paul Ehrlich Institut (PEI), 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 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 S.A. are diverse, the Company's 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 and services. 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 S.A. 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. At the date of this report, there are no pending proceedings regarding any infringement of intellectual and industrial property by the Company. 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.

2) Risks related to financial aspects

Liquidity risk

In 2021 and in H1 2022, 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 S.A. 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. Efforts to acquire a strategic investor are being vigorously and continuously pursued.

In line with the current assumptions for years to come, the Company's strategic objective in the area of therapeutic products remains further development, manufacturing, and sales of medicines used in the treatment of most serious cancer and autoimmune, diseases, including rare diseases, while in the area of contract manufacturing, the Company's strategic objective has become cooperation with Novavax (USA) in the area of development and production of new protein vaccines used in the fight against the pandemic. Moreover, the CDMO business will be developed in the coming years and the dynamics of this development will depend on the available new manufacturing and research capacities that the Company plans to expand. As a result of the annexes to the agreement entered into with Novavax, the Company perceives a need to review and resume the work on updating the schedule of project work aimed at developing MabionCD20 for registration in the European and US markets. The work plan for the next few years will be updated with account taken of the current format of cooperation with Novavax and the development of contract activities as a CDMO. As a result, the schedule and the expected expenditure on further work on the registration of MabionCD20 may change, which will also have a direct impact on the Company's strategy, including its strategy in the area of financing its current, research, and investment activities.

The Company's Management Board 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 also in a change to the financing strategy adopted in January 2021.

Risk related to the funding obtained

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

- *"Development and scaling of the innovative process for manufacturing the therapeutic recombined monoclonal antibody to enable the industrial implementation of the first Polish biotechnological medicine for oncological and autoimmune therapies"*
  - Value of the project: PLN 54,188 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. In 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). In May this year, the Company was informed that the Final Report and the final payment request had been accepted, and it received the final tranche of funding. Thus, the three-year period of the Project began.

> *"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 – 31.12.2023

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 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. On 19 April 2022, the Company concluded an annex to the Project funding agreement with the Ministry of Development Funds and Regional Policy, under which the eligibility period for expenditure has been extended to 31 December 2023 (previous deadline: 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 extended, among other things, through 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 thousand
  - Value of European Regional Development Fund co-financing: PLN 396 thousand
  - Project implementation period: 01.07.2021 – 30.06.2023.

The agreement for co-financing the Project as part of the Regional Operational Programme of the Łódzkie Voivodeship for 2014–2020 was entered into in December 2021. The main objective of the Project is to deploy an innovation process at Mabion S.A. 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 objective will be possible to achieve with the use of a high-performance and reproducible electrophoretic method.

The Company's liabilities arising from its agreement with Novavax and additional orders have necessitated a change in the timing of the Project. Consequently, the Company applied to the Intermediate Body (IB) for an extension of the Project implementation period. In June 2022, the IB agreed to extend the Project until 30 June 2023 (previous deadline: November 2022). In September 2022, the annex in question was signed.

> *"Development of an analytical methods panel to characterise immunogenicity in a clinical trial targeting rheumatoid arthritis patients using rituximab as a therapeutic substance"*
  - Value of the project: PLN 3,724 thousand
  - Value of European Regional Development Fund co-financing: PLN 2,368 thousand
  - Project implementation period: 18.09.2021 – 30.06.2023

The agreement for co-financing the Project as part of the Regional Operational Programme of the Łódzkie Voivodeship for 2014–2020 was entered into in May 2022. The subject matter and main objective of the Project is to boost R&D activity through the development and implementation of a new Company-wide panel of analytical methods to assess the immunogenicity of rituximab-based medicinal products in a clinical trial aimed at demonstrating the similarity between the biosimilar medicine MabionCD20 and the originator medicines MabThera® (EU) and Rituxan® (US) in the rheumatoid arthritis patient population.

The Project will result in the implementation of an innovative solution in the form of a product, i.e. a service consisting in running a panel of analytical methods for assessing the immunogenicity of biological products in clinical trials, rendered commercially. In a wider perspective, implementing the result of the Project, i.e. R&D work, will also contribute to deployment of innovation in the production process of MabionCD20 as an obligatory point in the registration procedure with the EMA and the FDA. The Company's liabilities arising from its agreement with Novavax and additional orders as well as the limited possibility of conducting the planned clinical trial in Ukraine present risks that can translate into delays in the adopted timetable for the Project.

In recognition of these risks, the Company has applied to the Intermediate Body for an extension of the implementation period until 31 December 2023, and was granted formal consent.

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.

During the project period (i.e. after the completion of project work and the settlement of the project in question with the IB), there are risks associated with the achievement of specific results and indicators assumed under the project. Should the latter not be met, there is a risk that part or all of the funding will have to be repaid, together with statutory interest calculated as from the date of payment of the tranche in question. The amount of reimbursement is decided by the relevant Body.

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.

Exchange rate risk

Some of the raw materials necessary for the production of the active substance are purchased in foreign currency (USD and EUR), or , respectively, at the date of purchase, the sales price is converted into the Polish currency. 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. In addition, some of the laboratory equipment and reagents used for research and development are also purchased 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, increase research and development costs and current costs, which may have an adverse effect on the Company's financial results.

On the other hand, 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 pursues a policy as part of which it hedges its foreign currency position by maintaining an adequate level of cash in foreign currency using such a natural hedging for expected outlays or expenditure in a foreign currency. 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.

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 Board does not deem it necessary to purchase instruments to mitigate the impact of changes resulting from temporary fluctuations in foreign exchange rates on the Company's financial results and capital position.

Risk of changes in interest rates

The Company is exposed to interest rate risk primarily in respect of its financing (interest-bearing liability) in the form of a borrowing from Glatton, which bears interest based on the 3M WIBOR rate for interbank deposits. The Company does not hedge this item given the expected repayment anticipated by the end of 2022. To limit the impact of changes on current financial performance, the Company invests surplus cash on an ongoing basis. Should there be significant levels of variable rate funding, the Company will consider the use of hedging derivatives backed up by an appropriate analysis of the risks and their impact on the current and future financial performance.

Risk related to operations in the Łódź Special Economic Zone

The Company 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, or interpretations as to the classification of particular items of income earned by the Company as being realised in the special economic zone in accordance with the permits held. 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, further operations of Mabion S.A. in the LSEZ may become unfavourable and increase tax burden.

3) Formal and legal risk

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 Company's 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. The Management Board of the Company monitors on an ongoing basis any changes in the provisions of tax law which are of crutial importance from the Company's point of view, and the manner of their interpretation, also consulting external experts in this area, and in the event of significant doubts, the Company applies for relevant interpretations to the competent tax authorities.

Risk related to administrative decisions

The Company is unable 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.

4) Other risk

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 (including raising electricity prices), 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. The Company's Management Board recognises the risk that the current situation in Ukraine will make it difficult or impossible to conduct the planned clinical trial in that country.

The economic situation in the East – due to the war in Ukraine – has caused the Company 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 continuous increases in 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 Company's Management Board is of the opinion that the invasion and its effects do not affect the measurement and classification of assets and liabilities in the financial statements as at 30 June 2022. The Management Board has assessed the possible impact on the Company and has included appropriate disclosures in the financial statements to describe 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.

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 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.

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 of the Company 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 Company's 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

4. ANALYSIS OF THE FINANCIAL AND ASSETS POSITION OF MABION S.A.

4.1. Principles for drawing up the semi-annual condensed financial statements

The condensed semi-annual financial statements of the Company for the period from 1 January 2022 to 30 June 2022 have been drawn up in conformity with the International Financial Reporting Standards (IFRS) as approved by the European Union at the reporting date. The financial statements cover a comparative period from 1 January to 30 June 2021, and comparative data as at 31 December 2021. 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 condensed semi-annual financial statements, with the exception of the cash flow statement, have been prepared on an accruals basis.

The accounting policies applied to draw up the condensed semi-annual financial statements are the same as those applied to draw up the 2021 annual financial statements. The condensed semi-annual financial statements do not include all the information required in the full financial statements compliant with IFRS as adopted for application in the European Union ("IFRS") and should be read in conjunction with the audited financial statements of the Company for the financial year ended 31 December 2021.

There were no changes in the rules for measuring assets and liabilities and financial result in H1 2022. The condensed semi-annual 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.

The condensed semi-annual financial statements of the Company for the period from 1 January 2022 to 30 June 2022 have not been audited. However, they have been reviewed by the audit firm PricewaterhouseCoopers Polska spółka z ograniczoną odpowiedzialnością Audyt sp.k.

4.2. Financial condition of Mabion S.A. after the first half of 2022

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

In H1 2022, there were no factors or events, including those of an unusual nature, other than those indicated in the other sections of the report, which would have a significant impact on the Company's condensed financial statements.

4.4. Factors to affect the results to be achieved within at least the next quarter

The main factors to affect the Company's performance in the coming quarters are:

- implementation of the commercial contract manufacturing agreement concerning the Nuvaxovid® antigen for Novavax, including its progress and schedule, and execution of additional orders placed under the agreement;
- the scope and timing of the work required to conduct the bridging clinical trial and submit a new marketing authorisation application (MAA) for MabionCD20 on the basis of the Scientific Advice procedure with the EMA;
- implementation of the work related to product stability tests and similarity and comparability tests for MabionCD20 originating from the large-scale validation batches and achievement of the expected results;
- costs of ongoing research and development for MabionCD20 and other medicines in the Company's pipeline;
- implementation of the Company's financing strategy adopted in 2021, including the possibility of acquiring a strategic investor and/or leveraging debt financing;
- possibility of establishing cooperation with new partners for the development of the Company's current or future therapeutic projects;
- possibility of acquiring a distribution partner or partners for the EU and US markets for MabionCD20;
- proceeds from the assistance granted from European funds and the possibility of obtaining additional funds from the EU;
- timely disbursement of funds by state institutions dealing with the distribution of means under projects co-financed from EU funds;
- staff costs and general administration costs of the Company;
- design and preparatory work for the launch of construction of another production plant on the existing plot of land of Mabion S.A. in Konstantynów Łódzki;
- to finance the planned increase in production capacity, taking into account the intensification of activities related to the new production plant construction project;
- exchange differences resulting from changes in foreign currency exchange rates;
- inflation and interest rates affecting the level of generated costs;
- receipts/refunds of costs incurred may be affected by possible delays in ongoing discussions or unforeseen departures from the schedules of agreements already signed.

On 24 February 2022, Russia invaded Ukraine, a neighbouring country of Poland. The international community has imposed heavy sanctions on Russia, targeting specific entities and economic sectors. As at the date of this report, the armed conflict in Ukraine is still in progress, while both the armed conflict itself and the

sanctions imposed have had no direct impact on the Company's business. In December 2021, the Ministry of Health in Ukraine granted authorisation for the Company to conduct a clinical trial of MabionCD20 in patients with RA in Ukraine – 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's Management Board acknowledges the risk that the situation in Ukraine, both now and in the years to come, may make it difficult or impossible to conduct the planned clinical trial in that country.

The Company has analysed the impact of the Russian military invasion of Ukraine and its current and future possible consequences for the Company. More detailed information on the risks associated with the current situation is included in section 3.5 of this report. The Company's Management Board is of the opinion that the invasion and its effects do not affect the measurement and classification of assets and liabilities in the financial statements as at 30 June 2022.

All the above mentioned phenomena may have a direct impact on the financial situation of the Company.

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

The Company has not published financial result forecasts for 2022.

5. SHARES AND SHAREHOLDERS

5.1. Share capital structure

As of 30 June 2022, the Company's share capital amounted to PLN 1,616,182.60 was 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.

Changes in the share capital of the Company in H1 2022 and up to the date of this report

As of 1 January 2022, 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/ The total number of votes resulting from all issued shares of the Company is 17,731,326 votes.

On 28 January 2022, 500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were allotted. The shares were granted within the meaning of Article 451 §2 of the Commercial Companies Code as soon as they were recorded on the securities accounts of the eligible persons and, pursuant to Article 452 §1 of the Commercial Companies Code, with the granting of the shares the share capital of the Company was increased to PLN 1,616,182.60. The aforementioned shares were issued under the 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. 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 shares were taken up for cash contributions made in full before the shares were allotted. On 18 January 2022, the Central Securities Depository of Poland (Krajowy Depozyt Papierów Wartościowych S.A., 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. 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 April 2022, the Board of the Warsaw Stock Exchange (Giełda Papierów Wartościowych w Warszawie S.A.) 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. On 21 April 2022, the KDPW issued a statement whereby, at the Company's request, it was decided to assimilate the above shares into the depository system on 26 April 2022. Thus, the condition for the introduction of the shares to trading on the WSE primary market on 26 April 2022 was fulfilled.

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, no. 12/2022 of 20 April 2022, and no. 13/2022 of 21 April 2022.

On 25 August 2022 (an event after the balance-sheet date), 500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were allotted. The shares were granted within the meaning of Article 451 §2 of the Commercial Companies Code as soon as they were recorded on the securities accounts of the eligible persons and, pursuant to Article 452 §1 of the Commercial Companies Code, with the granting of the shares the share capital of the Company was increased to PLN 1,616,232.60. The shares have been issued as part of the Incentive Scheme referred to above. On 4 July 2022, the Company issued 500 B series registered subscription warrants to which eligible persons are entitled as part of the implementation of the Incentive Scheme for 2021. Each subscription warrant entitled to take up 1 S series share of the Company at the issue price equal to the nominal value of shares. All eligible persons submitted declarations on taking up their S series shares on 4 July 2022. The S series shares were issued as part of a conditional share capital increase, therefore no allocation of shares took place. The shares were taken up between 4 July 2022 and 25 July 2022 together with the payment for the shares made by the respective individuals. All S series shares were taken up for cash contributions made in full before the shares were allotted. On 24 January 2022, the 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. 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.

As at the date of this report, 500 S shares of the Company referred to above have not been admitted to stock exchange trading on the main market of the WSE.

The Company informed of the above events in Current Reports no. 27/2022 of 8 August 2022, no. 28/2022 of 24 August 2022, and no. 29/2022 of 30 August 2022.

Accordingly, As of the date of submission of this report, the Company's share capital amounts to PLN 1,616,232.60 and is divided into 16,162,326 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,
- 00,000 O series ordinary bearer shares,
- 1,920,772 P series ordinary bearer shares,
- 11,000 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. The total number of votes resulting from all issued shares of the Company is 17,732,326 votes.

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

To the best knowledge of the Company, as at the date of this report, i.e. 29 September 2022, the following shareholders hold at least 5% of votes in the total number of votes at the General Meeting of the Company.

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%	18.43%
2.	Maciej Wieczorek 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.	Other	10,295,878	10,295,878	63.70%	58.06%
	Total	**16,162,326**	**17,732,326**	**100%**	**100%**

* Mr Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 58.79% of the share capital of Celon Pharma S.A. and 68.15% of the total number of votes in Celon Pharma S.A.

To the best knowledge of the Company, as at the date of the previous interim report, i.e. report for Q1 2022 published on 27 May 2022, the following shareholders held at least 5% of votes in the total number of votes at the General Meeting of the Company:

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 Wieczorek 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	8,792,729	8,792,729	54.40%	49.59%
	Total	**16,161,826**	**17,731,826**	**100%**	**100%**

* Mr Maciej Wieczorek held 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 58.8% of the share capital of Celon Pharma S.A. and 68.16% 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.

5.3. Number of shares held by managing and supervising persons

To the knowledge of the Company, as at the date of this report, i.e. 29 September 2022, and as at the date of the previous interim report, i.e. the report for Q1 2022 published on 27 May 2022, the managing persons hold shares in the Company in the following quantities:

	Shareholding as at the date of H1 2022 report (i.e. 29 September 2022).	Shareholding as at the date of Q1 2022 report (i.e. 27 May 2022).
Krzysztof Kaczmarczyk – President of the Management Board	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.	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.
Slawomir Jaros – Member of the Management Board (*)	holds directly 5,468 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; in addition, a person with regard to whom there is a presumption of agreement within the meaning of Article 87(4)(1) of the Act on Public Offering (...) directly holds 70 shares in the Company with a par value of PLN 0.10 each	holds directly 5.255 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; in addition, a person with regard to whom there is a presumption of agreement within the meaning of Article 87(4)(1) of the Act on Public Offering (...) directly holds 40 shares in the Company with a par value of PLN 0.10 each*
Grzegorz Grabowicz – Member of the Management Board	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.	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.
Adam Pietruszkiewicz – Member of the Management Board	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 0.06% of votes at the General Meeting.	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.

* by omission, the holding of this person was not disclosed in the Q1 2022 report and in the 2021 annual report.

To the Company's knowledge, the Members of the Supervisory Board of Mabion S.A. do not hold, nor have they held during the period referred to above, any shares in the Company.

Members of the Management Board and Supervisory Board of Mabion S.A do not hold, nor have they held during the aforesaid period, any rights to shares in the Company other than those indicated in this section.

As of 2018, there was an Incentive Scheme in place at the Company for the period 2018-2021. As part of the Incentive Scheme, the persons participating in it – the eligible persons, i.e. the key individuals in the Company – could obtain the right to take up A and B series subscription warrants, which were issued free of charge. In accordance with the resolutions of the Company's Supervisory Board of the different years of the Incentive Scheme, the persons entitled to take up subscription warrants for the different years in the period 2018–2020 as at the date of the previous interim report, i.e. 27 May 2022, included persons sitting on the Management Board of the Company:

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

In line with the terms and conditions of the Incentive Scheme, each A and B series subscription warrant entitled to subscribe, respectively, for 1 R and 1 S series share, and the issue price of shares for holders of A series subscription warrants was PLN 0.10 per each S series share, and for holders of B series warrants, PLN 91 per each R series share. The rights attached to the subscription warrants could be exercised until 31 July 2022.

A series subscription warrants for the different years in the period 2018–2021 were ultimately not awarded due to failure to meet the conditions set out in the Incentive Scheme, including but not limited to the failure to achieve the market target during the term of the Incentive Scheme. B series subscription warrants were awarded in each year of the Incentive Scheme, and the last time as part of the Incentive Scheme for 2021. In January 2022, the Supervisory Board conferred on the eligible persons the right to take up a total of 500 B series subscription warrants for 2021. On 4 July 2022, the B series subscription warrants for 2021 were issued and taken up by the eligible persons. All eligible persons made statements on 4 June 2022 on taking up the S series shares to which they are entitled. The S series shares were issued as part of the conditional share capital increase and therefore no allotment of shares took place. The shares were taken up between 4 July 2022 and 25 July 2022 together with the payment for the shares made by the respective individuals. On 25 August 2022, the shares were recorded in the securities accounts of the eligible persons, and thereby the allotment of shares within the meaning of Article 451 §2 of the Commercial Companies Code took place.

Due to the lapse of the deadline for exercising the rights attached to A series subscription warrants as part of the Incentive Scheme, i.e. on 31 July 2022, the entitlements to take up R series shares referred to above have come to an end.

Therefore, at the date of this report, the Company's managing and supervising persons are not entitled to shares in the Company.

6. OTHER MATERIAL INFORMATION AND EVENTS

6.1. Proceedings pending before a court, an authority competent to conduct arbitration proceedings, or a public administration body

In the period of H1 2022 as well as at the date of this report, no material proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority, or public administration authority.

6.2. Other information trelevant for the assessment of the staff, property, financial condition, financial result and changes thereof, as well as information that is relevant for the assessment of the possibility of Mabion S.A. fulfilling its obligations.

Composition agreement with Altiora d. o.o.

On 13 January 2022, the Company has signed with Altiora d. o.o., based in Zagreb ("Altiora"), 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, initiated by a lawsuit filed by Altiora, which was received by the Company on 31 March 2021, in relation to one of the agreements between the parties concerning the delivery of clinical trials ("Master Service Agreement" of July 2013). 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. However, considering the perspective of a long-term court dispute, and the related legal costs, as well as reasonable assumptions as to Altior'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. Further to that, the parties have unconditionally and irrevocably waived all claims under the agreement in question. 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 above event brought the dispute with Altiora to an end, which the Company reported on, among other things, in the Company's annual report for 2021.

Ordinary General Meeting of Mabion S.A.

On 21 June 2022, the Ordinary General Meeting of Mabion S.A. was held, which, among other things, adopted a resolution on the distribution of profit for the financial year 2021. Pursuant to the resolution, the Company's net profit for the financial year ending 31 December 2021, in the amount of PLN 1,903,385.37, was earmarked in its entirety to cover previous years' losses.

Furthermore, the Ordinary General Meeting of the Company also adopted a resolution to amend the Company's Articles of Association by, inter alia, changing the Company's business objects. The business objects were broadened following the Company's analysis of the possibilities of increasing the efficiency of its operations and in order to enable meeting the Company's intentions. The amendment to the Articles of Association of the Company will allow the latter to undertake activities in additional and complementary areas and thus will not have a material impact on the Company's core business. On 14 July 2022, the amendments to the Company's Articles of Association were registered by the District Court for Łódź-Śródmieście in Łódź, 20th Commercial Division of the National Court Register, of which the Company informed in Current Report no. 24/2022 of 18 July 2022.

As of the date of this report, there is no other information that is relevant for the assessment of the staff, property, financial condition, financial result and changes thereof, as well as information that is relevant for the assessment of the possibility of Mabion S.A. fulfilling its obligations.

Management Board of the Company

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, 29 September 2022

MABION

SCIENTIFIC AND INDUSTRIAL COMPLEX OF MEDICAL BIOTECHNOLOGY

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