MABION

Other information to the quarterly report of Mabion S.A. for Q3 2022

Konstantynów Łódzki, 24 November 2022

Contents

1 SELECTED FINANCIAL DATA

	in PLN thousand		in EUR thousand	
SELECTED FINANCIAL DATA	**from 01.01.2022 to 30.09.2022**	**from 01.01.2021 to 30.09.2021**	**from 01.01.2022 to 30.09.2022**	**from 01.01.2021 to 30.09.2021**
Net income from sales of products, commodities, and materials	121,035	1,590	25,818	349
Operating profit (loss)	3,763	-34,840	803	-7,643
Gross profit (loss)	7,499	-35,203	1,600	-7,722
Net profit (loss)	7,499	-35,203	1,600	-7,722
Net cash flows from operating activities	-24,254	-10,995	-5,174	-2,412
Net cash flows from investing activities	-6,533	-17,778	-1,394	-3,900
Net cash flows from financing activities	-7,288	111,456	-1,555	24,450
Total net cash flows	-38,075	82,683	-8,122	18,138
	30.09.2022	**31.12.2021**	**30.09.2022**	**31.12.2021**
Total assets	214,443	184,237	44,035	40,057
Liabilities and provisions for liabilities	153,630	130,924	31,547	28,465
Long-term liabilities	40,052	34,787	8,225	7,563
Current liabilities	113,577	96,137	23,323	20,902
Equity	60,814	53,313	12,488	11,591
Share capital	1,616	1,616	332	351
Number of shares (in pcs)	16,162,326	16,161,326	16,162,326	16,161,326
Profit (loss) per ordinary share (in PLN/EUR)	13.27	11.40	2.72	2.48

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 September 2022 (4.8698 PLN/EUR) and 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 being the arithmetic average of the average exchange rates announced by the National Bank of Poland for the euro effective as at the last day of each month in the period of nine months ended 30 September 2022 and the period of nine months ended 30 September 2021 (respectively: 4.6880 PLN/EUR and 4.5585 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. On 29 October 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 (targeted therapies). The Company's most advanced project 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.

Since 2021, the Company has been employing technologies it had developed also to execute commercial orders for partners in the field of manufacturing, analytics, and development of biopharmaceuticals (acting as a Contract Development and Manufacturing Organisation, CDMO). The Company's experience in the development, analytical, and regulatory areas made it possible for it to complete a commercial order 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 a result of the signing of annexes in Q3 2022 significantly expanding the scope and duration of the cooperation with Novavax, 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.

2.2 Bodies of the Company

2.2.1 Management Board

As at 30 September 2022 and as the date of submitting 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. Adam Pietruszkiewicz – Member of the Management Board,
- Mr. Grzegorz Grabowicz – Member of the Management Board

No changes in the composition of the Company's Management Board occurred in Q3 2022 and up to the date of submitting this report.

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 implementation of CDMO contracts, 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 in the CDMO area, 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.

2.2.2 Supervisory Board

As at 30 September 2022 and as the date of submitting 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),
- 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.

No changes in the composition of the Company's Supervisory Board occurred in Q3 2022 and up to the date of submitting this report.

2.3 Share capital structure

As at 30 September 2022 and as of the date 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,
- 300,000 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.

Changes in the Company's share capital in Q3 2022

As at 1 July 2022, the Company's share capital amounted to PLN 1,616,182.60 and was divided into 16,161,826 shares with a nominal value of PLN 0.10 each. The total number of votes resulting from all issued shares of the Company is 17,731,826 votes.

On 25 August 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 1,616,232.60. 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 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. The subscription warrants were taken up free of charge by eligible persons, i.e. persons appointed by the Company's Supervisory Board. 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, amounting to PLN 0.10 per one share. All eligible persons submitted declarations on taking up their S series shares on 4 July 2022. 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 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 Securities Depository 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.

The Company will undertake steps for the admission of the 500 S shares of the Company referred to above to 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.

2.4 Shareholding structure

To the best knowledge of the Management Board of the Company, as at the date of this report, i.e. 24 November 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%	18.43%
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., 58.84% of the share capital of Celon Pharma S.A. and 68.19% of the total number of votes in Celon Pharma S.A.

In the period from the date of submitting the previous interim report, i.e. the report for H1 2022 published on 29 September 2022, to the date of this report, there were no changes in the ownership structure of significant blocks of shares of the Company.

2.5 Number of shares held by managing and supervising persons

As at the date of this report, i.e. 24 November 2022, Members of the Management Board of Mabion S.A hold the following quantities of Company's shares:

Management Board	
Krzysztof Kaczmarczyk	holds directly 7,140 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.04% of the Company's share capital and entitling to 0.04% of votes at the General Meeting.
Sławomir Jaros	holds directly 5,468 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
Adam Pietruszkiewicz	holds directly 10.000 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.06% of the Company's share capital and entitling to 0.06% of votes at the General Meeting.
Grzegorz Grabowicz	holds directly 700 shares of the Company with a nominal value of PLN 0.10 each, constituting 0.004% of the Company's share capital and entitling to 0.004% of votes at the General Meeting.

As at the date of this report, i.e. 24 November 2022, members of the Supervisory Board of Mabion S.A. do not hold – to the best of the Company's knowledge – any shares in the Company.

Members of the Management Board and Supervisory Board of Mabion S.A. do not have any rights to Company's shares.

In the period from the date of submitting the previous interim report, i.e. the report for H1 2022 published on 29 September 2022, to the date of this report, there were no changes – to the best of the Company's knowledge – in the holdings of the Company's shares by management and supervisory personnel.

2.6 Changes in the organisation of the capital group

Mabion S.A. has no subsidiaries and does not form a capital group.

3 OPERATIONS OF MABION S.A.

3.1 Object of activity

The Company's core business includes:

- 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 the antigen, under which the collaboration is currently scheduled for 2022–2026,
- the development, analytics and manufacture of its own medicine candidates.

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. At the date of this report, work is under way 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 an ongoing project concerning a biosimilar medicine, MabionCD20, for which MabThera/Rituxan (rituximab) (Roche) are reference products. It is the Company's most advanced project. The Company's project portfolio also includes the possibility of developing MabionCD20 as an innovative product dedicated to the treatment of orphan autoimmune disorders.
In line with the previous classification, the group of active projects also includes MabionMS and MabionEGFR, for which the Company is not currently incurring capital expenditure, as they are in standby, awaiting continuation as part of a partnership model.

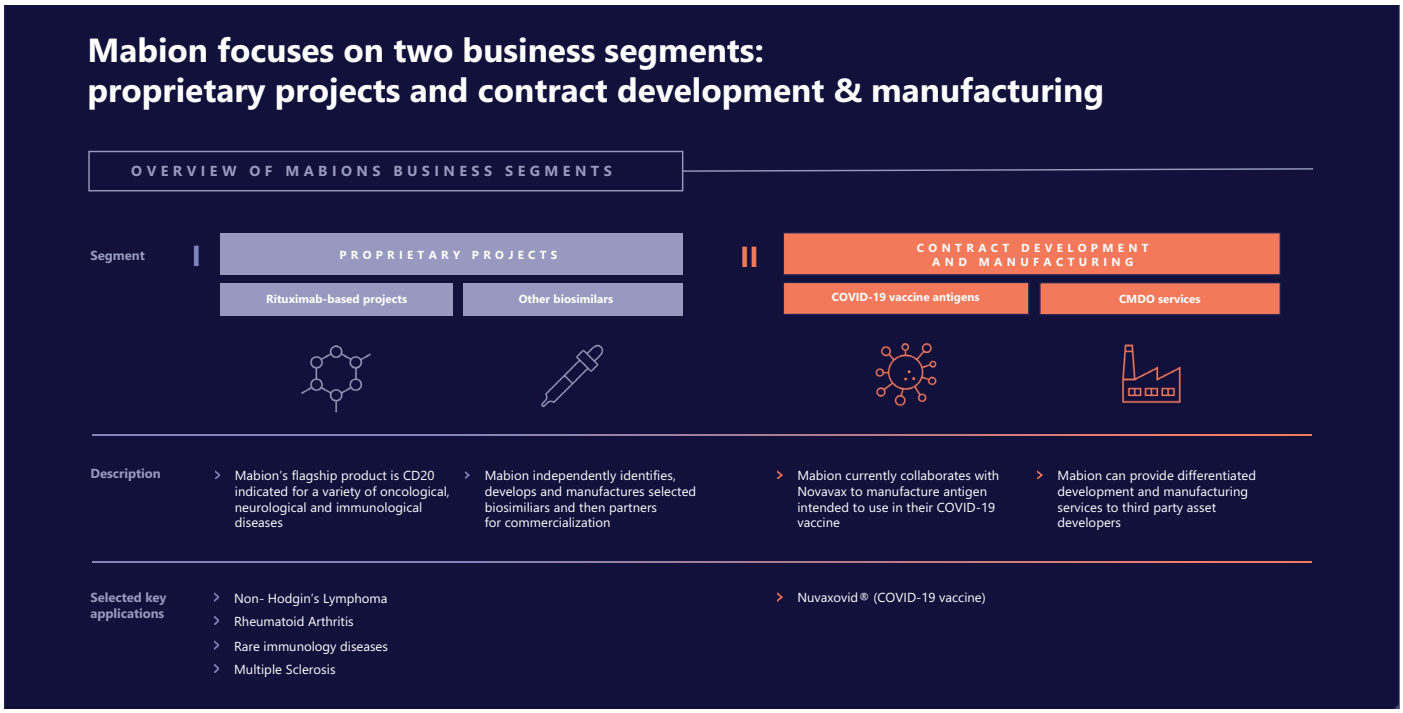
Projects involving the development and marketing of new medicinal products

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 (CDMO). 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
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 Q3 2022 were related to the Nuvaxovid® and MabionCD20:

Nuvaxovid®

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 Statement of Work #1 (SOW#1) with Novavax, under which the Company carries out commercial manufacturing of the Nuvaxovid® antigen, based on the GMP standard, for Novavax.

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. In Q3 2022, the parties agreed to changes to the original manufacturing schedule until the new arrangements are finalised and the schedule updated. Then, in an annex to the agreement, which is further described in more detail, 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.

In H1 2022, under the existing Manufacturing Agreement, the Company signed two further additional orders with Novavax in the form of:

- **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. In Q3 2022, the transfer of analytical methods was completed and sample analysis, currently under way at the Company, commenced.
- **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

[2] Own study of the Company.

of vaccine antigens of the Nuvaxovid® product. The work on cell banks preparation has been completed.

- **Statement of Work #4** ("SOW#4") covering 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.
- **Statement of Work #5** ("SOW#5") covering 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 were conducted according to the agreed schedule. Their results are summarised in two reports accepted by Novavax in October and November 2022, which constituted the basis for the settlement of SOW#5 and the completion of the order in accordance with its stated objective and by the set deadline.

Subsequently, in Q3 2022, further additional orders were signed in the form of:

- **Statement of Work #6** ("SOW#6") covering 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.
- **Statement of Work #7** ("SOW#7") entailing the Company's generation of virus 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. In November 2022, the work related to the preparation of the viral banks was completed and their evaluation by analytical testing began. According to the current schedule, the analytical tests should be completed and the banks released for trading in H1 2023.
- **Statement of Work #8** ("SOW#8") entailing 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. By the time of publication of this report, analyses had been carried out for 2 time points, in line with the original timetable for the work.

Moreover, 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. 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 referred to above, 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.

On 23 November 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 #9 (SOW#9).

The scope of SOW#9 involves the Company's tasks consisting in conducting peptide mapping analysis for the active substance (DS) as well as the finished product (DP) of rS SARS-CoV-2 protein samples of Novavax products – both Wuhan and Omicron variants. The contracted tasks involve a method feasibility study, method validation and regular testing of samples produced at Mabion and other entities providing manufacturing services to Novavax. If required by Novavax, routine testing of samples will be carried out in a GMP (Good Manufacturing Practice) compliant environment.

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 for MabionCD20.
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.

As regards the research and development work on MabionCD20 carried out in Q3 2022 and until the date of this report, the Company considers the following activities to be successfully completed:

- 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 resulted initially, among other things, from the cooperation commenced with Novavax which involved contract manufacturing of the vaccine antigen, and subsequently – an additional factor posed by the current situation in Ukraine. As a result of the annexes entered into with Novavax in Q3 2022, the Company continues to work on updating the project 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 Description of significant achievements and failures of the Company in Q3 2022 and after the balance-sheet date

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

On 6 July 2022, the Company signed an 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, 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. Under the annex, it was agreed that the Borrowing will be repaid in two tranches: the first tranche of PLN 5 million will be repaid by 30 September 2022, while the second tranche of PLN 10 million – 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.

Under the terms and conditions of the annex, on 28 September 2022 the Company repaid the first tranche of the loan in the amount of PLN 5 million together with due interest. Subsequently, on 2 November 2022 (an event after the balance-sheet date), the Company effected an early repayment of the second tranche in the amount of PLN 10 million, together with due interest, and therefore, as at the date of this report, the Company's liability under the loan has been fully repaid.

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, 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, 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, the Company entered into an addendum to the commercial contract manufacturing agreement with Novavax, Inc. and an annex to Statement of Work No. 1 (SOW#1) for the manufacture of the COVID-19 vaccine antigen under the name of NVX- CoV2373, in compliance with the GMP standard and at a commercial scale. As a result of the Annex the Agreement's duration has been

extended until the end of 2026 and, based on the schedule agreed between the parties, the Company will either receive remuneration for the Product batches manufactured or remuneration for the readiness to manufacture the Product based on the production capacity guaranteed to Novavax.
In the opinion of the Management Board, the Annex does not change the subject matter of the Agreement, but simply the mechanics of income calculation. In the original Agreement, Company's remuneration was determined depending on the manufactured batches in line with the order from the contractor, whether the manufactured goods were collected or not. The Annex has introduced a minimum remuneration (which varies from month to month, as specified in the schedule), which is independent of the occurrence of production (the so-called slot fee). In addition, under the Annex, there is no longer an option for a rolling budget of "guaranteed" orders.
As a result, the theoretical amount of total income under the agreement with Novavax before and after the annex was signed, under similar assumptions, calculated for the period from 22 September 2022 to the end of the Agreement, has changed. As the Company is capable of separating the number of batches of the active substance produced up to the date of the Annex from batches produced (or planned to be produced) after that date, then – in accordance with IFRS 15 – the Annex signed on 22 September 2022 was recognised as if, at its date, the Agreement in force had been terminated and a new agreement had been concluded.

Nevertheless, the changes introduced by the Annex do not alter the conditions for the performance obligation under the Agreement to be deemed to have been fulfilled over time. Therefore, income earned by the Company under the Annex is still recognized over time, in proportion to the degree to which the performance obligation has been fulfilled (the degree to which the work has progressed), using an input-based method.

Accordingly, as at 21 September 2022, the Company settled the existing Agreement and recognised income for the period up to the date of the Annex - at the value set out in the Agreement, but taking into account the arrangements contained in the Annex, which effectively reduced the income due to the Company under the provisions of the original Agreement for Q3 2022 (taking into account the amount of the slot fee during this period). The total amount of income to be settled under the Annex constituting the new agreement was reduced by the corresponding amount of income recognised under settlement of the original Agreement.
The scope of cooperation 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.
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 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. In 2026, the Company should achieve approximately 30% of the total value (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, 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 Statement of Work No. 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 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.

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 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 Agreement.

Taking into account the model adopted for the settlement of income from the agreement with Novavax, as well as the costs incurred and expected on account of the implementation of the agreement, taking into account purchases of materials made and expected to be made, the Company's Management Board estimates that the value of income from the implementation of the agreement with Novavax for the entire year 2022 should stand at a level of approximately PLN 150–160 million, of which the expected level of income, not taking into account income from the purchase of materials, but only income from sales and lease should amount to approximately PLN 80–90 million. The

above estimate may change should factors beyond the Company's control occur, such as, but not limited to: foreign currency exchange rates, the actual level of incurred costs and the value of expected agreement expenditures (including energy and other utilities), the amount of actual material purchases made, and changes in the agreement to take into account additional activity or higher volumes of orders resulting in a change in the level of expected income from the overall agreement.

Credit Committee of the European Bank for Reconstruction and Development approves financing for the Company

On 18 October 2022 (an event after the balance-sheet date), the Company received information that the Credit Committee of the European Bank for Reconstruction and Development ("EBRD") has given its approval for the provision of financing to the Company in the form of a secured long-term loan amounting to USD 15 million ("Loan"). The Loan is intended in particular to finance the expansion and modernisation of the Issuer's current facility located in Konstantynów Łódzki. The investment is related to the commercial contract manufacturing carried out under an agreement with Novavax, Inc., referred to in point 3.1 hereof, as well as other potential CDMO projects. It was agreed that the funding will also be partly used to refinance Company's existing debt. The Loan is to be granted by the EBRD for a period of 2 years as of signing the agreement, with early repayment possible. It will bear interest at a variable rate based on the SOFR, plus EBRD's margin.

The EBRD Credit Committee's approval represents an interim step in the process of obtaining the funds and is not tantamount to the completion of this process and the EBRD's commitment to disburse the resources. The availability of the latter will depend, among other things, on entering into a credit agreement with the EBRD, of which the Issuer will inform in a separate report, and on the fulfilment of the conditions precedent, including the establishment of appropriate collateralisation.

The Company informed about the event in Current Report no. 32/2022 of 18 October 2022.

Termination of 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 26 April 2022 (an event after the balance-sheet date), the Management Board of Mabion S.A decided to terminate the co-financing agreement for the project "Expansion of the Research and Development Centre of Mabion S.A. – research on the new generation of medicines", entered into in June 2018 as part of Measure 2.1 Support for investment in R&D infrastructure of enterprises of the Operational Programme Smart Development 2014–2020 co-financed by the European Regional Development Fund ("Agreement" and "Project" respectively).

The termination of the Agreement was related to the fact that the Company had been considering a change in the scope of the planned investment and that it had not been possible to implement the Project on the terms and conditions and within the timeframe stipulated in the Co-financing Agreement. Pursuant to the Agreement, the total cost of the Project was set in 2018 at approximately PLN 173 million, and the value of the co-financing was approximately PLN 63 million, of which the Company has used – up to the day on which it was decided to terminate the Agreement – payments totalling approximately PLN 0.3 million. As at the date of this report, the Company has already repaid the aforementioned liability. The Co-financing Agreement terminates on 26 November 2022.

However, its termination does not mean that the Company will abandon the construction of the new Mabion II facility as, in particular, the expansion of manufacturing and analytical capacity for external clients is of importance. The Company is currently working on an update of its development strategy, which will also address the Company's vision for further expansion of its manufacturing and R&D capacity, taking into account the development in the CDMO area and in line with the Company's current and projected needs and capabilities.

The Company informed of the conclusion of the Agreement and the annex to the Agreement in Current Reports no. 42/2018 of 11 June 2018 and no. 10/2022 of 19 April 2022, respectively. The Company informed about the Agreement termination in its Current Report no. 33/2022 of 26 October 2022.

Extension of cooperation with Novavax, Inc. – SOW#9

On 23 November 2022 (an event after the balance-sheet date), the Company's Management Board signed another extension to the scope of services under the Manufacturing Agreement with Novavax, in the form of Statement of Work #9 (SOW#9).

The scope of SOW#9 involves the Company's tasks consisting in conducting peptide mapping analysis for the active substance (DS) as well as the finished product (DP) of rS SARS-CoV-2 protein samples of Novavax products – both Wuhan and Omicron variants. The contracted tasks involve a method feasibility study, method validation and regular testing of samples produced at Mabion and other entities providing manufacturing services to Novavax. If required by Novavax, routine testing of samples will be carried out in a GMP (Good Manufacturing Practice) compliant environment.

The first stage of the work will consist of implementing the peptide mapping method. Next, regular analyses of the commissioned samples will be performed (within 1 month of the delivery of a given sample), ending with the issuance of an appropriate certificate. The remuneration for the work on the implementation of the method, which constitutes the first stage of the order, will amount to more than USD 500 thousand, while the total value of SOW#9 will depend on the next stage of the order, namely the number of regular analyses carried out by the Company in each reporting period.

The Company informed on the conclusion of SOW#9 in Current Report no. 34/2022 of 23 November 2022.

3.3 Description of factors and events, including of unusual nature, having a significant impact on the condensed financial statements

In Q3 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.

3.4 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, execution of additional orders placed under the agreement, and payments from the contractor;
- expenditure on the expansion and modernisation of the existing facility in Konstantynów Łódzki, related to commercial contract manufacturing for Novavax and the possibility of providing other CDMO services;
- implementation of the Company's financing strategy adopted in 2021, including the possibility of acquiring a strategic investor and using debt financing under the agreement with EBRD;
- future possible changes in the terms and conditions of the agreement with Novavax affecting settlement in the income recognition model over time, in proportion to the degree of fulfilment of the performance obligation;
- 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;
- 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;
- changes in remuneration costs and general administration costs of the Company;
- design and preparatory work for the launch of construction of another production facility on the property owned by Mabion S.A., located in Konstantynów Łódzki;
- 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.

Factors associated with the situation in Ukraine

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 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 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 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 September 2022.

Factors related to the coronavirus (SARS-CoV-2) pandemic

In the Company's opinion, as at the date of this report it is not possible to exclude a negative impact of the coronavirus (SARS-CoV-2) pandemic on the Company's operations if further waves of cases occur. In particular, there may be a risk that the work could be delayed against the schedule or put on hold for an unspecified period of time due to restrictions and constraints similar to those that were introduced globally at the beginning of 2020 due to the escalating epidemic threat. In order to prevent pandemic-related risks, the Management Board of the Company monitors the global situation on an ongoing basis, trying to adapt possible operations of the Company in advance. In the event of significant new circumstances related to SARS-CoV-2 coronavirus pandemic and affecting the Company's operations, the latter will introduce appropriate solutions, adapting to administrative decisions. An additional factor in this area 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.

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

3.5 Transactions with related parties

In Q3 2022, the Company did not enter into transactions with related parties on terms other than arm's length.

3.6 Sureties and guarantees granted

In Q3 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.

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

In Q3 2022, no material proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority, or public administration authority.

3.8 Position of the Management Board on the feasibility of previously published forecasts

The Company has not published financial result forecasts for 2022.

4 OTHER INFORMATION RELEVANT TO THE ASSESSMENT OF THE COMPANY'S CONDITION

In January 2021, Mabion S.A. adopted a new long-term strategy to finance its operations, which consists of parallel processes: commencement of activities aimed at acquiring a strategic investor and two issues of the Company's shares. The first share issue (U series shares) was conducted in March 2021, but due to its success and, in addition, the conclusion of a framework agreement with Novavax, Inc., the Extraordinary General Meeting which was to adopt a resolution on the second of the aforementioned issues, was cancelled. Efforts to acquire a strategic investor are being vigorously and continuously pursued.

The Company is also currently updating its business and product strategy for the years to come. 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 existing Company's projects may change, which will also have a direct impact on the strategy, including in the area of financing current, research, and investment activities. The development strategy will also address the Company's vision for further expansion of its manufacturing and R&D capacity, taking into account the development in the CDMO area and in line with the Company's current and projected needs and capabilities. The Company will inform on the adoption of the updated development strategy in a current report.

On 14 July 2022, the District Court for Łódź-Śródmieście in Łódź, 20th Commercial Division of the National Court Register, registered amendments to the Company's Articles of Association as adopted by the Ordinary General Meeting of the Company of 21 June 2022. In addition to changes to the Company's corporate governance, the amendments to the Articles of Association also related to the expansion of the Company's business objects, undertaken in connection with the Company's analysis of the possibilities of increasing the efficiency of the Company's operations and in order to enable the implementation of the Company's intentions. The amendment to the Articles of Association of the Company in the above scope will allow the Company to undertake specific activities in additional and complementary areas and thus will not have a material impact on the Company's core business. The Company informed on the registration of amendments to the Articles of Association in Current Report no. 24/2022 of 18 July 2022.

In October 2022 (an event after the balance-sheet date), the National Centre for Research and Development informed the Company that the project 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" was declared substantially and financially complete. Thus, the three-year period of the project duration commenced, which will end in October 2025. The final value of the funding received is PLN 3.9 million.

On 25 October 2022 (an event after the balance-sheet date), as a result of the expiry of the 36-month loan availability period, the agreements entered into in 2019 with the European Investment Bank, including the Financing Agreement for contingent financing of up to EUR 30,000 thousand in total and the Warrant Agreement, as communicated by the Company in Current Report no. 26/2019 of 21 October 2019 and subsequently in subsequent interim reports, expired. As the conditions for the disbursement of any of the loan tranches provided for in the Financing Agreement had not been met, and as the contractual conditions for the disbursement of the financing had not been amended, the Company did not utilise the financing.

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.

5 CONTACT DETAILS

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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, 24 November 2022

MABION

SCIENTIFIC AND INDUSTRIAL COMPLEX OF MEDICAL BIOTECHNOLOGY

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