## MABION

Other information to the Mabion S.A. quarterly report for Q1 2023

Konstantynów Łódzki, 23 May 2023

## 1 Contents

1.	SELECTED FINANCIAL DATA	1
2.1	Introduction	2
2.2	Bodies of the Company	2
2.2.1	Management Board	2
2.2.2	Supervisory Board	3
2.3	Share capital structure	3
2.4	Shareholding structure	4
2.5	Number of shares held by managing and supervising persons	4
2.6	Changes in the organisation of the capital group	4
3	OPERATIONS OF MABION S.A. IN Q1 2023	5
3.1	Object of activity	5
3.2	Description of significant achievements and failures of the Company in Q1 2023	6
3.3	Description of factors and events, including of unusual nature, having a significant impact	
	on the condensed financial statements	7
3.4	Transactions with related parties	7
3.5	Sureties and guarantees granted	7
3.6	Proceedings pending before a court, an authority competent to conduct arbitration proceedings,	
	or a public administration body	7
3.7	Position of the Management Board on the feasibility of previously published forecasts	7
3.8	Events after the balance-sheet date	7
3.9	Factors to affect the results to be achieved within at least the next quarter	9
4	OTHER INFORMATION RELEVANT FOR THE ASSESSMENT OF THE COMPANY'S CONDITION	11
5	CONTACT DETAILS	12

## 1. SELECTED FINANCIAL DATA

	in PLN thousand		in EUR thousand	
SELECTED FINANCIAL DATA	from 01.01.2023 to 31.03.2023	from 01.01.2022 to 31.03.2022	from 01.01.2023 to 31.03.2023	from 01.01.2022 to 31.03.2022
Net income from sales of products, commodities, and materials	39,545	38,640	8,413	8,315
Operating profit (loss)	18,036	7,102	3,837	1,528
Net profit (loss)	16,470	7,442	3,504	1,601
Net profit (loss)	16,470	7,442	3,504	1,601
Net cash flows from operating activities	17,551	(27,188)	3,734	(5,850)
Net cash flows from investing activities	(1,120)	(2,393)	(238)	(515)
Net cash flows from financing activities	(604)	(1,012)	(128)	(218)
Total net cash flows	15,827	(30,593)	3,367	(6,583)
	31.03.2023	31.12.2022	31.03.2023	31.12.2022
Total assets	198,594	186,175	42,476	39,697
Liabilities and provisions for liabilities	105,617	109,668	22,590	23,384
Long-term liabilities	35,053	35,366	7,497	7,541
Short-term liabilities	70,564	74,302	15,092	15,843
Equity	92,977	76,507	19,886	16,313
Share capital	1,616	1,616	346	345
Number of shares (in pcs)	16,162,326	16,162,326	16,162,326	16,162,326
Profit (loss) per ordinary share (in PLN/EUR)	1.02	1.43	0.22	0.31

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 31 March 2023 (4.6755 PLN/EUR) and 31 December 2022 (4.6899 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 three months ended 31 March 2023 and the period of three months ended 31 March 2022 (respectively: 4.7005 PLN/EUR i 4.6472 PLN/EUR).

### 2 INFORMACJE O 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. The legal form of the Company changed on 29 October 2009 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 registered office is located at ul. gen. Mariana Langiewicza 60 in Konstantynów Łódzki.

Mabion is a Polish biopharmaceutical company that was established to develop, manufacture, and market biological medicines in the form of recombinant proteins. Since 2021, Mabion has been cooperating with Novavax, Inc. ("Novavax"), which involves commercial manufacturing of a recombinant protein vaccine antigen which is the main component of the company's COVID-19 vaccine, as well as providing additional services, including analytical and development services.

The experience and competence built up over more than 15 years have enabled the Company to:

- developed advanced technological processes for the manufacture of recombinant-protein class biologics (e.g. monoclonal antibodies, vaccine antigens) using mammalian and insect cell lines;
- develop effective planning and control methods to repetitively produce high-quality products to schedules;
- achieve a high level of integration and the capacity to offer a broad range of services in the areas of protein development, analytics, and production, as well as consulting and regulatory advisory services;
- build a dynamic team with extensive interdisciplinary experience and capabilities to operate in compliance with GLP (Good Laboratory Practice) and GMP (Good Manufacturing Practice) standards;
- accumulate state-of-the-art GLP/GMP-certified analytical and manufacturing assets in the EU.

On 18 April 2023, the Management Board of Mabion S.A adopted the Company's Strategy for 2023-2027 ("Strategy for 2023-2027"), which was endorsed by the Company's Supervisory Board. In line with its strategy, the Company's Management Board intends to continue the Company's ongoing transformation into a fully integrated contract development and manufacturing organisation (CDMO) with a biological profile. As a target, the Company will provide the full range of services typical of an integrated CDMO to clients who need support at various stages of their product development and commercialisation (from early-stage projects to commercial-scale manufacturing).

The Company's shares are listed on the regulated market of the Warsaw Stock Exchange.

#### 2.2 Bodies of the Company

#### 2.2.1 Management Board

As at 31 March 2023 and as the date of submitting this report, the composition of the Company's Management Board was 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

In Q1 2023 and until the date of this report, there were no changes in the composition of the Company's Management Board.

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

- > Krzysztof Kaczmarczyk President of the Management Board, CEO – manages the work of the Management Board and coordinates the work of other Management Board Members. The main duties of the President of the Management Board include the development of the Company's business strategy and investment policy and the acquisition of business and strategic partners for the Company. The President of the Management Board is also responsible for risk management, disclosure obligations and investor relations, and for overseeing the proper performance of the Company's operating and financial activities.
- Sławomir Jaros Member of the Management Board, COO and CSO responsible for supervising, managing, and integrating the following areas in the Company: medicine design, technology development and analytics, clinical trials area, and occupational safety and pharmaceutical risk control. His duties include cooperation with external partners in the field of technology, science and commerce, and the development of strategies for new products and technologies. He is also responsible for the area of manufacturing, quality control and quality assurance, and for implementing technological and analytical processes in the pharmaceutical environment, for scaling up processes, process quality, time and cost optimisation, as well as for supervising manufacturing processes and operational management.
- > Adam Pietruszkiewicz, Member of the Management Board, CCO – responsible for business development of the Company, for strategic projects, and for acquisition of new clients. It was at his initiative that the business relationship with Novavax was established.

Serzegorz Grabowicz – Member of the Management Board, CFO – responsible for managing the Company's financial policy. He is responsible for acquiring funds, developing the Company's financial plans, for financial reporting and the day-to-day IT operation and development.

#### 2.2.2 Supervisory Board

As at 31 March 2023 and as the date of submitting this report, the composition of the Company's Supervisory Board was 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 Supervisory Board Member,
- Zofia Szewczuk Independent Member of the Supervisory Board.

In Q1 2023 and until the date of this report, there were no changes in the composition of the Company's Supervisory Board.

#### 2.3 Share capital structure

As at 31 June 2023 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:

Number of shares	Type of shares	Kinds of shares	Series
450,000	registered	preference	А
450,000	registered	preference	В
450,000	registered	preference	С
450,000	ordinary	ordinary	D
100,000	registered	preference	E
100,000	registered	preference	F
20,000	registered	preference	G
2,980,000	ordinary	ordinary	Н
1,900,000	ordinary	ordinary	I
2,600,000	ordinary	ordinary	J
790,000	ordinary	ordinary	K
510,000	ordinary	ordinary	L
360,000	ordinary	ordinary	M
340,000	ordinary	ordinary	N
300,000	ordinary	ordinary	0
1,920,772	ordinary	ordinary	Р
11,000	ordinary	ordinary	S
2,430,554	ordinary	ordinary	U

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.

In Q1 2023 and until the date of this report, there were no changes to the Company's share capital.

#### 2.4 Shareholding structure

To the best knowledge of the Management Board of the Company, as at the date of approval of this report, i.e. 23 May 2023, 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.	Other	10,295,878	10,295,878	63.70%	58.06%
	Total	16,162,326	17,732,326	100%	100%

<sup>\*</sup> 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 the previous interim report, i.e. the annual report for 2022 published on 18 April 2023, to the date of this report, there were no changes in the ownership structure of significant blocks of shares of the Issuer.

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

As at the date of this report, i.e. 23 May 2023, 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;
Siawoiiii Jaios	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.

To the Company's best knowledge, as at the date of this report, i.e. 23 April 2023, members of the Supervisory Board of Mabion. S.A. do not hold any shares in the Company.

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

In the period from the date of the previous interim report, i.e. the annual report for 2022 published on 18 April 2023, to the date of

this report, there were no changes in the holdings of shares and entitlements to shares in the Company among the management and supervisory staff.

## 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. IN Q1 2023

#### 3.1 Object of activity

In the reporting period, i.e. in Q1 2023, as since 2021, the Company has focused in its business activities on two areas of activity:

- implementation of commercial orders for partners in the field of contract development and manufacturing (as a Contract Development and Manufacturing Organisation, CDMO).
- development, manufacturing and marketing of own biosimilars, i.e. biological medicines that are developed to be similar to the original biotech drugs;

In Q1 2023 and after the balance-sheet date, until the Strategy for 2023-2027was adopted (18 April 2023), Mabion's project catalogue included three groups of projects: i.e. CDMO service projects (Nuvaxovid® vaccine), active in-house projects (MabionCD20, MabionMS and MabionEGFR), and new in-house projects (denosumab and omalizumab).

The Company's income from sales in Q1 2023 was mainly earned from a CDMO service project involving collaboration with Novavax, Inc. in the area of the Nuvaxovid vaccine. The Agreement with Novavax and the additional orders entered into thereunder were of the most critical importance to the Company in Q1 2023, both on the operational and financial level.

The cooperation with Novavax is based on the Manufacturing Agreement entered into in October 2021 for the contract manufacturing of an active substance, i.e. a vaccine antigen for COVID-19 branded as Nuvaxovid® ("Product"). In September 2022, annexes to the Manufacturing Agreement and Statement of Work #1 (Statement of Work #1) were executed, under which the parties updated the manufacturing schedule and agreed on a guaranteed amount of Mabion's manufacturing capacity for Novavax until Q2 2024. The term of the Manufacturing Agreement was extended to 2026 and the a remuneration for the Company was introduced in the absence of manufacturing orders, on account of Mabion guaranteeing and making its production capacity available. On 6 April 2023 (an event after the balance-sheet date), the Company entered into Annex No. 2 to Statement of Work No. 1 (SOW#1) with Novavax regarding the Company's ability to be contracted by Novavax to manufacture agreed batches of the COVID-19 Omicron variant vaccine antigen. The Omicron product will be manufactured within the capacity guaranteed to Novavax to date, and therefore, under the Manufacturing Agreement, the Company will be able to produce two antigen types (Wuhan and Omicron variants).

Having in mind the existing Manufacturing Agreement and taking into account its annex signed in September 2022, the Company estimated that it should realise more than 15% of the total value of the agreement in the period from the beginning to the end of 2023, 55% of the total value of the agreement in 2024–2025, and approximately 30% in 2026.

The percentage breakdown of the agreement performance was related to the expected benefits within the schedule of services covering both the guaranteed part of the Manufacturing Agreement as well as its non-guaranteed part. However, in view of the nature of the agreement and the expected scope of the cooperation, which currently includes the provision of a manufacturing service or the readiness to provide a manufacturing service, the Company refrains from making a percentage estimate of the expected implementation of the agreement in future periods.

The above decision is justified by a mismatch between the assumed income from the implementation of the agreement and the method of accounting for the agreement and recognising income for individual reporting periods, adopted in line with the applicable regulations (IFRS 15), as well as the existence of a contractual limitation on the guaranteed unconditional recognition of performance by the counterparty in the period up to Q2 2024.

In case of contract manufacturing, the Company recognises income using the progress measurement method based on inputs, which in the Company's opinion reflects in the best way the entity's results in fulfilling the identified performance obligation. The amount of remuneration allocated to this performance obligation is recognised as income in line with the performance stage in terms of cost.

In Q1 2023, Mabion completed additional orders for Novavax under the Manufacturing Agreement, based on the Statements of Work ("SOW") entered into by the Parties as set out in the table below.

Table 1. Additional orders implemented in Q1 2023 under the existing Manufacturing Agreement between Mabion and Novavax

No.	Order name	Order date	Scope	
1	SOW#2	18 January 2022	Additional analytical services in the area of analytical research related to the quality control of the Nuvaxovid® vaccine.	
			Order completed.	
2	SOW#4	27 May 2022	The extension of the range of analytical tests implemented by the Company to include a quality test performed for the purposes of the finished product analysis.	
			Order finalised.	
3	SOW#7	20 July 2022	The 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.	
			Order completed.	
4	SOW#8	SOW#8	2 August 2022	Stability tests on the SARS CoV-2 rS active substance.
				Order completed.
5	5 SOW#9 23 November 2022		The development of a method for and conducting a 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 the Wuhan and Omicron variant.	
			Order completed.	
6	SOW#10	9 February 2023	Logistics services, including the transportation and storage of materials, vaccine active substances, and finished products.	
		-	Order completed.	

The Company's own most advanced project was MabionCD20, a proposed biosimilar to reference medicines, MabThera/Rituxan® (Roche). To sum up, as part of the research and development work on MabionCD20 in Q1 2023, the Company considers the following activities to be successfully carried out:

- verification of the parameters of the antibody subjected to stability tests under routine and accelerated storage conditions for the validation batches;
- development of analytical methods for qualitative and comparative analyses of MabionCD20, as well as clinical analytics as part of the characterisation of pharmacokinetics, pharmacodynamics and immunogenicity in MabionCD20-003RA clinical trial;
- extending the scopes of Quality Target Product Profile (QTPP) to take into account rituximab reference products coming to the market, and to monitor, on an ongoing basis, the quality characteristics of the aforementioned products.

In Q1 2023, the implementation of the above activities in respect of the MabionCD20 project did not involve any income from sales for the Company, but only expenditure typical of research and development activities during the product development phase.

As regards the other Company's own projects in the active project group and the Company' own new projects, in Q1 2023 the Mabion did not carry out any significant development work or incur any significant expenditures, nor did it generate any income from sales.

## 3.2 Description of significant achievements and failures of the Company in Q1 2023

Signing of a loan agreement for USD 15,000 thousand with the European Bank for Reconstruction and Development

On 6 February 2023, the Company entered into a loan agreement with the European Bank for Reconstruction and Development ("EBRD") for USD 15,000 thousand ("Loan Agreement"). The financing to the Company was approved by the credit committee of the EBRD on 18 October 2022. The loan will be provided by the EBRD to finance the expansion and upgrade of the Company's facility located in Konstantynów Łódzki, to support the implementation of commercial contract manufacturing performed under the Manufacturing Agreement entered into with Novavax, and the implementation of other possible CDMO projects (hereinafter referred to as "Project"). The loan will be disbursed once the standard conditions precedent specified in

the Loan Agreement have been met, at the request of the Company, in one lump sum or in amounts of not less than USD 5,000,000. The loan will be disbursed at the latest within nine months of the date of the Loan Agreement, with the first loan disbursement occurring not later than within six months as of the date thereof. The loan will bear interest at a variable rate composed of the interest base, i.e. the compounded Secured Overnight Financing Rate (SOFR), plus a margin. It will be repaid in four different instalments on 30 September 2023, 31 December 2023, 31 March 2024, and 30 June 2024, in line with the schedule specified in the Loan Agreement.

The Company informed of the EBRD credit committee's approval of the financing in Current Report no. 32/2022 of 18 October 2022. The Company informed about entering into the Loan Agreement and the terms and conditions for the loan in Current Report no. 2/2023 of 6 February 2023.

## Termination of non-binding agreement with Polski Fundusz Rozwoju S.A.

On 6 February 2023, the Management Board of Mabion S.A., in connection with the conclusion of a Loan Agreement with EBRD, decided to terminate the non-binding agreement regarding the entry conditions of the investment of Polski Fundusz Rozwoju S.A. ("PFR") amounting to up to PLN 40 million, entered into by the Company and the PFR on 3 March 2021, as informed by the Company in Current Report No. 16/2021 of 3 March 2021, and to withdraw from further implementation of its provisions. To date, the agreement has been implemented in the part concerning the subscription of the Company's shares up to the amount of PLN 10 million as part of an issue of U series shares, of which the Company informed in Current Reports No. 12/2021 of 23 February 2021 and No. 23/2021 of 15 March 2021.

The Company informed of the termination of the agreement in Current Report no. 3/2023 of 6 February 2023.

## Extension of cooperation with Novavax, Inc. – SOW#10

On 9 February 2023, the Company signed another extension to the scope of services under the Manufacturing Agreement with Novavax, in the form of Statement of Work #10 (SOW#10). The scope of SOW#10 comprises logistics services, including the transportation and storage, by the Company, of materials, vaccine active substances, and finished products under suitable transport and storage conditions agreed by the parties. All these services will be provided in a GMP-compliant environment. The extension of services entered into force on the date of signing of SOW#10 and will remain in force until the services are completed in full, unless the parties jointly decide to terminate the work under the order at an earlier date. The value of SOW#10 will depend on the volume of transport services commissioned by Novavax and the products to be stored, and the duration of their storage by the Company.

The Company informed about concluding SOW#10 in Current Report no. 4/2023 of 9 February 2023.

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

In Q1 2023, 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 Transactions with related parties

In Q1 2023, the Company did not enter into any transactions with related parties.

#### 3.5 Sureties and guarantees granted

In Q1 2023, 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.

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

In Q1 2023, no material proceedings concerning the Company's liabilities or receivables were pending before any court, arbitration authority, or public administration authority.

## 3.7 Position of the Management Board on the feasibility of previously published forecasts

The Company has not published financial result forecasts for 2023.

#### 3.8 Events after the balance-sheet date

Entering into an annex with Novavax, Inc. for the manufacture of COVID-19 vaccine antigen: Omicron variant

On 6 April 2023, the Company entered into Annex No. 2 (Annex No. 2") to Statement of Work No. 1 (SOW#1) with Novavax regarding the Company's ability to be contracted by Novavax to manufacture agreed batches of the COVID-19 Omicron variant vaccine antigen ("Omicron").

Annex no. 2 specifies the previously agreed and partially implemented activities aimed at including a further Omicron product in the scope of the cooperation, including the performance of technology transfer, process validation and subsequent manufacturing of the Omicron product in compliance with the GMP standard, in line with the detailed rules set out in Annex no. 2. Pursuant to Annex no. 2, when Novavax places an order for the Omicron product, the Company's responsibilities include, in particular, manufacturing the product, analytical testing of product samples, stability research, procuring raw materials for

production, quality management and supervision, and supporting Novavax in complying with registration requirements by submitting the relevant documentation.

The number of batches of the Omicron product commissioned for manufacture will be agreed between the parties on an ongoing basis. The Omicron product will be manufactured within the capacity (manufacturing slots) guaranteed to Novavax to date. As a result of the applicable Annex no. 2, the original Agreement and the Statements of Work contained therein also apply to the Omicron product.

The Company informed about concluding Annex no. 2 in Current Report no. 5/2023 of 6 April 2023.

#### Mabion S.A. adopts the Strategy for 2023-2027

On 18 April 2023, the Company's Management Board passed a resolution on the adoption of the Mabion's Strategy for 2023–2027. Pursuant to §22 (1) (g) of the Company's Articles of Association, the Strategy was endorsed by the Company's Supervisory Board on the same date.

The Strategy is based on the expertise and resources accumulated over the years, enabling the Company to seize the market opportunity and begin its transformation into a fully integrated CDMO (Contract Development and Manufacturing Organization) in 2021.

#### The Company's strategic vision

As a fully integrated CDMO focused on biologics, Mabion provides a full spectrum of services for small to medium-sized projects, from early development phases for commercial manufacturing for clients. As a fully integrated CDMO, the Company intends to offer a full range of services to its clients, namely process development, preclinical and clinical analytics, manufacturing for both clinical and commercial stage, finished product manufacturing, medicinal product characterisation and batch release, regulatory advice. The Company has the ability to implement projects at different stages of development, as well as the ability to address only selected stages along the CDMO service value chain.

As part of the Strategy, the Company plans to deliver the following main strategic objectives in the different years:

#### 2023-2024:

Business model – shift of the Company's business model from products to services, including the marketing of MabionCD20 by acquiring a licensee and possibly acting as a CMO – Contract Manufacturing Organisation for MabionCD20, and completion of work on the Company's own portfolio of other products;

Transformation – completing the Company's transformation into a fully integrated CDMO, maximising expenditure and investment on the development of innovative CDMO services;

Upgrade and scale-up – upgrading the existing facility and laboratories to adapt the facility to the CDMO profile, achieving

technological diversification and develop a plan for Mabion II facility with a view to providing services as a CDMO, and selecting an appropriate structure and securing funding for the investment;

Recognisability – gaining recognition in the sector of companies providing CDMO services to global clients, and client portfolio diversification;

A self-funded entity – by seizing the income potential, Mabion will be a self-funded entity for its ongoing operations; the process of securing a strategic investor remains open for discussions with prospective partners. However, transformation to a CDMO becomes a priority.

#### 2025-2027:

Market positioning – Mabion becomes a recognisable business partner for international clients in the CDMO segment;

Diversification – achieving attractive business diversification in terms of services on offer and client portfolio;

Mabion II – implementation of the new facility investment, its qualification and validation. Use of optimal sources of investment funding;

Scale-up – reaching full operational and organisational readiness to scale up the business on the basis of Mabion II.

#### Then, from 2028 onwards:

Mabion II is fully operationally ready to render CDMO services;

New production lines and a significant increase in production capacity are in place.

The assumed effects of the Strategy's implementation in the horizon of the first 5 years of the investment will comprise, inter alia, an upgraded existing facility of the Company and a higher production capacity, a change in the profile of the manufacturing facility from a single-product plant to one enabling different processes to be carried out at the same time, stabilisation of income and ongoing cash flows allowing the Company to self-finance until the investment in Mabion II is commenced.

The Strategy also defines the plan and conditions for the further development of the MabionCD20 project and its commercialisation. In line with the Strategy, the Company anticipates further development of the project in a model involving licensing to an external partner who will carry out the registration of the medicine and will be responsible for sales and distribution. The Company's function in such a model would be to contract manufacture the medicine (CMO) for the licensee. The Company alone will not incur significant development expenditure on the project.

As regards the Company's other existing product projects, in view of the assumed continuation of the transformation of the Company's profile from products to services, the Strategy

provides for discontinuation of work on the Company's own product portfolio and limitation of expenditures on early-stage projects (including denosumab, omalizumab, MabionMS, MabionEGFR) to the extent necessary to maintain the projects and possibly commercialise them.

The Strategy also comprises the Company's objectives and the actions planned to be taken in the field of sustainability and ESG (Environmental, Social, and Governance).

The Company informed of the adoption of the Strategy in Current Report no. 7/2023 of 18 April 2023.

## **Decision to end the patent procedures for MabionMS**

On 26 April 2023, the Company decided to end its efforts to obtain patent protection under the applications submitted for the inventions called "Combination Therapy of Multiple Sclerosis comprising a CD20 Ligand" and "Low aggregate anti CD20 ligand formulation", developed as part of the MabionMS (multiple sclerosis) innovative therapy project. The Management Board's decision is based on the implementation of Mabion S.A.'s Strategy for 2023–2027. Analogous decisions have been taken with respect to all patent applications as part of the MabionMS project, of which the Company informed in interim reports, including most recently in the annual report for 2021 published on 21 April 2022.

The Company informed of termination of the patent procedures in Current Report no. 8/2023 of 26 April 2023.

## The Company terminates its agreement with Parexel for the clinical trial of MabionCD20

With reference to Current Report no. 41/2020 of 29 October 2020 on entering into an agreement with Parexel International (IRL) Limited with its registered office in Ireland, to conduct a bridging three-arm clinical trial of MabionCD20, the Management Board of Mabion S.A decided, on 22 May 2023, to terminate this agreement.

The Management Board's decision is based on the implementation of Mabion S.A.'s Strategy for 2023-2027 of whose adoption the Issuer informed in Current Report no. 7/2023 of 18 April 2023. Pursuant to the Company's Strategy for 2023–2027, the Company plans to further its transformation into a fully integrated CDMO focused on biologics.

The Agreement is terminated in accordance with its provisions and has no material financial consequences for the Company other than the necessary costs associated with the termination of the clinical trial. The expenditure incurred to date, as estimated by the Company, to carry out the activities under the Agreement, amounted to EUR 2.1 million, compared to a cost of approximately EUR 5.4 million for the trial as at estimated at the date of the Agreement.

Any further decisions as regards the MabionCD20 bridging clinical trial required for the purposes of the registration of the

drug will be at the discretion of a prospective third-party partner who will carry out the registration under a licence granted by the Company and will be responsible for sales and distribution of the product.

The Company informed about the agreement termination in its Current Report no. 10/2023 of 22 May 2023.

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

With reference to Current Report no. 64/2021 of 30 November 2021 regarding the conclusion of an agreement with Adolf Kühner AG with its registered office in Switzerland for the purchase of four bioreactors with a capacity of 2,500 litres each, together with additional services, the Management Board of Mabion S.A. entered, on 22 May 2023, into an annex to this agreement.

Under the Annex, the parties agreed that the supplier will manufacture and deliver two new bioreactors to the Company within the timeframe agreed for Q3 2023 (previously, the Agreement provided for the delivery of four bioreactors within 15 months from its date). With the Annex in place, the value of the Agreement has changed and amounts to EUR 1.8 million, and reflects additional services ordered by the Company (original amount: EUR 2.3 million). As a result, two new orbital shaking bioreactors will be installed at the Company to replace the two bioreactors used presently.

The Annex is a result of changes that the Company is implementing as a consequence of the adoption of the new Company Strategy for 2023–2027 whereof the Issuer informed in Current Report no. 7/2023 of 18 April 2023. In accordance with the Strategy, one of the objectives the Company is pursuing is to achieve diversification in bioreactor breeding technology.

Such bioreactor technology diversification is aimed at complementing the Company's development and process equipment with bioreactors employing conventional mixing technology. As a result of the above activities, Mabion will be able to offer services using both of these technologies. The resulting expanded panel of available bioreactor technologies will bring greater flexibility to the Company in discussions with future clients as part of the CDMO services offering, which should lead to greater business diversification, which the Management Board believes is one of the key factors for the Company's further growth.

The Company informed about concluding the annex in Current Report no. 11/2023 of 22 May 2023.

## 3.9 Factors to affect the results to be achieved within at least the next quarter

Pursuant to the Strategy for 2023–2027, the Management Board intends to complete the Company's transformation, which began in 2021, into a fully integrated CDMO focused on biologics. As a

target, the Company will provide the full range of services to clients who need support at various stages of their product development (from early-stage projects to commercial-scale manufacturing).

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 (Wuhan and Omicron variant) for Novavax, including its progress and schedule, execution of additional orders placed under the agreement, and payments from the contractor;
- > the possibility of changes to production plans due to Novavax's financial situation, as reported by the latter (Novavax informed of its financial situation and the risk to its going concern beyond 2023 in its 2022 annual report);
- > 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 opportunity to acquire new clients in the CDMO area;
- > 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;
- > the possibility of using EBRD financing to expand and modernise the current facility, as well as the possibility of obtaining funding to build another facility (Mabion II);
- a possibility of acquiring a licensee for MabionCD20 and the ability to produce this antibody for a business partner that will choose to launch MabionCD20 on the market under a licence acquired from Mabion;
- > 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. 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 at the date of this report, the sanctions and the armed conflict have not had a direct impact on the Company's business and therefore, having analysed the impact of the Russian invasion to date and its current and future possible effects for the Company, the 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 31 March 2023.

However, 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 current economic situation in the East 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 a further increase in prices of, for example, energy, restrictions on free trade, or other business restrictions, including disruptions in the supply chain for goods and services. All the above mentioned phenomena may have a direct impact on the financial situation of the Company in the future.

# 4 OTHER INFORMATION RELEVANT FOR THE ASSESSMENT OF THE COMPANY'S CONDITION

In January 2023, the US Food and Drug Administration (FDA) granted the Orphan Drug Designation (ODD) status to Mabion S.A. for rituximab in the indication of membranous nephropathy. In February 2023, the FDA issued another positive decision for the Company, granting the ODD status to Mabion S.A. for rituximab in the indication of autoimmune haemolytic anaemia.

Owing to this, the Company has a prospective business advantage when licensing the MabionCD20 antibody to an external partner, as this status may increase the value of this product to the licensee. Obtaining FDA registration for an orphan drug with the ODD status can ensure, inter alia, market exclusivity (the FDA will not approve the same or a similar drug in the same indication unless the drug demonstrates clinical superiority) for up to seven years.

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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#### **Management Board of the Company**

#### Krzysztof Kaczmarczyk

President of the Management Board

**Sławomir Jaros** 

**Grzegorz Grabowicz** 

**Adam Pietruszkiewicz** 

Member of the Management Board

Member of the Management Board

Member of the Management Board

Konstantynów Łódzki, 23 May 2023

### MABION

## SCIENTIFIC AND INDUSTRIAL COMPLEX OF MEDICAL BIOTECHNOLOGY

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