

**MABION**

Other information  
to the quarterly report  
of Mabion S.A.  
for the Q1 2022

Konstantynów Łódzki, 27 May 2022

# Contents

1	Selected financial data	1
2	Information on Mabion S.A.	2
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	5
3	Operations of Mabion S.A.	6
3.1	Object of activity	6
3.2	Description of significant achievements and failures of the Company in Q1 2022 and after the balance-sheet date	9
3.3	Description of factors and events, including of unusual nature, having a significant impact on the condensed financial statements	10
3.4	Factors to affect the results to be achieved within at least the next quarter	10
3.5	Transactions with related parties	11
3.6	Sureties and guarantees granted	11
3.7	Proceedings pending before a court, an authority competent to conduct arbitration proceedings, or a public administration body	11
3.8	Position of the Management Board on the feasibility of previously published forecasts	11
4	Other information relevant to the assessment of the Company's condition	12
5	Contact details	13

# 1 SELECTED FINANCIAL DATA

## 1 Selected financial data

Wybrane dane finansowe	in PLN thousand		in EUR thousand	
	from 01.01.2022 to 31.03.2022	from 01.01.2021 to 31.03.2021	from 01.01.2022 to 31.03.2022	from 01.01.2021 to 31.03.2021
Net income from sales of products, commodities, and materials	38,640	0	8,315	0
Operating profit (loss)	7,102	-14,078	1,528	-3,079
Gross profit (loss)	7,442	-17,075	1,601	-3,735
Net profit (loss)	7,442	-17,075	1,601	-3,735
Net cash flows from operating activities	-27,188	14,480	5,850	3,167
Net cash flows from investing activities	-2,393	-14	-515	-3
Net cash flows from financing activities	-1,012	-13,457	-218	-2,943
Total net cash flows	-30,593	1,009	-6,583	221
	<b>31.03.2022</b>	<b>31.12.2021</b>	<b>31.03.2022</b>	<b>31.12.2021</b>
Total assets	167,830	213,342	36,073	45,779
Liabilities and provisions for liabilities	107,073	174,049	23,014	37,347
Long-term liabilities	35,993	50,865	7,736	10,915
Current liabilities	71,080	123,184	15,278	26,433
Equity	60,757	39,293	13,059	8,431
Share capital	1,616	1,373	347	295
Number of shares (in pcs)	16,161,826	13,730,772	16,161,826	13,730,772
Profit (loss) per ordinary share (in PLN/EUR)	0.46	-1.24	0.10	-0.27

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 2022 (4.6525 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 three months ended 31 March 2022 and the period of three months ended 31 March 2021 (respectively: 4.6472 PLN/EUR and 4.5721 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 registered office is located at ul. gen. Mariana Langiewicza 60 in Konstancin Łódzki.

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

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

As regards the Company's own projects, the most advanced one is MabionCD20, a proposed biosimilar to the reference drug MabThera/Rituxan (Roche). To date, the Company has completed most of the work within the project (development of technology, analytical tools, Phase III clinical trials, scaling up production to commercial scale with validation). The remaining tasks include a clinical bridging trial in a limited patient population to demonstrate the equivalence of the commercially manufactured medicine with the product previously tested in the Phase III trial and originating from the clinical manufacturing scale, as well as an analytical study. At present, the Company is updating its work schedules so that the structure of activities in the context of the implementation of its own projects and commercial orders would enable optimum use of its resources and financial results, which would translate into an optimum structure of income in the short, medium and long term.

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 2022 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

No changes in the composition of the Company's Management Board occurred in Q1 2022 and up to the date of submitting this report. On 25 March 2022 (an event after the balance-sheet date), the Supervisory Board of the Company adopted resolutions appointing the current members to the Management Board of the Company for the second joint term of office.

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

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

optimisation, as well as for supervising manufacturing processes and operational management.

- > Adam Pietruszkiewicz  
– Member of the Management Board, CCO – on the Management Board, he is responsible for business development of the Company in the CDMO area, for strategic projects, as well as for acquiring new partners – including cooperation with Novavax, Inc. (managing the vaccine antigen manufacturing project).
- > Grzegorz Grabowicz  
– Member of the Management Board, CFO - he is responsible for supervising and managing the Company's financial policy. His duties include raising of funds, negotiation of significant financial operations and business transactions of the Company, and development of the Company's financial plans, and its financial reporting.

### 2.2.2 Supervisory Board

As at 31 March 2022 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 (until 20.04.2022, Member 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 Q1 2022 and up to the date of submitting this report.

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

## 2.3 Share capital structure

As at 31 March 2022 and as of the date of this report, the Company's share capital amounts to PLN 1,616,182.60 and is divided into 16,161,826 shares with a nominal value of PLN 0.10 each, including:

- > 450,000 A series registered preference shares,
- > 450,000 B series registered preference shares,
- > 450,000 C series registered preference shares,
- > 450,000 D series ordinary bearer shares,
- > 100,000 E series registered preference shares,
- > 100,000 F series registered preference shares,
- > 20,000 G series registered preference shares,
- > 2,980,000 H series ordinary bearer shares,

- > 1,900,000 I series ordinary bearer shares,
- > 2,600,000 J series ordinary bearer shares,
- > 790,000 K series ordinary bearer shares,
- > 510,000 L series ordinary bearer shares,
- > 360,000 M series ordinary bearer shares,
- > 340,000 N series ordinary bearer shares,
- > 300,000 O series ordinary bearer shares,
- > 1,920,772 P series ordinary bearer shares,
- > 10,500 S series ordinary bearer shares,
- > 2,430,554 U series ordinary bearer shares.

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

### Changes in the Company's share capital in Q1 2022

As of 1 January 2022, the Company's share capital amounted to PLN 1,616,132.60 and was divided into 16,161,326 shares with a nominal value of PLN 0.10 each. The total number of votes resulting from all issued shares of the Company is 17,731,326 votes.

On 28 January 2022, 500 S series ordinary bearer shares of the Company with a nominal value of PLN 0.10 each were allotted. The allotment of shares within the meaning of Article 451 §2 of the Commercial Companies Code took place upon their entry in the securities accounts of the eligible persons, and pursuant to Article 452 §1 of the Commercial Companies Code, together with the allotment of shares, the Company's share capital was increased to PLN 1,616,182.60. The shares discussed above were issued as part of the Incentive Scheme adopted by Resolution No. 24/VI/2018 of the Ordinary General Meeting of the Company of 28 June 2018 on the introduction of the Incentive Scheme. On 2 July 2021, the Company issued 500 B series registered subscription warrants as part of the implementation of the Incentive Scheme for 2020. The subscription warrants were taken up on 18 November 2019, free of charge, by eligible persons, i.e. persons appointed by the Company's Supervisory Board. Each B series subscription warrant entitled to take up 1 S series ordinary bearer share of the Company at the issue price equal to the nominal value of shares of PLN 0.10 each. All eligible persons submitted declarations on taking up their S series shares in the period ended 15 December 2021. The S series shares (500 pcs) were issued as part of a conditional share capital increase, therefore no allocation of shares took place. The shares were taken up for cash contributions made in full before the shares were allotted. On 18 January 2022, the National Depository for Securities (KDPW) issued a statement announcing that, in response to the Company's application, an agreement had been concluded for the registration with the Depository for Securities of up to 500 S ordinary bearer shares of the Company. The above-mentioned shares were registered on the basis of settlement orders, in connection with the deregistration of subscription warrants under which the right to take up the above-mentioned shares was exercised.

On 20 February 2022 (an event after the balance-sheet date), the Warsaw Stock Exchange (GPW) Board adopted a resolution on the admission and introduction to exchange trading on the

WSE Main Market of S shares of the Company, in which the WSE's Board stated that 500 S series ordinary bearer shares of the Company are admitted to trading on the main market. At the same time, the WSE's Board decided to introduce, as of 26 April 2022, the above mentioned Company's shares to trading, on the condition of assimilation, on 26 April 2022, of these shares with outstanding shares of the Company by the KDPW. On 21 April 2022, the KDPW issued a statement pursuant to which, at the request of the Company, it was decided to assimilate the above shares on 26 April 2022. Therefore, the condition for the introduction of the above-mentioned shares to trading on the WSE primary market as of 26 April 2022 was fulfilled.

The Company informed about the above events in Current Reports no. 68/2021 of 20 December 2021, no. 4/2022 of 18 January 2022, no. 5/2022 of 31 January 2022, no. 22/2022 of 20 April 2022 and no. 13/2022 of 21 April 2022.

## 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. 27 May 2022, the following shareholders held at least 5% of votes in the total number of votes at the General Meeting of the Company.

**Table 1: Shareholding structure.**

No.	Shareholder	Number of shares	Number of votes	Participation in the share capital	Share in the total number of votes
1.	Twiti Investments Limited	2,674,617	3,268,917	16.55%	18.44%
2.	Maciej Wieczorek through*: Glatton Sp. z o.o.	1,717,485	2,210,335	10.63%	12.47%
	Celon Pharma S.A.	1,097,135	1,097,135	6.79%	6.19%
		620,350	1,113,200	3.84%	6.28%
3.	Polfarmex S.A.	1,474,346	1,957,196	9.12%	11.04%
4.	Funds managed by Investors TFI S.A.**	1,502,649	1,502,649	9.30%	8.47%
5.	Other	8,792,729	8,792,729	54.40%	49.59%
	<b>Total</b>	<b>16,161,826</b>	<b>17,731,826</b>	<b>100%</b>	<b>100%</b>

\* Mr Maciej Wieczorek holds 100% of the share capital of Glatton Sp. z o.o. and indirectly, through Glatton Sp. z o.o., 58.83% of the share capital of Celon Pharma S.A. and 68.19% of the total number of votes in Celon Pharma S.A.

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

In the period from the date of the previous interim report, i.e. the annual report for 2021 published on 21 April 2022, 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 publication of this report, i.e. 27 May 2022, Members of the Management Board and the Supervisory Board of Mabion S.A hold the quantities of the Company's shares indicated below.

**Table 2. Number of shares held by managing and supervising persons**

### Number of shares held by managing and supervising persons as at the date of the report for Q1 2022 (i.e. as at 27 May 2022)

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

As at the date of publication of this report, i.e. 27 May 2022, members of the Supervisory Board of Mabion S.A. do not hold any shares in the Company.

In the period from the date of the previous interim report, i.e. the annual report for 2021 published on 21 April 2022, to the date of this report, there were no changes in the holding of shares in the Company by managing and supervising persons.

Members of the Management Board and Supervisory Board of Mabion S.A. do not hold any title to the Company's shares other than indicated below.

Since 2018, the Company has in place an Incentive Scheme for the period 2018–2021. As part of the Incentive Scheme, the persons participating in it – the eligible persons, i.e. the key persons in the Company – may obtain the right to take up A and B series subscription warrants. The subscription warrants are issued free of charge. Each A and B series subscription warrant entitles to subscribe, respectively, for 1 R and 1 S series share. The issue price of shares for holders of A series subscription warrants is PLN 91 per each R series share, and for holders of B series warrants, it is PLN 0.10 per each S series share. The rights attached to the subscription warrants may be exercised until 31 July 2022. The Incentive Scheme allows for settlement in the form of an offer, extended by the Company to persons who have taken up the warrants, to purchase them against payment for the purpose of redemption. The decision on the form of exercising the rights is taken by the Supervisory Board of the Company after verification of the fulfilment of the criteria specified in the Incentive Scheme and on the basis of the recommendation of the Management Board.

In accordance with the resolutions of the Company's Supervisory Board of the different years of the Incentive Scheme, the persons entitled to take up subscription warrants for different years in the period 2018–2020 include persons sitting on the Management Board of the Company as at the date of this report:

- > Mr. Sławomir Jaros (Member of the Management Board) – for 2018: granted the right to take up a maximum of 5,644 A series warrants; for 2019: granted the right to take up a maximum of 3,960 A series warrants; for 2020: granted the right to take up a maximum of 6,099 A series warrants; for 2021: granted the right to take up a maximum of 213 B series warrants and a maximum of 6,099 A series warrants;
- > Mr. Grzegorz Grabowicz (Member of the Management Board) – for 2019: the right to take up a maximum of 3,300 A series warrants; for 2020: the right to take up a maximum of 5,101 A series warrants; for 2021: the right to take up a maximum of 5,101 A series warrants.

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

As regards the implementation of the Incentive Scheme for 2021, in April 2021 the Company's Supervisory Board determined that the eligible persons are entitled to take up in total a maximum of 28,215 A series warrants for 2021, and then in January 2022, the Supervisory Board adjusted the number of A series warrants for 2021 to 27,645 warrants due to the fact that the seniority criterion was not met by two eligible persons, and concluded as a result of verification that the market target with respect to A series subscription warrants was also not met.

As regards B subscription warrants, the condition for the right to take up and exercise rights attached to B warrants was fulfilled, and thus the Supervisory Board granted the eligible persons, in January 2022, the right to take up a total of 500 B subscription warrants for 2021. By the date of publication of this report, the B series subscription warrants for 2021 were neither issued nor taken up by the eligible persons.

## 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 consists of the development, analytics and manufacture of its own drug candidates, as well as contracting activities as a CDMO (Contract Development and Manufacturing Organisation). In March 2021, the Company has undertaken to start a transfer of technology related to the production of an antigen for the COVID-19 infection vaccine developed by Novavax Inc., and then in October 2021, it entered into a commercial manufacturing agreement for the period 2022–2025.

The current project pipeline of the Company in 2021 is reduced to three project groups: i.e. active projects, new projects, and partnership projects. With the end of 2021, the Management Board of Mabion S.A. started to work on updating the Company's business and product strategy for the years to come. As at the date of this report, work to review and analyse the strategic areas is ongoing. The Company intends to adopt an updated development strategy in H1 2022.

#### Active projects

This is a group of projects of high importance for the Company, as part of which the Company carries out work and invests funds. The group includes projects currently under way: MabionCD20, MabionMS, and MabionEGFR. The Company's most advanced product is a biosimilar medicine, MabionCD20, a reference drug to MabThera/ Rituxan (Roche). As part of these projects, the Company allocates most of its human, organisational and financial resources to MabionCD20.

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

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

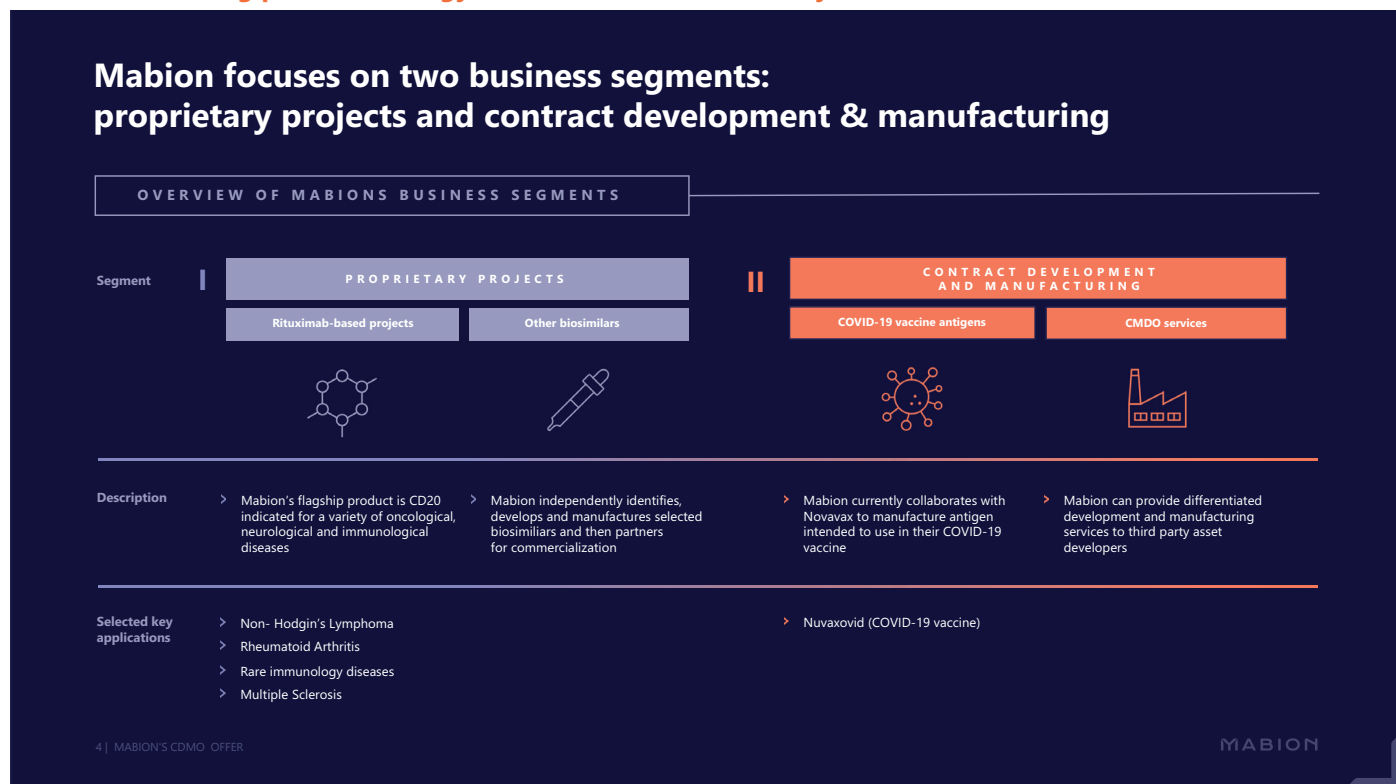
#### Partnership projects

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

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



**Table 3. Preexisting product strategy of Mabion S.A. – a summary.<sup>1</sup>**



**Table 4. R&D project portfolio of Mabion S.A.<sup>2</sup>**

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

<sup>1</sup> Own study of the Company.

<sup>2</sup> Own study of the Company.

The Company's most significant operations in Q1 2022 were related to the MabionCD20 project and Nuvaxovid®:

### **MabionCD20 project**

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

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

The Company has obtained approvals from the relevant authorities and bioethics committees in order to commence the clinical bridging trial. 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 Q1 2022, and until the date of publication of this report, the Company considers the following activities to be successfully carried out:

- > verification of the parameters of the antibody subjected to stability tests under routine and accelerated storage conditions for the validation batches;
- > 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.

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

### **Nuvaxovid® (formerly NVX-CoV2373)**

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

trial runs of the process on a laboratory and commercial scale at the Company's facility.

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

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

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

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

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

On 19 November 2021, a quality agreement was concluded which marked an important step in the implementation of the manufacturing agreement, covering technical and regulatory arrangements for the production of Nuvaxovid® antigen, including relevant GMP standards. The agreement sets forth the obligations and technical and regulatory arrangements required for the manufacture, testing, storage and shipment of the product. It also sets out the principles of cooperation between the departments involved in the implementation of the Agreement.

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

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

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

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

### **3.2 Description of significant achievements and failures of the Company in Q1 2022 and after the balance-sheet date**

#### **Order to manufacture cell banks under the manufacturing agreement with Novavax, Inc.**

On 14 January 2022, as part of the commercial contract manufacturing agreement of 8 October 2021 entered into by the Company with Novavax, Inc. ("Novavax") ("Master Contract Manufacturing Agreement"), the parties signed an additional order in the form of Statement of Work #3 ("SOW#3"). Based on the SOW#3, in addition to its existing work, the Company has produced GMP-compliant cell banks for Novavax, which will be used as key biological material to form the basis for the production of vaccine antigens of the Nuvaxovid® product. The production was carried out in compliance with the technical and quality requirements specified in SOW#3. In line with the assumptions, the Company has produced cell banks in accordance with the GMP standard and confirmed the sterility of the resulting material in Q1 2022. The cell banks were sent to external entities for an additional series of analytical tests. The external analyses are scheduled to be completed around mid-2022. Upon the completion of all analytical testing, Mabion will place the cell banks at Novavax's disposal within the existing network of entities involved in the production of the Nuvaxovid® vaccine.

Despite the fact that, in relation to the originally signed Manufacturing Agreement, the financial value of SOW#3 itself is not relevant for the assessment of the materiality of the order for the Company, the extension of the cooperation with Novavax into another new area, i.e. the production of cell banks, remains an important and key business value for the Company. At the same time, the event in question represents a major operational action to increase Novavax's vaccine production capacity. In the opinion of the Management Board, the Company's selection in the bidding process held by the contractor confirms the Company's qualifications as a Contract Development and Manufacturing Organisation (CDMO).

The Company informed on receiving SOW#3 in Current Report no. 2/2022 of 14 January 2022.

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

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

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

The Company informed on receiving SOW#2 in Current Report no. 3/2022 of 18 January 2022.

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

On 24 February 2022, the Management Board of Mabion S.A. decided to abandon further implementation of the research project concerning the development of MabionEGFR, entitled "Development of a biotechnological medicine through the development of an innovative monoclonal IgG1 subclass antibody with reduced content of unfavourable glycoforms compared with the reference medicine – targeted against EGFR", due to the fact that, in the opinion of the Management Board, the continuation of the project was not justified.

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

The Company informed about the decision in Current Report no. 7/2022 of 24 February 2022.

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

On 19 April 2022 (an event after the balance-sheet date), the Company concluded, with the Ministry of Development Funds and Regional Policy, an annex to the agreement of 11 June 2018 on co-financing of the project entitled "Expansion of the Research and Development Centre of Mabion S.A. - research on the new generation of medicines". According to the annex, the period of expenditure eligibility for the project was extended until 31 December 2023 (previously, it was 31 December 2021). Moreover, due to the inclusion of an additional research area in the Company's activity, i.e. vaccine therapies, the objective and material and financial scope of the Project were changed to the extent enabling the introduction of the aforementioned research area to the Project. The annex was entered into at the request of the Company due to circumstances affecting the implementation of the project in previous years, i.e. at first issues related to own contribution financing, and then the COVID-19 pandemic and the need to account for the area of vaccine therapies.

The Company informed on signing the annex to the agreement in Current Report no. 10/2022 of 19 April 2022.

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

On 19 April 2022 (an event after the balance-sheet date), the Company received information that the Company's activity as a manufacturer of active substance SARS-CoV-2 rS was entered into the National Register of Manufacturers, Importers and Distributors of Active Substances kept by the Chief Pharmaceutical Inspectorate (GIF).

Obtaining an entry is a neutral event from the operational side of the implementation of the manufacturing agreement entered into on 8 October 2021 with Novavax, i.e. it was not related to the tasks and settlements carried out so far, nor did it affect the tasks planned in future periods, settlements between the parties, or the schedule for the production of the vaccine antigen. All these elements are governed by the manufacturing agreement for 2022–2025, which the Company implements on schedule. The event was of material importance to the Company in the regulatory context. It represented the final regulatory element for which the Company, as the entity conducting the manufacturing activities, was responsible as part of its cooperation with Novavax, i.e. holding an appropriate up-to-date GMP certificate and ensuring that the Company, as the manufacturer of the active substance SARS-CoV-2 rS, is entered in the Register of the Chief Pharmaceutical Inspectorate as the competent authority for the Company. The other regulatory activities – those related to updating regulatory documentation on the product side, rest with Novavax. As a result of obtaining the Entry, all batches of the product, i.e. a COVID-19 vaccine named Nuvaxovid®, manufactured by the Company in GMP standard for Novavax, once the formalities have been completed by Novavax, will be sellable by Novavax. The Company is remunerated on an ongoing basis upon completion of the manufacturing and quality control of a batch.

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

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

In Q1 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:

- > the scope and timing of the work required to conduct the bridging clinical trial and submit a new marketing authorisation application (MAA) for MabionCD20 on the basis of the Scientific Advice procedure with the EMA;
- > implementation of the work related to product stability tests and similarity and comparability tests for MabionCD20 originating from the large-scale validation batches and achievement of the expected results;
- > costs of ongoing research and development for MabionCD20 and other medicines in the Company's pipeline;
- > implementation of the commercial contract manufacturing agreement concerning the Nuvaxovid® antigen for Novavax, including its progress and schedule;
- > implementation of the Company's financing strategy adopted on 27 January 2021, including the possibility of acquiring a strategic investor and/or leveraging debt financing;
- > possibility of establishing cooperation with new partners for the development of the Company's current or future therapeutic projects;
- > possibility of acquiring a distribution partner or partners for the EU and US markets for MabionCD20;
- > proceeds from the assistance granted from European funds and the possibility of obtaining additional funds from the EU;
- > timely disbursement of funds by state institutions dealing with the distribution of means under projects co-financed from EU funds;
- > staff costs and general administration costs of the Company;
- > completion of research and development work on and registration of MabionCD20 on key markets: European and American;
- > to finance the planned increase in production capacity, taking into account the intensification of activities related to the new production plant construction project;
- > exchange differences resulting from changes in foreign currency exchange rates.

Receipts/refunds of costs incurred may be affected by possible delays in ongoing discussions or unforeseen departures from the schedules of agreements already signed.

On 24 February 2022, Russia invaded Ukraine. 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. In December 2021, the Ministry of Health in Ukraine granted permission for the Company to conduct a clinical trial of MabionCD20 in patients with rheumatoid arthritis 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 ongoing situation make it possible. 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. Notwithstanding the above, volatile exchange rates, interest rates, the potential for economic growth, the impact of higher immigration and the possibility of the proliferation of conflict, have increased the uncertainty of the environment in which the Company operates. Therefore, as part of the work related to the update of the MabionCD20 project schedule, the Company is currently analysing possible actions to mitigate the impact of the situation in Ukraine.

The ongoing economic situation in the East - due to the war in Ukraine – has caused the Management Board to also closely monitor the regulations introduced by the Polish Government, the governments of other EU countries, and the United States. A protracted conflict may result in higher prices of, for example, energy, restrictions on free trade, or other business restrictions, including disruptions in the supply chain for goods and services. The Company has analysed the impact of the Russian military invasion of Ukraine and its current and future possible consequences for the Company. The Management Board is of the opinion that the invasion and its effects do not affect the measurement and classification of assets and liabilities in the financial statements as at 31 December 2022.

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

### **3.5 Transactions with related parties**

In Q1 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 Q1 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 Q1 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

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**

Member of the Management Board

**Grzegorz Grabowicz**

Member of the Management Board

**Adam Pietruszkiewicz**

Member of the Management Board

Konstantynów Łódzki, 27 May 2022



# MABION

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