



Separate Semi-Annual Report

for period 01.01.–30.06.2023

Wrocław, August 31, 2023

Table of contents

PART I	3
I. SELECTED FINANCIAL DATA.....	3
II. ABBREVIATED INTERIM FINANCIAL STATEMENTS OF PURE BIOLOGICS INC.....	4
PART II – HALF-YEARLY ACTIVITY REPORT	5
III. BASIC INFORMATION ABOUT THE COMPANY AND ITS ACTIVITIES.....	5
1. Information about the company	5
2. Information on branches or establishments owned	6
3. Organisational or capital links.....	7
4. Characteristics of external factors significant for the development of the Company	7
5. Information on Pure Biologics Inc.'s development strategy.....	12
6. Description of Pure Biologics Inc.'s activities	17
7. Information on major achievements in research and development	22
Introduction	22
Antibody-based immune-oncology drug development projects	24
Drug development project PBO01 (MultiBody).....	24
Drug development project PBO03a	25
Drug development project PBO03g	27
Drug development project PBO04 (PureBIKE)	29
Aptamer-based therapeutic projects	31
Therapeutic project PBO02 (AptaPheresis)	31
Therapeutic project PBO05 (AptaMG)	32
Therapeutic project PB103	33
Collaborative science and technology projects	36
Project PBO13 (ALTERCAR)	36
Project PBO14 (DualDrug)	36
8. Information on events significantly affecting the Company's operations during and after the financial period.....	37
9. Identification of shareholders holding, directly or indirectly, significant blocks of shares, along with an indication of the number of shares held by these entities, their percentage share in the share capital, the number of votes resulting from them and their percentage share in the total number of votes at the general meeting	45
10. Company shares held by members of the Management Board and the Supervisory Board	46

11. Indication of any restrictions regarding the transfer of the ownership of the Issuer's securities	46
12. Information on agreements known to the Company, including those concluded after the balance sheet date, which may result in future changes in the proportions of shares held by existing shareholders	46
IV. BASIC ECONOMIC AND FINANCIAL FIGURES.....	48
1. Commentary on the current and projected financial situation.....	48
2. Key financial and non-financial performance indicators.	52
3. Description of the use of proceeds from the issue of securities.....	54
4. Evaluation of the management of financial resources	54
5. Assessment of the feasibility of investment intentions.....	55
PART III – STATEMENTS	56
V. STATEMENT OF THE MANAGEMENT BOARD OF PURE BIOLOGICS S.A. ON THE PREPARATION OF THE FINANCIAL STATEMENTS AND THE MANAGEMENT REPORT	56

PART I

I. SELECTED FINANCIAL DATA

The selected financial data presented in the report have been converted into euro as follows:

- 1) Items relating to the statement of profit or loss and other comprehensive income, the cash flow statement have been translated at an exchange rate which is the arithmetic mean of the exchange rates announced by the National Bank of Poland on the last day of each month:
 - for period 01.01.2023 – 30.06.2023: PLN 4,6130
 - for period 01.01.2022 – 30.06.2022: PLN 4,6427
- 2) The items of the statement of financial position were translated at the average exchange rate announced by the National Bank of Poland as at the balance sheet date, which was as follows:
 - as at 30.06.2023: PLN 4,4503
 - as at 31.12.2022: PLN 4,6899

	For period 01.01.2023 – 30.06.2023	For period 01.01.2022 – 30.06.2022	For period 01.01.2023 – 30.06.2023	For period 01.01.2022 – 30.06.2022
in PLN thousand				
Operating income	9 807	6 523	2 126	1 405
Total operating expenses	23 961	17 561	5 194	3 783
Operating profit (loss)	(15 610)	(10 980)	(3 384)	(2 365)
Profit (loss) before tax	(16 959)	(12 023)	(3 676)	(2 590)
Net profit (loss)	(16 959)	(12 023)	(3 676)	(2 590)
Net cash flow from operating activities	(12 934)	(1 808)	(2 804)	(389)
Net cash flow from investing activities	(7 391)	23 655	(1 602)	5 095
Net cash flow from financing activities	26 119	(1 103)	5 662	(238)
Total net cash flow	5 794	20 744	1 256	4 468

	As at 30.06.2023	As at 31.12.2022	As at 30.06.2023	As at 31.12.2022
in PLN thousand				
Total assets/liabilities	74 560	33 009	16 754	7 038
Fixed assets	36 286	8 838	8 154	1 884
Current assets	38 274	24 171	8 600	5 154
Equity	20 617	18 297	4 633	3 901
Liabilities and provisions for liabilities	53 944	14 712	12 121	3 137
Long-term liabilities	38 987	1 877	8 761	400
Short-term liabilities	14 957	12 834	3 361	2 737
Weighted average number of shares	3 145 050	2 254 000	3 145 050	2 254 000
Profit (loss) per ordinary share (PLN / EUR)	(5,39)	(5,33)	(1,17)	(1,15)
Number of shares at the end of the period	3 214 000	2 254 000	3 214 000	2 254 000
Book value per share (in PLN/EUR)	6,56	8,12	1,47	1,73

II. ABBREVIATED INTERIM FINANCIAL STATEMENTS OF PURE BIOLOGICS INC.

Pure Biologics Inc.'s abbreviated interim financial statements are attached as Appendix 1 to this report.

PART II – HALF-YEARLY ACTIVITY REPORT

III. BASIC INFORMATION ABOUT THE COMPANY AND ITS ACTIVITIES

1. Information about the company

On April 30, 2014 Pure Biologics Inc. (the "Company", "Entity") was entered into the Register of Entrepreneurs of the National Court Register, kept by the Regional Court for Wrocław-Fabryczna in Wrocław, 6th Commercial Division of the National Court Register, under KRS number 0000712811. On 10 January 2018 the conversion of the Entity into a joint-stock company was registered. The Company's registered office is located in Wrocław (54-427), address: 11 Duńska Street. The Entity has been assigned the Tax Identification Number (NIP) number 8943003192 and the Register of National Economy (REGON) number 021305772. The Company maintains a corporate website at www.purebiologics.com and has an e-mail box at info@purebiologics.com.

The Company operates under the provisions of the Commercial Companies Code and the Company's Articles of Association. The duration of the Company is indefinite.

Pure Biologics specializes in research and development in the field of innovative biological medicines, medical devices with therapeutic and diagnostic applications. The Company also conducts contract research for pharmaceutical and biotechnology companies particularly in the area of selection of active molecules (antibodies and aptamers) for medical applications (drugs and therapeutic procedures, diagnostics) and the production, purification and analysis of recombinant proteins and the development of measurement methods.

Since the first quarter of 2023, the company's laboratory and offices have been located in new premises in the Business Garden complex at 48E Legnicka Street.

Management Board

As on June, 30 2023 and as on the date of this report the Management Board consists of:

- Mr. Filip Jeleń – President of the Management Board,
- Mr. Romuald Harwas – Vice-President of the Management Board,
- Mr. Petrus Spee – Vice-President of the Management Board.

During the period covered by this report, the composition of the Management Board did not change.

Due to the expiry of the term of office of the Management Board on the date of approval of the Financial Statements for the financial year 2022, i.e. 25 May 2023, on 26 May 2023 the Supervisory Board of the Company appointed the Management Board with an unchanged composition for a new five-year term of office.

Supervisory Board

As on June, 30 2023 and as on the date of this report, the Supervisory Board consists of:

- Mr. Andrzej Trznadel – Chairman of the Supervisory Board,
- Mr. Paweł Wiśniewski – Deputy Chairman of the Supervisory Board,
- Mr. Tadeusz Wesołowski – Member of the Supervisory Board,
- Ms. Julia Bar – Member of the Supervisory Board,
- Mr. Mariusz Czekala – Member of the Supervisory Board.

To May, 25 2023 the Supervisory Body was composed of:

- Mr. Andrzej Trznadel – Chairman of the Supervisory Board,
- Mr. Tadeusz Wesołowski – Deputy Chairman of the Supervisory Board,
- Ms. Julia Bar – Member of the Supervisory Board,
- Mr. Andrzej Kierzkowski – Member of the Supervisory Board,
- Mr. Mariusz Czekala – Member of the Supervisory Board.

During the period covered by this report, the term of office of the Supervisory Board came to an end. The election of the Supervisory Board for a new five-year term took place at the General Meeting of Shareholders on 25 May 2023.

Audit Committee

As on June, 30 2023 and as on the date of this report, the Audit Committee of the Supervisory Board is composed of:

- Mr. Mariusz Czekala – Chairman of the Audit Committee,
- Ms. Julia Bar – Member of the Audit Committee,
- Mr. Andrzej Trznadel – Member of the Audit Committee.

Mr. Mariusz Czekala is a member of the Audit Committee who fulfils the conditions of the Act on Statutory Auditors concerning having knowledge and skills in accounting or auditing, while Ms. Julia Bar has knowledge of the industry in which the Company operates. Julia Bar and Mariusz Czekala are also the independent members within the meaning of the Act on Statutory Auditors.

Due to the expiry of its term of office on the date of approval of the Financial Statements for the financial year 2022, i.e. 25 May 2023, on 26 May 2023 the Company's Supervisory Board appointed an audit committee with an unchanged composition.

2. Information on branches or establishments owned

In the first half of 2023, the Company did not have any branch or plant.

3. Organisational or capital links

On 1 December 2022, Pure Biologics Inc. established a subsidiary in which it acquired 100% of the shares, Doto Medical Ltd. with its registered office in Wrocław, at: 48E Legnicka Street, 54-202 Wrocław, entered in the Register of Entrepreneurs under the KRS number 0001006044, whose registration files are kept by the District Court for Wrocław-Fabryczna in Wrocław, IX Economic Division of the National Court Register, holding the tax identification number NIP 8943200107, with a share capital of PLN 5,000.00, represented by Filip Jeleń, President of the Management Board.

Due to qualitative and quantitative parameters, the Company waived the preparation of consolidated financial statements for the 6 months ended 30 June 2023.

4. Characteristics of external factors significant for the development of the Company

The pharmaceutical market – key drivers and trends

Overview of selected newly registered anticancer drugs in 2022

The US Food and Drug Administration, FDA registered in 2022. 37 new drugs, of which 12 were new cancer therapies and in the first half of 2023. 26 new drugs, among which were five therapeutic antibodies.

Among the newly registered anticancer drugs, it is worth mentioning several that involved antibodies:

January 2022 saw the registration of the first T-cell receptor (TCR)-based drug, tebentafusp (Kimmtrak, from Immunocore). This is a bispecific fusion protein that is a combination of a soluble T-cell receptor (TCR) targeting the melanoma tumour antigen protein gp100, with an antibody fragment targeting CD3, which is responsible for binding and activating cytotoxic T cells. The approach used offers an alternative to CAR-T therapies based on genetic modification of the patient's own cells. It also enables the targeting of tumour antigens expressed intracellularly, which until now has mainly been the domain of small-molecule compound therapy. Tebentafusp has been registered as a monotherapy for adults with human leukocyte antigen (HLA)-A*02:01 disease suffering from inoperable or metastatic uveal melanoma. Immunocore was founded in 2008 as a spin-out from MediGene AG. In 2015, Immunocore closed the largest Series A private company funding round in European history with \$320m. In 2017, the company's growth support was bolstered by \$40m invested by the Bill & Melinda Gates Foundation. In March 2020, Immunocore raised an additional \$130m in a Series B private placement, followed by a further \$75m in a Series C private round in January 2021. Immunocore has been listed on Nasdaq since February 2021. In its latest report, the company announced that total revenue (total revenue) from Kimmtrak sales for 2022 was \$141.1m.

In March 2022, FDA registration took place for the first drug targeting the immune checkpoint LAG3 (anti-LAG3 antibody – relatlimab) for use in combination therapy with nivolumab (anti-PD-1), under the common name Opdualag (from Bristol Myers Squibb) in patients with inoperable or metastatic melanoma.

This therapy is expected to be a safer alternative than the previously used combination of ipilimumab (anti-CTLA4) with nivolumab (anti-PD-1) and more effective than nivolumab or pembrolizumab (anti-PD-1) monotherapy.

In August 2022, conditional marketing authorisation was granted by the EMA for teclistamab (Tecvayli, Janssen), for relapsed or refractory multiple myeloma in adults who have received at least three prior lines of therapy and whose disease has worsened since their last treatment. Teclistamab is a first-in-class bispecific antibody (CD3 x BCMA) that induces CD3+ T lymphocytes to eliminate tumour cells expressing the BCMA antigen.

An interesting case is the anti-CTLA-4 antibody tremelimumab (Imjudo, AstraZeneca), registered by the FDA in October 2022 for the treatment of unresectable hepatocellular carcinoma (HCC). The molecule first entered the clinical trial phase more than 20 years ago, in the meantime scoring a number of failures. It was finally approved for marketing in combination therapy with durvalumab (Imfinzi, AstraZeneca).

All of the above-mentioned drugs have also been approved for marketing in 2022 by the EMA in the European Union and by the FDA in the United States of America.

In January 2023, the FDA issued a positive decision for an antibody called retifanlimab-dlwr (Zynyz, from Incyte). It is a drug that blocks the PD-1/PD-L1 pathway registered for the treatment of adult patients suffering from metastatic or advanced Merkel cell carcinoma (MCC), a rare skin cancer with very high malignancy. The drug was also granted orphan drug status by the European Medicines Agency (EMA) in January 2023.

In May 2023, the FDA registered the antibody epcoritamab-bysp (Epkinly, by Genmab and AbbVie) for the treatment of relapsed or refractory unspecified diffuse large B-cell lymphoma (DLBCL), which is the most common type of lymphoma diagnosed in adults. Diffuse large B-cell lymphoma (DLBCL), which is the most common type of lymphoma diagnosed in adults, and for the treatment of relapsed or refractory high-grade B-cell lymphoma after two or more lines of systemic therapy. The drug is a bispecific antibody that targets CD20 x CD3 to activate T cells. The drug was developed in collaboration between AbbVie and Genmab, under a partnership agreement between the companies signed in June 2020. The agreement was for collaboration on the further development and co-commercialisation of three Genmab-owned molecules (including epcoritamab), and provided for an upfront payment of \$750m and potential milestone achievement payments totalling \$3.15bn.

June 2023 brought FDA registration of an antibody called glofitamab-gxbm (Columvi, from Genentech/Roche Group). It is a highly competitive product to epcoritamab, both in form and function – it too is a bispecific antibody targeting CD20 x CD3 – and in therapeutic scope – it has been approved for the treatment of adult patients with relapsed or refractory indolent diffuse large B-cell lymphoma, and in patients with large B-cell lymphoma (LBCL). Large B-cell lymphoma (LBCL) of follicular lymphoma origin after 2 or more unsuccessful lines of systemic therapy.

The first half of 2023 also saw the registration of:

- in January – lecanemab-irmb antibody (Leqembi, from Eisai/Biogen) for the treatment of Alzheimer's disease
- in June, an antibody called rozanolixizumab-noli (Rystiggo, from UCB) for the treatment of generalised myasthenia gravis in patients who have anti-AChR (against acetylcholine receptor) or anti-MuSK (against muscle-specific tyrosine kinase receptor) antibodies. The mechanism of action of this drug is based on binding to the neonatal Fc receptor (FcRn), resulting in an overall reduction of IgG class antibodies in the plasma of patients, including the aforementioned pathological anti-AChR and anti-MuSK autoantibodies.

Anti-cancer drugs withdrawn from the market

In addition to newly registered therapies, 2022 also brought two FDA decisions to withdraw registered drugs from the market. Both decisions concerned the low-molecular-weight kinase inhibitors idelalisib (Zydelig, Gilead) for the treatment of small lymphocytic lymphoma (B-cell lymphoma) and follicular lymphoma, and umbralisib (Ukoniq, TG Therapeutics) previously used for the treatment of marginal zone lymphoma (MBL) and follicular lymphoma. Both decisions were influenced by concerns about the safety of the therapy. Zydelig was withdrawn voluntarily at the request of Gilead.

Review of selected partnering deals concluded in 2022

Transactions made on molecules in the pre-clinical development stage:

DragonFly Tx & Gilead (5T4 TriNKETM)

In May 2022, Dragonfly Therapeutics and Gilead announced a collaboration on anti-cancer and anti-inflammatory immunotherapies being developed by Dragonfly based on the use of biological molecules that cause activation and recruitment of NK cells and cytotoxic T cells to the tumour. Under the agreement, Gilead is to receive an exclusive and territorially unlimited licence for the molecule DF7001, targeting the recognition of cancer cells overexpressing the 5T4 protein. The agreement also provides an additional option for Gilead to extend the collaboration to additional molecules within Dragonfly's TriNKETM platform once they reach certain stages of preclinical testing. The agreement includes an upfront payment of \$300m to Dragonfly, as well as additional milestone payments for undisclosed amounts, and royalties of up to 20% of total global net revenues from future sales of the drug.

Harbour BioMed vs AstraZeneca (Claudin 18.2 x CD3 bsAb)

In April 2022, Harbour BioMed and AstraZeneca entered into a licensing agreement under which AstraZeneca obtained the rights to further develop and commercialise the bispecific antibody HBM7022, which targets the tumour-associated antigen (T-cell CD3 coreceptor) protein Claudin18.2. The molecule was in preclinical development at the time of signing the agreement. The financial terms of the agreement included an upfront payment to Harbour BioMed of \$25 million, milestone achievement payments of up to \$325 million, and royalties on future sales of the drug by AstraZeneca.

ABL Bio vs Sanofi (alpha-synuclein x IGF1R bsAb)

In January 2022, ABL Bio Corp and Sanofi announced a collaboration and licensing agreement for the rights to the bispecific antibody ABL301 being developed by ABL Bio and directed against the alpha-synuclein protein and insulin-like growth factor 1 receptor (IGF1R). The antibody is being developed for the treatment of Parkinson's disease and other potential indications associated with increased penetration of the blood-brain barrier. Under the agreement, ABL Bio is entitled to receive an initial payment of \$75m. In addition, if certain milestones are met, Sanofi will pay ABL Bio up to \$985m, of which a payment of \$45m is expected in the short term. The agreement also includes royalty provisions from future sales of the drug following its successful registration and commercialisation. ABL Bio is responsible for further preclinical development and conducting Phase I clinical trials. Sanofi, on the other hand, will be required to continue the clinical development of the antibody in question.

Lava Therapeutics vs Seagen (EGFR x TCRgd bsAb)

Another deal involves Lava Therapeutics' LAVA-1223 molecule, a bispecific antibody that recruits gamma delta T cells, a subpopulation (approximately 4 per cent) of T cells characterised by expression of a TCR receptor composed of gamma and delta chains, as opposed to classical T cells with a TCR receptor composed of alpha and beta chains. LAVA-1223 recognises tumour cells with overexpression of the epidermal growth factor receptor (EGFR) and induces the recruitment of gamma delta T cells, resulting in the elimination of tumour cells.

Under the agreement, signed in September 2022, in exchange for an upfront fee of \$50m, potential milestone achievement payments of up to a total of \$650m, and royalties in the range of a few to several per cent on future sales of the drug, Seagen acquired the right to an exclusive licence for the further development and commercialisation of the said antibody, as well as the opportunity for further exclusive negotiations for a further two antibodies targeting distinct cancer targets.

Transactions made on molecules in the clinical development stage:

Kelun-Biotech vs Merck & Co.

In May 2022, Kelun-Biotech entered into a licence agreement with Merck & Co./MSD granting an exclusive licence for the further development and commercialisation, excluding the Chinese territory, of an antibody-drug conjugate (ADC) molecule under the name SKB-264/MK-2870. The molecule recognises the TROP-2 protein overexpressed on the surface of tumours and, at the time of signing, was being tested in Phase III clinical trials in patients with metastatic triple-negative breast cancer and in Phase II clinical trials in patients with non-small cell lung cancer and other advanced-stage solid tumours. The terms of the agreement included an upfront payment of \$47m, a potential \$1.36bn milestone achievement payment, and royalties from future sales.

At the end of July 2022, the companies made a further announcement expanding their collaboration to include a second ADC-type molecule under development by Kelun-Biotech in clinical trials. The agreement was for a \$35m upfront fee, \$901m in potential milestone achievement fees and royalties from future sales, and guaranteed Merck exclusive global rights to continue its development.

In December 2022, the aforementioned collaboration was extended again to include a further seven ADC-type molecules with anti-cancer potential in preclinical testing. Based on this agreement, Kelun-Biotech will receive a \$175m upfront fee, potential cumulative milestone payments totalling up to \$9.3bn (when it relinquishes rights to the Chinese market) and will acquire royalty rights from future sales of any of the drug candidates. Merck has also indicated its intention to make an equity investment in Kelun-Biotech.

Innovent Biologics vs Sanofi

In August 2022, Sanofi and Innovent Biologics entered into a strategic partnership to accelerate the development and availability of oncology drugs and expand Sanofi's presence in the Chinese market. As part of this agreement, Sanofi plans to accelerate the development and commercialisation in China of its two anti-cancer molecules being tested in clinical trials, i.e. SAR408701 (tusamitamab ravtansine, an anti-CEACAM5 ADC) – which is in Phase III clinical trials – and SAR444245/THOR-707 (recombinant IL-2) – which is being tested in Phase II clinical trials, in combination with Innovent Biologics' PD1 checkpoint inhibitor sintilimab. Sanofi has committed to an equity investment of €300m through the subscription of new ordinary shares of Innovent Biologics.

Review of selected partnership deals concluded in the first half of 2023

The first half of 2023 saw several M&A transactions between large players, among them Pfizer's \$43bn acquisition of Seagen (with its antibody-drug conjugate (ADC) generation platform) in March, and Merck's \$10.8bn purchase of Prometheus Biosciences in April, expanding its portfolio in the development of new therapies for autoimmune diseases. Other deals worth mentioning include Astellas Pharma's acquisition of Iveric Bio (US\$5.9bn, ophthalmology) and Sanofi's acquisition of Provention Bio (US\$2.9bn, type 1 diabetes).

In the immuno-oncology sector, it is worth mentioning that in March 2023, invoX Pharma first finalised (for a total of USD 161 million) the acquisition of F-star Therapeutics, which is developing bispecific antibodies in the area of immunotherapy for phase II clinical trials, to announce two weeks later (second to the first between F-star and Takeda in July 2022) a transaction based on the granting to Takeda of an exclusive and unlimited territorial licence to use two technology platforms owned by F-star for Takeda's development of a bispecific antibody against an undisclosed immuno-oncology molecular target.

Subsequently, in July 2023, invoX announced a further deepening of its collaboration with Takeda, by entering into a strategic partnership and granting Takeda a further third, exclusive and territorially unlimited licence to use its technology platforms to develop further next-generation multispecific therapeutic antibodies. Under the latter agreement, F-star will receive an upfront payment of an undisclosed amount, and will be entitled to potential milestone payments of up to US\$1 billion (if all targets are achieved), as well as receive royalties on net sales in the event of commercialisation of products developed using the licence in question.

Availability of new non-dilutive financing options

Given the Company's adopted and successful model of funding research and development work largely with non-dilutive capital in the form of grants, the Company monitors and identifies the availability of the aforementioned forms of R&D funding on an ongoing basis.

Innovative drug development projects, due to their pioneering nature, carry a high investment risk, but at the same time have great commercialisation potential. Thanks to the use of grant funding, the shaping of the Company's project portfolio can take place with minimal impact on the shareholder structure and minimisation of investment risk for all shareholders of the Company. Both national, European (administered by both Polish and EU agencies) and US funds are monitored.

In 2022, funding was available from the following sources:

- Horizon Europe 2021 – this programme provides support for innovation across the EU with a total budget of €95.5 billion. One sub-programme of particular interest to the Company is 'Mission: Cancer', aimed at co-funding oncology projects, with a budget of €255 million for 2021–22.
- The Medical Research Agency, set up to support clinical trials in Poland, has allocated PLN 250 million in 2022 for the development of targeted or personalised medicine based on cell therapies or protein products. Pure Biologics managed to secure PLN 65 million from this fund for phase 1 clinical trials for projects PBO03g and PBO04.
- National Cancer Institute Clinical and Translational Exploratory/Developmental Studies (R21) – a programme of the US government agency, National Institutes of Health.

In addition, a schedule of competitions was announced in January 2023 as part of the European programme 'European Funds for the Modern Economy 2021–2027' (FENG), a continuation of the

Intelligent Development 2014–2020 programme, which the Company has used and continues to use to co-finance R&D projects. The budget for this programme is EUR 7.9 billion. In February 2023, PARP announced the first competition under the SMART path, with an allocation of PLN 4.5 billion.

5. Information on Pure Biologics Inc.'s development strategy.

Execution of own B+R projects

Pure Biologics' goal is to continuously deliver value to shareholders by 1) creating new projects for the development of innovative therapies in commercially attractive areas and 2) developing the current portfolio of highly innovative projects towards clinical stages, with the aim of significantly increasing the value of the assets at the commercialisation stage. Pure Biologics' ambition is to initiate a first-time-in-human study by the end of 2023.

Pure Biologics is developing original drugs with the potential to become first-in-class on the market. The company focuses on developing drug candidates in-house up to the lead candidate selection stage, in its state-of-the-art research facility and with a highly trained team of more than 50 experts, approximately half of whom hold doctoral degrees. In addition, Pure Biologics is building a strong international team of specialists who can lead preclinical development, manufacturing development (CMC), regulatory and safety issues, as well as clinical development of lead candidates by outsourcing.

A key element of Pure Biologics' strategy is so-called 'smart development' of drugs. Pure Biologics' projects are based on the opportunity to significantly improve drug candidates that have demonstrated clear therapeutic potential at an early stage of clinical development in previously conducted clinical trials. Accordingly, Pure Biologics undertakes the development of a drug candidate with a clear competitive advantage over other solutions under development, while largely reducing risk by building on a successful clinical development plan for similar molecules. Another aspect of 'smart growth' is the creation of a clinical development pathway for each project with a strong focus on demonstrating signs of therapeutic efficacy at an early stage. Pure Biologics will focus on introducing phase 0 clinical trials in its projects to obtain pharmacodynamic data even before conventional phase 1–3 clinical trials are conducted. This will significantly increase the valuation of early-stage projects, but will also guide the design of subsequent clinical phases, which will be based on active and multifaceted patient stratification, rather than studies involving broad populations, and will include biomarkers as additional trial endpoints to demonstrate therapeutic activity. This aspect of the implementation of 'smart clinical development' will provide valuable pharmacodynamic data at an early stage of drug development to (1) reduce the risk of failure of later, costly clinical stages and (2) significantly increase the valuation of early clinical development projects.

Development of contract research

In the Polish market, Pure Biologics is a leader in in vitro antibody and aptamer selection technology and is also one of the few commercial entities involved in this field in Europe. With its ongoing research and development projects (technology platforms), it has a real opportunity to further strengthen its market position. In vitro selection is an efficient and cost-optimised way of obtaining active molecules (antibodies and aptamers) that bind a selected molecular target. It is both a basis for the development of biological drugs and diagnostic tests for internal projects and a technology that can be successfully used for the provision of external contract research, the volume and margins of which will increase many times over when the above platforms are used as a service.

Pure Biologics' extensive expertise and solid scientific background, as well as the innovation and uniqueness of the technological solutions it offers, mean that it is able to carry out complete drug development projects on behalf of pharmaceutical companies, from the discovery stage through to early preclinical studies.

Sources of funding in the Company's development strategy are own resources and subsidies from EU and national funds. Since the beginning of its operations, the Company has obtained a total of approximately PLN 183,000 thousand in grants for the implementation of research and development projects. The Company raises its own contribution to the implementation of R&D projects from share issues conducted successively as the research work progresses and milestones of individual project stages are reached. Between 2018 and 2022, the Company carried out four share issues, thus raising its own contribution to the implementation of R&D projects in the amount of PLN 86 168 thousand.

Strategic financial objectives adopted in accordance with the schedule of ongoing R&D projects based on the provisions of the agreements concluded with NCBR, the Company plans to obtain the first proceeds from the commercialisation of individual projects after 2023. In view of the above, the Company should achieve its first revenues from upfront payments no earlier than in 2024, while subsequent years should see revenues related to the achievement of milestones planned for individual projects. However, at the date of publication of the report, the Company is not in a position to accurately determine the amounts of revenue from the commercialisation of individual projects.

The Company's dividend policy in the coming years is to prioritise the use of funds from commercial activities conducted in the contract research segment and equity raised through the issue of shares on the capital market in Poland to cover the Company's own share of innovative R&D projects. Given the number and size of the R&D projects underway and the associated high level of need for an own contribution to supplement the funding received, the Company does not anticipate paying dividends until revenues from the commercialisation of the first successfully completed R&D projects are achieved. At the same time, due to the early stage of the Company's development and the ongoing need for additional capital, the Issuer's Board of Directors cannot determine the year in which it will first recommend the payment of dividends.

The Issuer is not party to any agreements or obligations that would restrict in any way the payment of dividends in the future.

Key measures to implement the Issuer's strategy

Proprietary platforms for the generation of active bio-molecules.

Thanks to the independent development of technological platforms for the selection of antibodies (PureSelect2) and aptamers (PureApta), the Company has two technologies for the rapid and efficient generation of new active bio-molecules, i.e. antibodies and aptamers, which are the subject of further research for diagnostic tests or therapeutic molecules. In the course of further research, the generated bio-molecules are investigated for their potential development into new drugs and biosensors. As a result of the above, the Company is able to operate in three potential market segments in which it can commercialise the results of independently conducted research projects.

Focus on innovative therapies and patient needs

Pure Biologics is focused on developing innovative therapeutic solutions for patients in groups with highly unmet medical needs (HMEs). The Company's strategy includes identifying medical needs by analysing available therapeutic options and currently developing products and designing solutions with a clear competitive advantage. Pure Biologics is developing next-generation

antibodies for immuno-oncology, one of the most ground-breaking areas of modern cancer therapy. The Company is also developing aptamers for therapeutic applications, a relatively young and promising class of molecules active in drugs and medical devices. On the basis of aptamers, it is planned to develop carrier-drug conjugates for oncology applications, particularly in indications where immunotherapy has not yet had significant success, as well as adsorbers for the selective removal of pathogenic molecules from the blood of patients suffering from inflammatory diseases.

Key share of public funding for research projects.

From the beginning of its operations to the date of this report, the Company has obtained approximately PLN 183,000 thousand in public funds, both domestic and European, for the development of research and development projects. The vast majority of these funds, i.e. more than 64%, were granted between 2017 and 2020. During the period covered by this report (and up to the date of publication), the Company obtained approximately PLN 64,880 thousand in grants from the Medical Research Agency to finance the continuation of work on projects PBO03 and PBO04.

Own, highly competent research and development team.

The Company's employees form a research and development team with broad competences and extensive experience gained in Polish and foreign units.

In line with the 2023-1H2024 development plans announced in May 2023, the company optimised its human resources in the first quarter of 2023, which, among other things, reduced the number of employees in all departments of the company.

At the end of 1H2023, the company has 56 employees, the majority of whom (around 57%, a ratio up from around 40% reported previously) with a PhD degree and long tenure (66% over 3 years). The above employment structure therefore reflects the focus on an experienced team with high scientific competence.

Qualified staff, many years of experience and a focus on effective cooperation make it possible both to achieve milestones in our own projects and – in parallel – to carry out commercial orders.

Possibility of reserving rights to all generated molecules.

Thanks to the specificity of the technology for generating active bio-molecules (antibodies and aptamers), each newly generated molecule has a different amino acid or nucleotide sequence in the binding region of the molecular target. At the same time, each such sequence is recognised in patent law as an NCE (new chemical entity), which allows it to be covered by patent protection. The Issuer's aim is to exploit this specificity and extend patent protection to all molecules, both in terms of sequence and potential use. This will apply to molecules that demonstrate efficacy in in vitro disease models and early stage in vivo testing. Due to its ownership of the intellectual property rights to its own libraries from which active molecules are generated, the Company has significant research and business opportunities in this area.

Cooperation with research and scientific centres.

In its ongoing projects, the Company actively cooperates with research centres located both in Poland and abroad. These include: Institute of Immunology and Experimental Therapy of the Polish Academy of Sciences (PAN) in Wrocław, University of Wrocław, University of Lodz, Warsaw Medical University – Department of Immunology, Faculty of Medicine, French Institute of Health and Medical Research – Immunology Research Center (France), Oslo University Hospital – Institute for Cancer Research (Norway).

In the past Pure Biologics has also carried out joint projects with Vall d'Hebron Research Institute (Spain), Institut de Ciència de Materials de Barcelona (Spain), University of Artois (France), Ospedale San Raffaele IRCCS (Italy), Institute of Experimental Physics SAS (Slovakia), AIT Austrian Institute of Technology GmbH (Austria), Albert-Ludwigs-Universität Freiburg (Germany), Imperial College Of Science Technology And Medicine in London (UK), Aarhus Universitet (Denmark) and Łukasiewicz Research Network – PORT Polish Centre for Technology Development.

Activities undertaken as part of the implementation of the development strategy (during the reporting period)

Activities concerning the progress of the Company's R&D projects in the reporting period are presented in Chapter IV, point 7.

The measures relating to the incentive scheme and the employment stability policy, with particular reference to the Company's research and scientific staff and management under the Incentive Scheme, are set out in Note IX.3 "Share-based payments" of the Separate Financial Statements for the period ended 30.06.2023 attached to this report.

Activities including securing funds obtained from the basic sources of financing the Company's activity, i.e. subsidising institutions and own capital, with particular emphasis on funds coming from the capital market, are presented in the Financial Report for the period 01.01-30.06.2023. In December 2022, the Issuer conducted a public offering of a series E share issue, raising PLN 19 120 thousand gross for the implementation of ongoing R&D projects.

Development of research infrastructure.

One of Pure Biologics' goals in 2022 was to prepare and launch the company's new headquarters. The work carried out resulted in the creation of a modern laboratory and office complex with a total area of almost 3,200 sq.m in one of the largest business parks in Poland, Business Garden in Wrocław. In the last quarter of 2022, 1,400 sq.m of laboratory space and 1,800 sq.m of office space were made available to the Company. The laboratory area consists of more than thirty highly specialised laboratories, a storage module and auxiliary installations (such as an external carbon dioxide distribution system or a BMS management system). Some of the rooms are brand new laboratories dedicated to the development of innovative, advanced research methods designed to broaden the Company's research portfolio. Due to the nature of the work being carried out, the Laboratory has been divided into three independent segments served from individual air handling units: cellular, microbiology and specialist laboratories.

The remainder of the complex is made up of office and conference facilities, comprising: three areas for collaborative work (open space), individual offices, seven fully equipped conference rooms, including two rooms that can be combined into one large auditorium.

The company has implemented a dedicated conference room booking system, compatible with calendar services (including M365, Google) equipped with an automatic cancellation function in case of no-shows. Each of the rooms is equipped with high-resolution screens, conference systems or Mersive remote sharing and presentation systems, which allows several meeting participants to wirelessly share and collaborate around content. In addition, the three meeting rooms are equipped with the ability to control the blinds, screens, projector, light intensity or sound directly from the control panel.

As part of the increased and improved security at the new premises, a new, secure, IT infrastructure was provided, with wired (LAN) and wireless (WLAN) networks covering the entire area, managed by state-of-the-art server rooms and intermediate distribution points, based on a fibre-optic

infrastructure. High-bandwidth internet, based on symmetrical optical fibre with an independent back-up link. The area is monitored by 24 IP cameras, with the possibility of increasing the number of cameras, and managed by an internal access control system with the possibility of demarcating access rights to each section and IP monitoring.

The first half of 2023 saw the completion of the 'start-up' phase, which involved adapting and optimising the new workspace to meet the needs identified after the move. The laboratory and offices are functioning smoothly.

Assessment of the feasibility of strategic intentions

When analysing the information on the Issuer's strategy presented in the Report, it should be borne in mind that the degree to which the described intentions are realised is largely dependent on the global economic situation. As at the date of publication of the Report, the Management Board does not foresee any direct, significantly negative impact of the coronavirus pandemic (SARS-CoV-2) on the Company's operations, financial position and R&D project results in the annual period. The outbreak of the armed conflict in Ukraine will have an indirect and limited impact on Pure Biologics S.A.'s financial position. The exact impact of the armed conflict in Ukraine is described in chap. VII par. 10.

However, it cannot be ruled out that a prolonged period of business restrictions, the extension and prolongation of the armed conflict in Ukraine, may in the long term negatively affect the financial situation and the pace of results in R&D projects. Management is monitoring the situation on an ongoing basis and will react accordingly to mitigate the impact of these events if they occur.

Prospects for the development of the Issuer's business in the coming financial year

In 2023. The Company continues to implement the strategy implemented in the previous year for immuno-oncology projects involving phase 0 clinical trials as an intermediate step prior to traditional phases 1-3. This allows early assessment of therapeutic efficacy in the complex tumour environment and provides a cost-effective decision point prior to further expensive clinical trials. On the basis of consultations with the recipients of the assets under development, the above also provides an attractive decision-making element for partnering agreements. The promising results obtained for the flagship projects (PBO03a, PBO03g and PBO04) and the secured access to substantial non-dilutive funds will enable the lead molecules to be produced in the current year and subjected to preclinical testing for safety and anti-tumour efficacy, with a view to commencing clinical development with entry into Phase 0 in December.

Given the market conditions, the Company has redirected its activities in the area of aptamer-based extracorporeal therapies, from the development of targeted plasmapheresis products for niche markets, to products for the treatment of chronic conditions, including targeted haemodialysis for patients with chronic kidney disease, which represents an urgent and unmet medical need for innovative treatments in a large and growing market.

Aiming at the reproducibility of the business model, in addition to the intensification of business development activities leading to the commercialisation of the projects going forward, the Company is working on the conceptualisation of new drug development programmes and plans to start implementing them as early as 2023, upon receipt of funding under the FENG perspective. The expansion of the current project portfolio will allow Pure Biologics to effectively utilise its scientific-technological, infrastructural and operational potential in order to be able to lead to further partnership deals with pharmaceutical companies in the future.

6. Description of Pure Biologics Inc.'s activities

Subject of the Issuer's activity

Pure Biologics specializes in research and development in the field of innovative biological medicines, medical devices with therapeutic and diagnostic applications. The Company also conducts contract research for pharmaceutical and biotechnology companies particularly in the area of selection of active molecules (antibodies and aptamers) for medical applications (drugs and therapeutic procedures, diagnostics).

Development of innovative drugs and therapies

The company's core business is the development of new drugs, extracorporeal therapies and diagnostic methods based on its extensive experience in areas such as molecular biology, cell biology, protein engineering and biochemistry, kinetics of biochemical interactions, pharmacology of biological molecules, or in vitro selections from combinatorial libraries.

A key element of the strategy is 'smart development' of drugs (also presented as a 'Smart IO' approach). The portfolio is developing drug candidates whose molecular profile of action is highly likely to have significant advantages over molecules with a similar mechanism of action that have already demonstrated therapeutic potential and safety in clinical trials (competitor molecules). This means that the risks associated with the development of drug candidates based on a non-clinically validated mechanism are reduced, while remaining competitive by improving and/or adding new parameters in terms of action and/or efficacy. The company targets projects with significant advantages over existing and developing solutions, while also having the potential to be first-in-class.

Another aspect of 'smart growth' is the creation of a clinical development pathway for each project with a strong focus on demonstrating signs of therapeutic efficacy as early as possible.

In the case of projects PBO03G and PBO04 Pure Biologics is focusing on the introduction of phase 0 clinical trials in its projects in order to obtain pharmacodynamic data (efficacy markers) even before conventional phase 1-3 clinical trials are conducted. This will significantly increase the valuation of early-stage projects, but will also guide the design of subsequent clinical phases, which will be based on active and multifaceted patient stratification, rather than the broad population-based studies practised in the classical approach. In addition, biomarkers selected on the basis of phase 0 data will be included as additional endpoints of the study, in order to demonstrate therapeutic activity and clinical efficacy already in phase 1 clinical trials.

Monitoring of the thematic areas of research conducted by other entities and the results obtained by them is carried out independently by the Company's internal Business Intelligence team, based on publicly available information and industry knowledge.

Research and development programmes

Pure Biologics' activities focus on two areas: 1) the development of advanced antibody-based cancer immunotherapy drugs; 2) the use of aptamers for the development of innovative medical devices to selectively remove pathogenic molecules from the blood of patients with inflammatory diseases and those suffering from chronic kidney disease.

The first area (projects PBO01, PBO03A, PBO03G and PBO04) develops next-generation antibodies – bispecific antibodies, bifunctional molecules and molecular target binding molecules with novel

formats to improve their pharmacokinetic properties. These molecules are designed to interact with immune cells in the tumour microenvironment to activate them to kill tumour cells or to lift the immune blockade induced by the tumour. For the discovery of molecular target binding sequences used in the design of next-generation antibodies, Pure Biologics uses its proprietary PureSelect2, technology platform, as well as its own library of sequences (ScFv antibody fragments) PureLibra, in addition to libraries licensed from Twist Bioscience.

The second area (projects PB002, PB005, PB006 and PB103) uses aptamers to create innovative therapeutic solutions – aptamer–drug conjugates for oncology and adsorbers that selectively remove pathogenic molecules from patients' blood for applications in neurology and nephrology. Pure Biologics has a proprietary, patented PureApta technology platform for aptamer selection and is one of the few companies worldwide developing aptamers for therapeutic use. As aptamers are a relatively young class of drugs, the Company is also conducting internal technology projects, including research into improving aptamer stability and investigating the safety of modified nucleotides.

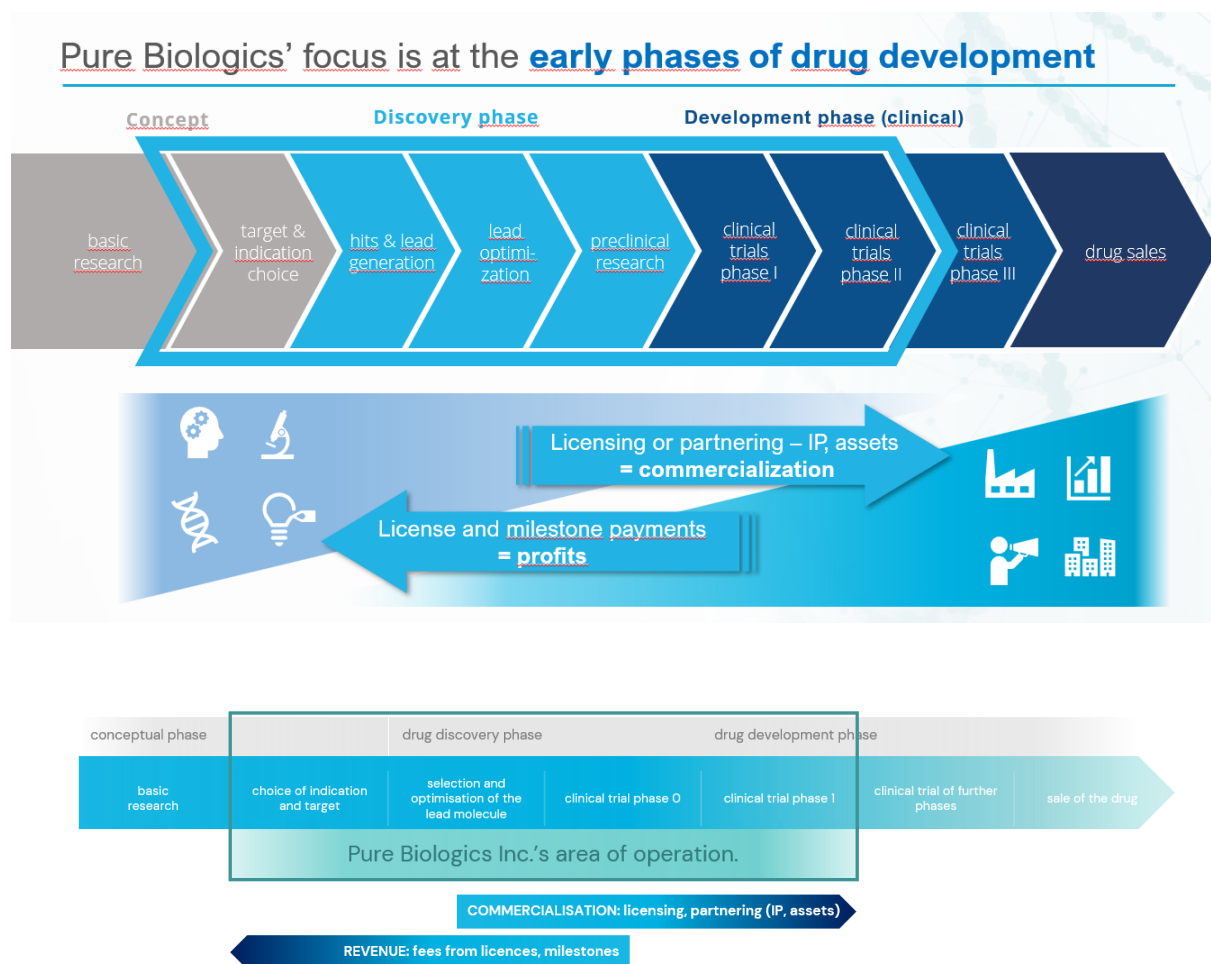


Fig. 1: Phases of drug discovery and Pure Biologics Inc.'s area of activity. The Company operates in the early stages of drug development.

Innovative R&D projects supported by grants

Pure Biologics actively uses public funds to support R&D activities in companies and has repeatedly successfully applied for funding for its projects at both the NCBR and the European Commission. Only in the period 2018–1Q2023 the Company obtained nearly PLN 175 million in funding for the implementation of projects scheduled for 2018–2026.

Science and technology projects

The objective of the scientific and technological projects carried out by the Company is the continuous development of competencies based on proprietary solutions and maximising the areas of IP and know-how utilization. The implementation of this objective includes testing platforms developed by the Company, exploring the possibilities of their commercial applications beyond those arising from the Company's own drug and therapy development projects, and exchanging knowledge and experience between recognised foreign scientific and research units and teams in Europe and worldwide. The collaboration carried out on research projects builds international relationships and provides references for the research concepts and subject matter expertise of Pure Biologics' scientists. The Company's priority objective remains to ensure the repeatability of the business model. In parallel with the development and pursuit of commercialisation of the Company's major projects, activities are directed towards initiating further ultra-innovative programmes. The development of further projects will depend on the acquisition of non-dilutive funding, including primarily in the form of grants.

Contract research

Pure Biologics is a leader in in vitro antibody and aptamer selection technology on the Polish market and is also one of the few commercial entities acting in this field in Europe. Thanks to its research and development projects (technology platforms), it has a real opportunity to further strengthen its market position. In vitro selection is an efficient and cost-optimal way to obtain active molecules (antibodies and aptamers) that bind a selected molecular target. This is both the basis for the development of biological drugs and diagnostic tests for internal projects, and technology that can be successfully used for the provision of external contract research, the volume and margins of which will multiply when the above platforms are used as a service.

Pure Biologics' extensive expertise and solid scientific basis, together with the innovation and uniqueness of the technological solutions it offers, means that it is able to carry out complete drug development projects on behalf of pharmaceutical companies, from the discovery stage through to early pre-clinical testing.

Human resources

The company has modern and well-equipped laboratory and office facilities with 56 employees, 57,1% with doctoral degrees.

The Company engages staff on the basis of employment contracts as well as commissions activities on the basis of civil law contracts.

In the current quarter, the Company has continued its balanced human resources management policy, whereby the size of its research team has been maintained and the focus is on retaining experienced staff within the Company's structures (employment stability index: 87.5%, permanent contract level index: 91.07%).

In line with the announced plans 2023-1H2024, the team composition was optimised, including staff reductions, as reflected in the general turnover rate for 1H2023 (26.38%).

There has been no significant and disruptive employee absenteeism, with a general absenteeism rate of 1.37% for the period to Q3, and no accidental absenteeism.

Competitive advantages

Focus on first-in-class drugs.

The company is building a portfolio of drug and medical device development projects based on the following assumptions:

1. Each project addresses a significant medical need for patients and doctors;
2. Each project has clear market potential and is attractive for third party licensing in the early stages of clinical development;
3. The therapeutic solutions proposed in each project are significant improvements on current and developing therapies, with the potential to be 'first-in-class'.
4. In addition to the standard safety assessment, each project places great emphasis on demonstrating signs of therapeutic efficacy in the early phases of clinical development (phases 0 and 1).

Building a portfolio on the idea of 'me-better', based on studies of original drugs and therapies previously carried out successfully, significantly reduces the risks associated with clinical development failure, while retaining the potential for 'first-in-class'.

Pure Biologics focuses on demonstrating early signs of therapeutic efficacy in Phase 0 and Phase 1 clinical trials through appropriate patient selection, use of biomarkers, etc., which 1) contributes to a significant increase in the valuation of the project in the context of its subsequent commercialisation and 2) allows a more accurate assessment of the likelihood of success of costly phases 2 and 3 of clinical development.

The Company expects that the current strategy will translate into higher value assets generated in a shorter timeframe, a faster regulatory pathway, a higher probability of commercialisation and minimisation of risk due to previous positive results obtained by competitors in drug development programmes with a similar mechanism of action.

Unique competences in areas of antibodies' and aptamers selection and of proteins' production and analysis.

Out of the ten world's best-selling drugs eight are protein-based ones, including antibodies. According to the knowledge of the Management Board based on publicly available information, the Issuer is the only commercial entity in Poland that has its own technology of antibodies' and aptamers' selection. Moreover, the Issuer is one of the few entities in the world that works over this subject. Due to the degree of advancement of its R&D projects, the Issuer has a real possibility of strengthening its market position. Domestic and international biotechnological and pharmaceutical companies as well as R&D institutes and universities are the Issuer's clients.

Research projects on immunooncology which is a breakthrough in fight against cancer.

The Company's own research projects focus on searching for drugs and therapies supporting human immune system. This direction of research in cancer treatment in recent years became the most important in cancer control. Immunooncologic treatments brought into the market are rarely limited to one tumour type, turning out to be efficient in at least several types of illnesses. Therefore it broadens their range of application and number of potential patients. An important issue is also the use of so-called combination therapies, in which two different treatments are used (both of the immunooncology field or a treatment consisting in combining immunooncologic drug with classical anti-cancer therapy, for example chemo- or radiotherapy), which additionally broadens the range of indications for use of this type of drugs. Taking into account the immunooncology's development in recent years, systematically confirmed by partnering and licensing transactions which, in value terms, dominated the pharmaceutical market, one can qualify the future positive results of the Company's research projects among assets with significant profit potential.

Total control over the key discovery phase of drug development.

Company's competence allows it the execution of projects of drug and medical device development from the phase of choosing the molecular target to the phase of in vitro tests inclusive, entirely basing on its own scientific and technological resources. This ensures full independence in obtaining (licensing) drug candidates from other R&D entities or universities, and from services provided by third parties to the pre-clinical phase. This translates into control and confidentiality of the studies carried out at all stages, in particular at their initial, most sensitive stage.

Ability to generate large numbers of new lead molecules through self-designed technology platforms.

The PureSelect2 and PureApta technology platforms developed by the Company allow in vitro techniques (without immunizing animals), and thus relatively quickly and at relatively low cost, to generate each time multiple bio-molecules binding a molecular target – antibodies and aptamers, respectively. From the broad pool of molecules generated, those variants are selected that have parameters best suited to the task at hand and can be further optimised. Importantly, these platforms can work in parallel on multiple molecular targets.

7. Information on major achievements in research and development

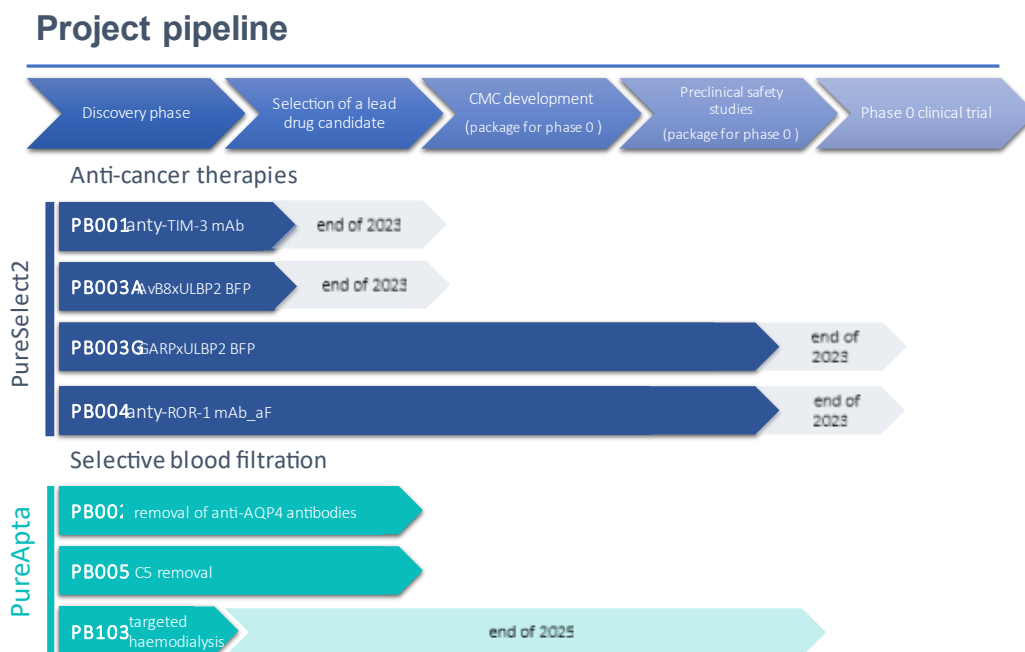


Fig. 2: Status of work on projects.

For a more complete understanding of the information contained in this section, a glossary of terms and a list of abbreviations used is provided at the end of the section.

Introduction

The first half of 2023 has been a very fruitful period for Pure Biologics. Pure Biologics' portfolio currently includes four immuno-oncology antibody-based projects: PB001, PB003a, PB003g and PB004, each of which aims to overcome in different ways immunosuppression – the main obstacle to the elimination of cancer cells by the human immune system.

For both lead projects, PB003g and PB004, the Company announced the selection of lead candidates for preclinical and clinical development in April 2023. In June 2023, patent applications were filed for both projects to secure intellectual property rights for both drug candidates and their applications. PB004 has achieved preclinical proof-of-concept data in humanised mouse models of cancer that warrant entry into both Phase 0 clinical trials in patients with solid tumours and Phase 1 clinical trials in B-cell malignancies. With ongoing safety studies and manufacturing of the drug product for clinical trials, PB004 is on track to submit an eIND (exploratory investigational new drug) application in October 2023 for FDA approval of the planned Phase 0 trial, which is expected to begin in December 2023. The PB003g project developed a preclinical proof of concept for PBA-0091-induced killing of immunosuppressive regulatory T cells (Treg), a population of cells that limit the immune system's intrinsic ability to clear tumour cells and that represent a major limitation to the efficacy of current immune therapies. The data obtained are entirely consistent with the observed mode of action of PBA-0091 using human Treg cells in vivo. With ongoing safety studies and the manufacture of a drug product for clinical trials, the PB003g project is also on track to

submit an eIND application in October 2023 for FDA approval of the planned Phase 0 study, which is expected to start in December 2023. Pure Biologics has implemented phase 0 clinical trials into its projects as an intermediate step, preceding the traditional phases 1-3. A phase 0 trial, in the form of micro-dose delivery of a drug candidate into a tumour, allows early assessment of therapeutic efficacy in the complex human tumour environment, and provides an economically rational decision point prior to further expensive clinical trials. In addition, obtaining pharmacodynamic data in humans significantly increases the value of a project at a relatively early stage, maximising the chance of its commercialisation.

Projects PBOO1 and PBOO3a are in the early stages of discovering and developing drug candidates, as well as collecting data to confirm the medical hypothesis of the projects. In project PBOO1, a proof-of-concept study in a humanised mouse tumour model, using a bispecific molecule designed to simultaneously target TIM-3 and a hitherto undisclosed tumour-associated antigen (TAA) on tumour cells, showed no superior therapeutic efficacy compared to anti-TIM-3 antibodies currently in clinical development. Pure Biologics is ceasing work on the bispecific anti-TIM-3xTAA antibody and is currently exploring alternative uses for the anti-TIM-3 antibody it has discovered. Project PBOO3a has continued to produce anti-AvB β antibodies that meet the criteria for a target product. Candidates are being tested in both phenotypic and functional assays to identify potential drug candidates that can safely and effectively eliminate tumour-associated Treg cells.

The PB103 project was launched in mid-2022 to develop a medical device to actively remove selected proteins from the blood of chronic kidney disease (CKD) patients on haemodialysis. PB103 has the potential to revolutionise the quality of life for a group of patients for whom no significant progress has been made in recent decades. Together with its Dutch partner Relitech B.V., Pure Biologics, through its established special purpose vehicle Doto Medical, is on track to achieve its first two main business objectives in the PB103 project. A prototype of the planned medical device was used to achieve a proof-of-concept, enabling the separation of blood and plasma and the subsequent removal of a single molecular target from plasma using a model absorber containing aptamers developed by Pure Biologics. In addition, the PB103 project achieved the goal of generating aptamers directed against two different target proteins that play a key role in renal degradation and cardiovascular risk in patients with CKD.

In the coming period, Pure Biologics will mainly focus on the introduction of PBA-0091 and PBA-0405 into first-in-human studies. In addition, Pure Biologics intends to make decisions on the further development of anti-TIM3 antibodies under project PBOO1, as well as anti-AvB8 antibodies under project PBOO3a. Pure Biologics will actively seek opportunities to pursue new antibody-based drug development projects that align with the company's 'me better' and 'smart clinical trial design' strategy. Pure Biologics will also pursue the PB103 project towards its intended business objectives, including achieving proof of concept for two sub-projects that target renal degradation and cardiovascular risk respectively.

Antibody-based immune-oncology drug development projects

project	therapeutic area	indication	active molecule
PB001	immunooncology	solid tumours, e.g. cancer of the colon and rectum (CRC)	bispecific antibody TIM3xTTA
PB003a	immunooncology	solid tumours, e.g. non-small cell lung cancer (NSCLC)	bifunctional fusion protein (antibody-immunoligand) anti- α V β 8
PB003g	immunooncology	solid tumours, e.g. non-small cell lung cancer (NSCLC)	bifunctional fusion protein (antibody-immunoligand) anti- GARP
PB004	immunooncology	haematological malignancies	afucosylated antibody anti-ROR1

Fig. 3: Antibody-based projects.

Drug development project PB001 (MultiBody)

Aim of the project

The PB001 (MultiBody) project aims to develop a therapeutic antibody, which simultaneously binds the TIM-3 protein on immune cells and a yet undisclosed antigen on the surface of tumour-associated antigen (TAA) – TIM-3xTAA. Depletion of cytotoxic immune cells is a major obstacle to immune surveillance of cancer. TIM-3 on the surface of cytotoxic T lymphocytes (CTL) and natural killer (NK) cells, plays a key role in the depletion phenomenon. By targeting TIM-3, PB001 is designed to 'release the brakes' on CTL and NK cells in cancer patients. At the same time, PB001 will directly attack cancer cells, exposing them to the immune system and creating anchor points for cytotoxic cells for more efficient elimination of tumour cells. PB001 will find application in the treatment of colon cancer, which is one of the malignancies defined as an 'unmet medical need' and at the same time it is a market-active therapeutic area with many partnering and licensing deals being observed.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the co-financing agreement, the total cost of the project is PLN 32,037 thousand, and the value of the grant is PLN 23,998 thousand. The eligibility period for costs lasts until 31 December 2023. The Company's own contribution in the amount of PLN 8,002 thousand is covered by the Company from equity.

Implementation and results of the project in the reported period

In the first half of 2023, project PB001 continued work on the previously identified proprietary anti-TIM3 antibody, as well as on the validation of the advantages of the bispecific TIM3xTAA format in an in vivo study.

The humanised mouse tumour model study was conducted in June, in collaboration with GemPharmatech (China). It aimed to validate the therapeutic format of TIM3xTAA by comparing its

anti-tumour activity with an anti-TIM3 monoclonal antibody, as well as to validate the activity of the resulting unique antibody PBO01.TM14 against anti-TIM3 reference molecules currently in clinical development: Sabatolimab (Novartis) and Sym023 (Symphogen).

The study did not demonstrate an advantage of the TIM3xTAA bispecific format over anti-TIM3 monospecific antibodies in terms of therapeutic efficacy, meaning that a proof of concept for the PBO01 project could not be achieved. This result, together with previous failures in anti-TAA antibody selections, suggests the need to complete work on the bispecific molecule. Nevertheless, the results obtained for the PBO01.TM14 antibody were comparable to those of the reference molecules (Sabatolimab, Sym023), confirming previously obtained in vitro results. Also, the preliminary safety profile of the test molecule was comparable to the antibodies currently being tested in the clinical trial, a satisfactory result from the perspective of further development of the drug candidate.

In the coming weeks, the results obtained from the mouse blood test will be analysed and preliminary histopathological examinations of tissues obtained in the study will be performed for a full evaluation of the safety of the molecule under development. In addition, an additional control group has been included in the study to pre-evaluate the combination therapy of anti-TIM3 with chemotherapy, thus evaluating a potentially new therapeutic concept using the discovered antibody. A full analysis of the results will allow final conclusions to be drawn from the in vivo study and a decision to be made on the possibility of further development of the PBO01.TM14 antibody in the future. However, given the project timeline, such a major change in development strategy from the original assumptions would not be feasible at this stage due to time and budget considerations.

Events after the date of the report

On 18 August 2023, the final information on the PBO01 project was submitted to the NCB. The Company is currently awaiting a response from the intermediary institution.

Drug development project PBO03a

Aim of the project

Project PBO03a aims to develop an anti-cancer drug in the format of a bifunctional molecule that specifically recognises the $\alpha V\beta 8$ integrin, with significantly better properties than traditional therapeutic antibodies targeting $\alpha V\beta 8$ currently in preclinical and early clinical development (e.g. molecule PF-06940434, Pfizer). Integrin $\alpha V\beta 8$ plays a key role in the inhibition by regulatory T cells (Treg) of lymphocyte cytotoxicity against tumour cells. While the mechanism of action of competing drug candidates is to block $\alpha V\beta 8$ activity to reduce immunosuppression in the tumour environment, Project PBO03a aims to develop a much more effective drug candidate that kills $\alpha V\beta 8$ -mediated Treg cells. As $\alpha V\beta 8$ is also overproduced on cells of various tumour types (e.g. lung, colorectal, head and neck, breast), PBO03a will also directly induce the killing of tumour cells by cytotoxic lymphocytes, resulting in much more effective anti-cancer therapy. To achieve this, drug candidate PBO03a is being developed in the form of a so-called bi-functional therapeutic molecule (bifunctional fusion protein, BFP), in which a traditional antibody will be combined with ULBP2, the natural immunoligand of the NKG2D receptor present on most cytotoxic NK and T cells in the tumour environment. This unique therapeutic format will not only demonstrate a qualitative advantage over conventional antibodies, but will also lead to the recruitment of significantly more cytotoxic cells. The goal in project PBO03a is to develop a lead candidate that will enter a Phase 0 clinical trial by the end of 2023. The implementation of a Phase 0 study, as the first phase of clinical development for immuno-oncology projects, is in line with Pure Biologics' 'smart clinical development' strategy of capturing valuable pharmacodynamic data directly in patients at an early

clinical stage, in order to 1) reduce the risk of failure of later, costly clinical trial phases, and 2) significantly increase the value of the project in a more cost-effective manner compared to conventional Phase 1-3-based clinical development, with the benefit of future commercialisation of the project.

Financing

Project PBO03a originally was a part of PBO03 project, co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. Project PBO03 involved the selection of antibodies against different molecular targets associated with the activity of the immunosuppressive protein TGF β in the tumour microenvironment, to ultimately select the most promising drug candidate. The R&D work led to the division of project PBO03 into two separate projects focused on different molecular targets (α V β 8/PBO03a and GARP/PBO03g). The first project to successfully identify a lead drug candidate was project PBO03g, which thus received priority access to resources and NCRD funding, continuing to meet the conditions of the grant agreement.

Nevertheless, α V β 8 remains a promising molecular target for anti-cancer therapeutics, so Pure Biologics intends to continue the search for anti- α V β 8 antibodies. In the coming months, Pure Biologics plans to submit applications for non-dilutive funding to support the implementation of the PBO03a project, as well as solicit private funding from strategic partners.

Implementation and results of the project in the reported period

In the reported first half of 2023, the project's main activities focused on continuing the search for a drug candidate binding the molecular target α V β 8.

In earlier selections by phage presentation, α V β 8 antigen-binding antibody sequences were obtained and produced in IgG1 antibody format for functional analysis of the intended mechanism of therapeutic action. In a primary screening assay, the ability of anti- α V β 8 antibodies to induce the killing of α V β 8-expressing tumour cells by cytotoxic immune cells was tested. Based on the results, five sequences with the highest potential to induce cytotoxicity were selected and used to develop therapeutic molecule candidates in the bifunctional protein targeting (BFP) format, as well as in the afucosylated antibody (af-IgG) format. These two therapeutic antibody formats were chosen to significantly enhance the ability of α V β 8-targeted antibodies to activate immune cells and induce immune cell-mediated tumour cell death. Selected antibodies in BFP and af-IgG format are currently being produced for further characterisation in bioassays, both in vitro and in vivo, as well as in CMC-related assays, including production efficiency, potential aggregation, stability in buffer and serum. In parallel, further selections were made by phage presentation to obtain α V β 8 antigen-binding antibody sequences using new antibody libraries and selection strategies to increase the likelihood of discovering an optimal candidate that meets the target product criteria. In the near future, it is planned to analyse the obtained sequences in NGS (next-generation sequencing), followed by their production in IgG1 format and the study of binding to the molecular target.

In parallel, the PBO03a project continues to develop and optimise in vitro cellular assays that complement the characterisation of the mechanism of action of the model molecules, including testing the activation of cytotoxic T lymphocytes and their ability to induce the killing of α V β 8-expressing cells and the induction of Treg cell killing by effector cells.

While the PBO03a project will continue the development of proprietary therapeutic molecules targeting α V β 8, due to the strategic decisions taken by Pure Biologics and the priority given to the PBO03g and PBO04 projects, the planned Phase O clinical trial for lead candidate PBO03a has been postponed.

Planned works

In the second half of 2023, the aim of the project will be to identify antibodies that bind the molecular target $\alpha V\beta 8$ and characterise them in bioassays, as well as to further develop and optimise in vitro cellular assays that complement the characterisation of the mechanism of action of the model molecules, which is congenial to the further development of the drug candidate.

Drug development project PBO03g

Aim of the project

Project PBO03g aims to develop an anti-cancer drug in the format of a bifunctional molecule that specifically recognises the GARP-TGF β 1 protein complex, with significantly greater therapeutic efficacy than traditional antibodies directed against GARP currently in early clinical development (e.g. molecules ABBV-151, Abbvie and DS-1055, Daichii-Sankyo). The accumulation of regulatory T cells (Treg) in the tumour microenvironment is associated with an unfavourable prognosis in various types of solid tumours. The GARP-TGF β 1 complex is highly expressed on various tumour cells (including lung, colorectal, breast, head and neck), as well as on regulatory T cells (Treg), and plays a key role in immunosuppression. While ABBV-151 aims to restore immune function by blocking the release of immunosuppressive TGF β 1 from the complex with GARP, DS-1055 recruits and activates NK cells to directly kill Treg and tumour cells. Project PBO03g aims to develop a therapeutic molecule that eliminates Treg and tumour cells with GARP-TGF β 1 expression much more effectively than competing molecules. To achieve this, drug candidate PBO03g is being developed in the form of a so-called bifunctional therapeutic molecule (BFP), in which a traditional antibody will be combined with ULBP2, a natural immunoligand of the NKG2D receptor present on the majority of cytotoxic NK and T cells in the tumour environment. This unique therapeutic format developed by Pure Biologics will not only demonstrate a qualitative advantage over conventional antibodies, but will also lead to the recruitment of significantly more cytotoxic cells capable of killing cancer cells. The aim of the work in project PBO03g in 2023 is to identify a lead candidate to enter the Phase O clinical trial till the end of 2023. The implementation of the Phase O study, as the first stage of clinical development of immuno-oncology projects, is in line with Pure Biologics' 'smart clinical development' strategy of capturing valuable pharmacodynamic data at an early clinical stage to 1) reduce the risk of failure of later, costly phases of clinical trials, and 2) significantly increase the value of the project at the early stage of clinical development. In the second half of 2023, PBO03g intends to commence CMC (Chemistry, manufacturing and controls) and preclinical development for phase 1-3 clinical trials starting in 2025.

Financing

Project PBO03g is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the co-financing agreement, the total cost of the project is PLN 39,905 thousand, and the value of the grant is PLN 30,969 thousand. The eligibility period for costs lasts until 31 December 2023. The Company's own contribution amounting to PLN 8,969 thousand the Company intends to cover from equity.

In April 2023, the Company received approval from the NCBR to make key changes to the project application, which included the inclusion of model molecule studies and the change from Phase 1 clinical trials to Phase O as the endpoint of the NCRD-funded project. The phase O clinical trial will involve injecting microdoses of the drug directly into tumours and will positively and cost-effectively impact the commercialisation potential of the project.

In March 2023 Pure Biologics has signed an agreement with the Medical Research Agency for funding for a project entitled 'Phase 1 clinical trial to investigate the safety, tolerability and efficacy of a bispecific compound in patients with advanced solid tumours' for molecule PBO03g. Funding amounts to PLN 32,439 thousand, with a total project budget of PLN 48,897 thousand.

Implementation and results of the project in the reported period

In the first half of 2023, the PBO03g project focused primarily on identifying and characterising a lead candidate for preclinical and clinical development. In April this year, the bifunctional molecule PBA-0091 was nominated as lead candidate for further development. PBA-0091 and back-up molecules have been comprehensively characterised in vitro, in terms of specificity, stability in serum and intended therapeutic mechanism of action. Extensive analyses of Pure Biologics' manufactured antibodies directed against GARP in both IgG and BFP formats, including PBA0091, revealed unique binding properties to GARP and the GARP-TGFβ1 complex, which form, in part, the basis of a patent application filed during the reporting period. With the patent application 'Anti-GARP/TGFβ1 antibodies and methods of use', Pure Biologics has achieved an important milestone in the PBO03g project. The patent application covers both the unique anti-GARP antibodies and the highly innovative BFP therapeutic format developed by Pure Biologics.

PBA-0091 and three stock molecules in the therapeutic format of BFP (n=3) and afucosylated IgG1 were produced by Evitria (Switzerland) and used in two in vivo studies in humanised mice for preclinical proof-of-concept (pcPoC). The first study, which is being conducted by GemPharmatech (China), investigates the critical ability of PBA-0091 to eliminate immunosuppressive regulatory T cells (Treg) for therapeutic applications, using a tumour model derived from the HT-29 cell line. In a second study conducted at the Jackson Laboratory (USA), the ability of PBA-0091 to kill tumours expressing its molecular target is being tested in a tumour model derived from a Raji cell line overexpressing GARP-TGFβ1. In parallel, in vivo studies evaluating the safety profile of PBA-0091 and a dose-response study have been initiated. These studies are conducted to determine the anticipated dose needed to induce a biological effect (MABEL, minimal anticipated biological effect level), which is an important parameter for determining therapeutic doses of PBA-0091 in preclinical and clinical studies.

In order to identify optimal animal models for preclinical safety testing of PBA-0091, necessary to obtain regulatory approval for Phase 0 and Phase I clinical trials, the binding of PBA-0091 and reserve candidates to GARP and GARP-TGFβ1 homologues from different species: mouse, rat and macaque were analysed. Binding was confirmed to monkey-derived GARP and GARP-TGFβ1 proteins, while no interaction was found with mouse or rat proteins. Based on these results, a tumour model based on humanised mice (i.e. mice with human immune effector cells) was selected as the rodent model for preclinical safety studies. Rodent studies are essential for both phase 0 and phase 1 clinical trials. Non-human primates, on the other hand, will be the main model in safety studies for phase 1 clinical trials to meet regulatory requirements and complement our rodent studies. PBA-0091 has been manufactured and shipped to the CRO (GemPharmatech), which will conduct the safety studies in humanised mice required to obtain approval for the first human study. The study has been initiated and the results are expected in September 2023. Pure Biologics plans to submit eIND (exploratory investigational new drug) application to the FDA for Phase 0 clinical trial approval in October 2023.

At the time of reporting, Presage (USA) and Pure Biologics are finalising the documentation necessary to initiate a Phase 0 clinical trial in patients with solid tumours, including a study protocol and biomarker analysis plan that will verify the mechanism of action of PBA-0091 in the complex environment of human tumours. The study, which will include patients with head and neck cancer, among others, will be a multicentre trial conducted in the US, starting in late 2023.

Planned works

The objective of the PBO03g project in the next quarter is to continue and finalise the pre-clinical studies required for the eIND submission for the Phase O clinical trial. In addition, the drug batch for the Phase O clinical trial will undergo a series of qualitative analyses. The project plans to submit an application for regulatory approval of the Phase O clinical trial early in the fourth quarter, with a planned start of the clinical trial in December 2023.

Drug development project PBO04 (PureBIKE)

Aim of the project

The objective of the PBO04 project is to develop an anti-cancer drug based on an anti-ROR1 antibody with significantly improved therapeutic properties compared to Zilovetamab, anti-ROR1 antibody currently in phase 3 of clinical development. ROR1 is a surface molecule expressed in many types of cancer, involved in the survival, proliferation and migration of cancer cells, while absent in most healthy tissues, making ROR1 an excellent therapeutic target. The PBO04 project developed an anti-ROR1 antibody that binds to a specific epitope of the ROR1 molecule and has an increased affinity for the CD16 receptor, present on natural killer (NK) cells. In this way, it induces tumour cell death through activation of NK cells and induction of so-called antibody-dependent cell cytotoxicity (ADCC). The developed antibody has great potential for the treatment of patients with ROR1-expressing cancers, especially lymphomas and leukaemias such as mantle cell lymphoma (MCL) and chronic lymphocyte leukaemia (CLL). Pure Biologics plans to take the drug candidate to the first phases of clinical trials in order to then commercialise the project by making it available under licence. The PBO04 project is an important item in the Company's portfolio of highly innovative drug development projects in the immuno-oncology therapy segment.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014–2020 programme. According to the co-financing agreement, the total cost of the project is PLN 40,417 thousand and the value of the grant is PLN 29,869 thousand. On 21 August 2022, NCBR accepted the Company's proposed amendments to the project application, which included, among others, change of format and the change from Phase 1 clinical trials to Phase O as the endpoint of the NCRD-funded project. The changes in scope are related to changes in the total project budget (from PLN 40,417 thousand to PLN 38,617 thousand) and the amount of funding (from PLN 29,869 thousand to PLN 28,789 thousand). The planned cost eligibility period lasts until December 31, 2023. The Issuer intends to cover its own contribution to the project in the amount of PLN 9,898 thousand by equity.

In 2022, a grant application for the continuation of the project was submitted to the Medical Research Agency competition. The project was recommended for funding. The grant agreement, which amounts to PLN 32,439 thousand (total project budget: PLN 48,897 thousand), was signed in January 2023.

Implementation and results of the project in the reported period

In H1 2023, the molecule PBA-O405, which is an afucosylated anti-ROR1 antibody, was selected as the lead candidate in project PBO04. The lead molecule has been comprehensively characterised in vitro for specificity, stability in serum and anti-tumour activity. The specificity and binding strength of the PBA-O405 molecule to its molecular target ROR1 on cancer cells was confirmed in binding assays by biophysical and cellular methods. The intended mode of action of PBA-O405, i.e.

the induction of ROR1-presenting tumour cell killing by cytotoxic immune cells, was confirmed in NK cell activation assays and in tumour cell killing assays by NK cells in vitro. A multiplicative tumour cell killing effect was also confirmed using afucosylation of the Fc fragment of the PBA-O4O5 antibody. In cell-based assays, the PBA-O4O5 molecule activated NK cells more effectively than the standard antibody format, and induced up to 30 times more potent NK cell-mediated killing of ROR1-expressing cancer cells. The PBA-O4O5 molecule was also shown to induce significantly more effective cancer cell killing than Zilovetamab, a therapeutic anti-ROR1 antibody that has reached Phase III clinical trials for the treatment of B-cell malignancies and solid tumours. In collaboration with the Ludwik Hirsfeld Institute of Immunology and Experimental Therapy of the Polish Academy of Sciences (PAS) in Wrocław, the ability of PBA-O4O5 to kill tumour cells obtained from patients with B-cell chronic lymphocytic leukaemia (B-CLL) was confirmed, an important observation in the context of planned phase 1 trials in B-CLL patients in 2025. Analysis of a possible additional mode of action of PBA-O4O5 and back-up candidates such as phagocytosis, complement activation and blocking of the ROR1 signalling pathway is ongoing. All of these mechanisms may contribute to the antitumour efficacy of PBA-O4O5 in oncology patients.

The development potential of the PBA-O4O5 molecule (developability) from the perspective of the chemistry, manufacturing, controls (CMC) process was confirmed in a series of pilot experiments, including analysis of in vitro cell production efficiency, purity and stability in buffer and serum. Additionally, the feasibility of developing the PBA-O4O5 molecule from the perspective of post-translational modifications and immunogenicity was investigated in silico, by comparing the sequence of the PBA-O4O5 molecule to that of other clinically developed antibodies.

During the reported period, the potential of PBA-O4O5 for the treatment of B-cell malignancies was demonstrated in a pilot study performed by IVRS (Sweden). The study was conducted in mice injected with MEC1-ROR1 malignant tumour cells, thus using a model previously used in a preclinical study with Zilovetamab. The study with the molecule PBA-O4O5, administered twice weekly, showed after three weeks a 90% reduction in the number of ROR1-presenting tumour cells in the spleen and bone marrow compared to the control group. These data support the planned development pathway of PBA-O4O5 in B-cell malignancies in a phase 1 clinical trial. A preclinical proof-of-concept, confirming the potential to inhibit the growth of solid tumours with ROR1 expression, was obtained in humanised mice with subcutaneously implanted tumours from human JEKO-1 cells. The data obtained, generated by GemPharmatech (China), confirm the validity of the planned Phase O study in patients with head and neck tumours, which will start in late 2023, and support the future development of PBA-O4O5 for the treatment of solid tumours. A safety study to qualify PBA-O4O5 for the first human clinical trials is currently underway in humanised mice at GemPharmatech. We expect the full results of the study to be reported in time to allow submission of an application for regulatory approval of the Phase O clinical trial in October 2023.

At the time of reporting, Presage (USA) and Pure Biologics are on schedule to complete the documentation needed to initiate a Phase O clinical trial in patients with solid tumours, including a study protocol and biomarker analysis plan to verify the mechanism of action of PBA-O4O5 in the complex human tumour microenvironment. The batch of PBA-O4O5 protein intended for the Phase O study was manufactured by Wuxi (China). The planned study, which will include head and neck cancer patients, will investigate early signs of clinical activity in cancer patients. The study will be a multicentre trial conducted in the US and will start at the end of 2023.

During the reporting period, a patent application 'Anti-ROR1 antibodies and methods of use' was filed, securing the unique antibody sequences discovered within PBOO4. The filing of the application represents an important milestone for the project.

Planned works

The objective of the PBO04 project in the next quarter is to finalise the preclinical studies required for the eIND application for Phase 0 clinical trial approval. In addition, a batch of protein for the Phase 0 clinical trial will undergo qualitative analyses. Submission of the regulatory approval application for the Phase 0 clinical trial is planned for early Q4, with the clinical trial commencing in December 2023. Additionally, the project will prepare the full CMC process for the phase 1 clinical trial.

Aptamer-based therapeutic projects

project	therapeutic area	indication	product
PBO02	neurology / rare diseases	Devic's syndrome (NMO)	selective aptamer adsorber
PBO05	neurology / rare diseases	myasthenia gravis	selective aptamer adsorber
PB103	neprology	chronic kidney disease	selective aptamer adsorber

Fig. 4: Aptamer-based projects.

Therapeutic project PBO02 (AptaPheresis)*Aim of the project*

The PBO02 project aims to develop a highly innovative targeted apheresis therapy for the treatment of patients suffering from Neuromyelitis Optica (NMO). NMO is a potential fatal neurological disease caused by auto-immune antibodies that target the spinal cord and optic nerves, leading to severe paralyses of limbs and blindness. It is characterised by varying severity of symptoms; periods of remission alter with exacerbations, which often lead to hospitalisation and a significant increase in treatment costs. Therapeutic options for NMO patients during exacerbation periods are non-selective and are associated with serious side effects. Therefore, there is still an unmet medical need for more efficient NMO treatments, with an improved safety profile and cost-efficient. Under project PBO02, Pure Biologics is developing a medical procedure in which auto-antibodies against aquaporin-4, a pathogenic factor in NMO, are selectively removed from patients' bloodstreams. PBO02 is a medical device that will capture auto-antibodies using highly specific aptamers developed using proprietary PureApta technology. PBO02 has the potential to significantly improve care of the estimated 300,000 NMO patients world-wide, while reducing treatment costs.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014–2020 programme. According to the co-financing agreement, the

total cost of the project is PLN 14,282 thousand and the value of the grant is PLN 10,542 thousand. The Company intends to cover its own contribution of PLN 3,740 thousand from equity.

Implementation and results of the project in the reported period

During the first half of 2023, the analysis of the results obtained in project PB002 was ongoing. In addition, the transfer of the developed know-how to the PB103 project, which will be carried out by the special purpose vehicle Doto Medical set up by Pure Biologics and in which it will be used to develop therapeutic solutions towards the improvement of the standard dialysis procedure was conducted.

In May, the final information on the PB002 project was submitted to NCBR. 2 August 2023. The National Centre for Research and Development, having analysed the information submitted by the Company, recognised that further implementation of the project would not lead to the achievement of the objective defined in the funding agreement within the stipulated timeframe and, in accordance with the agreement, considers the project completed. The cost of the project up to the date of its completion amounted to PLN 7,824 thousand, and the Company has so far received a subsidy in proportion to the scope of work completed, i.e. PLN 6,259 thousand.

To the best of the Company's knowledge, the grant received has been disbursed in accordance with the project assumptions set out in the Agreement, which should result in the acceptance of the realised budget. The final decision of NCRD in this respect will be formally delivered to the Company.

Therapeutic project PB005 (AptaMG)

Aim of the project

The PB005 project aims to develop a highly innovative, targeted apheresis-based therapy for the treatment of patients suffering from Myasthenia Gravis (MG). Myasthenia Gravis is an autoimmune disease caused by disturbances in neurotransmission in the neuromuscular junction. During the course of disease, patients experience exacerbations that severely weaken limb muscles, thus affecting their daily lives, as well as life-threatening myasthenic crises that cause respiratory failure. Exacerbation is regarded as a possible prodromal stage of a crisis and requires hospital treatment. One of the main factors responsible for disease symptoms is the complement system, and it is clinically proven that inhibition of complement 5 (C5) protein is beneficial for patients in exacerbation. Under PB005 Pure Biologics is developing a medical device that will capture C5 protein from the patients' blood, improving apheresis procedures currently used for patients with severe symptoms. The device will use highly specific aptamers for capturing C5 from blood, developed using Pure Biologics' proprietary PureApta technology. PB005 has the potential to significantly improve care of the estimated 800,000 NMO patients world-wide, while reducing treatment costs.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014–2020 programme. According to the co-financing agreement, the total cost of the project is PLN 14,730 thousand and the value of the grant is PLN 10,775 thousand. The cost eligibility period lasts until December 31, 2023. The Company intends to cover its own contribution of PLN 3,958 thousand from equity.

Implementation and results of the project in the reported period

In the first half of 2023, the analysis of the results obtained and the preparation of a strategy to protect the intellectual property developed in project PBO05 continued. The results will become the basis for a patent application. In addition, the transfer of the developed know-how was conducted to the PB103 project, which will be conducted by the special purpose vehicle Doto Medical set up by Pure Biologics and in which it will be used to develop therapeutic solutions towards improving the standard dialysis procedure.

In June, the final information on the PBO05 project was submitted to the NCBR. The Company is currently awaiting a response from the intermediary institution

Therapeutic project PB103

Aim of the project

The aim of project PB103 is to develop an innovative medical device based on Pure Biologics' PureApta technology, which will significantly improve the efficiency of toxin removal during haemodialysis performed in patients suffering from chronic kidney disease (CKD). The project is divided into sub-projects PB103a and PB103b, each of which will develop an adsorber targeting different molecular targets. The effect of toxin capture by the PB103a adsorber will be to preserve residual renal function, while the use of the adsorber being developed in PB103b project will reduce the risk of developing cardiovascular disease and mortality in patients with CKD.

In patients with CKD when the kidneys stop functioning, the body's water balance is disrupted. Problems with urine production result in a sharp decline in quality of life of patients who, feeling constantly thirsty, can only consume a small amount of fluids, as excess fluid in the body can only be regulated by sweating and excretion with the stool. Therefore, there is an unmet medical need to develop therapies to extend kidney function time in patients with CKD. Chronic inflammation underlies the deterioration of renal function. Therapeutic strategies that inhibit chronic inflammation, for example by blocking the activity of pro-inflammatory cytokines, can prolong renal function. The main disadvantage of existing therapies is that a single injection of the drug weakens patients' immunity for many weeks, making this group of patients particularly susceptible to infections such as COVID and influenza. Another major barrier is the cost of antibody therapy reaching several thousand dollars per month. To address this medical need, Pure Biologics will develop a medical device, complementary to the current haemodialysis procedure, that will safely remove pro-inflammatory cytokines from the blood of CKD patients. The effect of the device being developed under sub-project PB103a will be to preserve residual kidney function in CKD patients to maintain water homeostasis, without compromising immunity.

Patients with chronic kidney disease on dialysis have a 9 to 12 times greater risk of death compared to the general population. Cardiovascular disease (CVD), including heart failure, accounts for approximately 50% of deaths in patients on dialysis. The link between the presence of toxins in patients' blood and vascular deterioration is direct but poorly addressed by current dialysis therapy. Therefore, there is an unmet medical need to develop therapies that would offset vascular deterioration in haemodialysis patients. Certain proteins are present in much higher amounts in the blood of CKD patients with CVD and appear to play a direct role in their clinical deterioration. In addition, they are not removed during current dialysis therapy and may therefore contribute to the disease and worsening of the patient's condition. The aim of the project is to develop a medical device as an add-on module to the apparatus used in haemodialysis, which will safely remove the above proteins from the blood of CKD patients. The effect of the medical device developed in sub-project PB103b will be a significant reduction in CVD mortality in patients with CKD, as well as a reduction in the societal costs associated with CVD treatment.

Worldwide, more than 2 million CKD patients undergo dialysis, typically 3–4 times a week for an average of 5–10 years. In the US, treatment typically costs between \$3.3k and \$10.4k per month, with treatment of comorbidities raising the average price of care to as much as \$14.4k per month. In order to maximise project PB103's chance of success in a market far more attractive than the niche markets targeted by the products being developed under PBO02 and PBO05, Pure Biologics decided to focus its efforts entirely on the development of extracorporeal treatment under project PB103.

Project PB103, divided into sub-projects PB103a and PB103b, is a joint development programme between Pure Biologics and Relitech B.V. (Nijkerk, the Netherlands). Pure Biologics has developed unique technical expertise in extracorporeal blood purification using aptamers in projects PBO02 and PBO05. Building on its experience to date, the Company will develop 'molecular magnets' in the form of aptamers that can actively remove selected uremic toxins from the blood of CKD patients, based on its patented PureApta technology. Relitech will use its expertise and intellectual property rights to develop a medical device for extracorporeal blood purification. The end product, a medical device that can significantly improve current dialysis therapy, will enter an ever-growing market with a global value of more than \$105 billion in 2021.

Financing

Project PB103 is being carried out in collaboration with the Dutch company Relitech B.V. (Nijkerk, the Netherlands). On 3 June 2022, a collaboration agreement was signed covering the first phase of the project, in which Pure Biologics will select aptamers against the first two molecular targets and Relitech will build a prototype device. Both companies will incur their own costs at this stage of the project.

During the course of implementation, the project was expanded and divided into two sub-projects, PB103a and PB103b, addressing different complications in CKD patients. In the next stages, the Companies plan to develop a device based on selected aptamers and their preclinical and clinical development.

Pure Biologics has formed a special purpose vehicle (SPV) Doto Medical Ltd. and is actively seeking financing in the form of non-dilutive capital and venture capital for project PB103. In May 2023, a grant application has now been completed for the competition organised by PARP under the SMART (FENG) pathway with a deadline for applications scheduled for September 2023.

Implementation and results of the project in the reported period

In the first half of 2023, research work in the PB103 project focused on achieving the first two business objectives: 1) the development of a prototype ABD medical device that can be used for proof-of-concept studies on filtering target molecules from the blood, and 2) the development of aptamer-based absorbers that will serve as active filters in the ABD device to remove selected pathogenic molecules from the bloodstream.

A prototype automated ABD device has been developed by partner Relitech. The prototype ABD device is compatible with both a commercially available plasmapheresis filter for separating blood cells from plasma and aptamer-based adsorbers under development by Doto Medical. To test the functionality of the ABD prototype, a proof-of-principle pilot study was conducted using a model aptamer specific to a model human protein, previously developed by Pure Biologics. The ABD device prototype effectively separated blood into cellular and plasma components under ex vivo conditions, reflecting the first stage of targeted plasmapheresis technology. The ABD device prototype effectively captured a model protein from plasma using a model absorber, confirming the effectiveness of the prototype in selectively capturing molecules from a highly complex

biological fluid. Research is currently underway to further optimise the technical aspects of a prototype ABD device, guiding the development of a product for assisted blood detoxification in dialysis patients.

Using Pure Biologics' patented PureApta™ aptamer discovery platform, more than ten aptamers have been obtained that specifically bind two proteins identified as molecular targets for the treatment of chronic kidney disease. The first molecular target is associated with renal deterioration, and the aptamer-based extracorporeal therapy under development in subproject PB103a aims to prolong residual renal function in dialysis patients. The second target is related to cardiovascular complications in patients with CKD, the removal of which, using aptamers obtained in subproject PB103b, is expected to result in a reduction in mortality in dialysis patients due to cardiovascular complications.

As part of sub-project PB103a, aptamers with high affinity for the molecular target were obtained. These aptamers were shortened to the minimum length to guarantee their functionality in order to reduce the cost of manufacturing the final product in the future. The shortened aptamers were then optimised for resistance to the degrading action of nucleases naturally found in human blood. The high nucleolytic stability of aptamers is an important parameter for both the efficacy and safety of the adsorber, as it minimises the risk of aptamer degradation products being released into the patient's blood during targeted plasmapheresis. We have successfully synthesised aptamers on a solid substrate under conditions that will be used for industrial-scale aptamer production. Furthermore, aptamers have been shown to retain their functionality when bound to the matrix used in the adsorber. The next step in the development of the adsorber will be to test the efficiency of molecular target capture from blood plasma on its prototype. The results of the study will allow the identification of a lead candidate for the prototyping of a suitable adsorber for the ABD device in subproject PB103a. The aptamers obtained to date only show specificity towards the human target protein. In order to enable future in vivo preclinical studies, necessary for proof of concept and safety profile, additional aptamer selection for an animal equivalent of the target protein is underway to produce a replacement molecule.

The PB103b project has yielded aptamers with affinity for the human target protein, which will be tested for cross-reactivity with animal proteins in the near future. The identification of aptamers that bind both human and animal proteins will enable the same aptamer to be used in preclinical and clinical studies, significantly reducing the time and cost of the project. In the next step, the aptamers obtained under subproject PB103b will be optimised for length and nucleolytic stability and subjected to functional testing.

Planned works

The beneficial effect of removing specific disease molecules from patients' blood in delaying the deterioration of renal function is the premise of the PB103a project. Preclinical animal tests are required to confirm this assumption. In the near future, a suitable animal model of kidney disease will be developed to further investigate the effect of prolonging residual renal function in response to blocking or removing selected pathogenic proteins from the blood. At the same time, laboratory work will focus on developing an aptamer-based prototype adsorber targeting pathogenic proteins found in chronic kidney disease and achieving full functionality of the ABD device to remove these molecules from the blood in ex vivo proof-of-concept studies.

Collaborative science and technology projects

Project PB013 (ALTERCAR)

Aim of the project

The aim of the project is to pilot the development of a novel cell therapy using T cells with an inserted chimeric antigen receptor (CAR-T) against newly selected molecular targets overrepresented in selected leukaemias and lymphomas. The Polish-Norwegian consortium will lead research from the selection of new targets, through the selection of antibody fragments (scFvs) that bind these targets and the development of a CAR receptor equipped with the selected binding molecule, to animal studies demonstrating the efficacy of the new therapy for use in patients resistant to standard treatment (Rituximab, CD19-CAR T).

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the 'Applied Research' programme funded by the Norwegian Financial Mechanism 2014-2021. The total value of the project for the consortium is PLN 6,655 thousand, with an allocated EU funding of PLN 6,573 thousand. The budget of the stages implemented by the Company is PLN 413 thousand (total cost), and the granted amount of funding is PLN 330 thousand. The Company's own contribution to the project in the amount of PLN 83 thousand is covered from equity. The project has been implemented as part of a consortium since January 1, 2021, and the planned completion of the project is December 31, 2023.

The Consortium

The consortium leader is the Medical University of Warsaw, where the team is led by Dr Magdalena Winiarska, and in addition to Pure Biologics, the consortium includes Oslo University Hospital, Institute for Cancer Research, Cancer Division, where the leader is Dr Sébastien Wälchli.

Implementation and results of the project in the reported period

In the first half of 2023, 'epitope binning' experiments were performed at Pure Biologics for pre-selected antibodies to pre-map the binding sites (epitopes) of the antibodies to the molecular target. The results of these types of experiments allow a certain degree of prediction of the biological activity of the antibodies, and will therefore be used by the partners to design further studies.

At the same time, the partners conducted research on chimeric receptors (CARs) created from antibodies selected at Pure Biologics and presented on the surface of T lymphocytes. The results of their research will determine the Company's possible further participation in the project.

Project PB014 (DualDrug)

Aim of the project

The aim of the project is to develop a conjugate of a human growth factor protein with two different cytostatic drug molecules. This type of therapeutic molecule, which is preferentially internalised by the cells of selected tumours, is expected to effectively eliminate these cells due to the strong synergistic effect of the two cytotoxic drugs. The collaboration with the University of Wrocław and Oslo University Hospital will allow the consortia's expertise to be combined to develop a new drug candidate more quickly and with greater likelihood up to the animal testing stage.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the 'Applied Research' programme funded by the Norwegian Financial Mechanism 2014–2021. The total value of the project for the consortium is PLN 6 571 thousand, with an allocated EU funding of PLN 6 508 thousand. The budget of the stages implemented by the Company is PLN 158 thousand (total cost), and the granted amount of funding is PLN 95 thousand. The Company's own contribution to the project in the amount of PLN 63 thousand, is covered from equity. The project has been implemented as part of a consortium since October 1, 2020, and the planned completion of the project is September 30, 2023.

The Consortium

The Consortium leader is the University of Wrocław, where the team is led by Professor Jacek Otlewski, and in addition to Pure Biologics, the Consortium also includes Oslo University Hospital, Institute for Cancer Research, where the leader is Dr Antoni Więdłocha.

Implementation and results of the project in the reported period

During the first half of 2023, the Consortium partners continued to work on the mechanism of action of selected cytostatic drugs and the preparation of growth factor conjugates with these drugs. Pure Biologics' further participation in the project, if any, will depend on the results obtained by the Consortium partners.

8. Information on events significantly affecting the Company's operations during and after the financial period

Due to the specific nature and profile of Pure Biologics S.A.'s business, events that significantly affect the Company's operations are related to its R&D activities and are described in detail in point.7 above. In addition to the events mentioned in the aforementioned section, the activities in the business development and corporate area of the Company, which are described below, may be relevant for a proper assessment of the Issuer's activities in the period covered by this report.

Actions taken to secure new grants and subsidies

The Company is actively working to obtain new grants for the implementation of further projects. On 8 May 2023, the Company submitted proposals for three projects in the competition of the Polish Agency for Enterprise Development (SMART I; FENG.O1.O1-IP.O2-001/23), two of which are related to drug development, while the third is a technology project to optimise the process of discovering therapeutic antibodies at Pure Biologics:

- FENG.O1.O1-IP.O2-0359/23 "Development of an innovative biological drug to inhibit immunosuppression in tumour for the treatment of prostate cancer". To be implemented from June 2023 to June 2028; total budget PLN 83.95 million.
- FENG.O1.O1-IP.O2-0495/23 „Development of a bifunctional fusion antibody for innovative immunotherapy targeting the chemokine receptor for the treatment of metastatic renal cell carcinoma". To be implemented from June 2023 to June 2028; total budget PLN 87.39 million.
- FENG.O1.O1-IP.O2-0363/23 „Innovative platform for the development of therapeutic antibodies". To be implemented from September 2023 to August 2028. Total budget PLN 30.04 million.

Doto Medical Ltd. submitted an application in the same competition for the development of a therapeutic medical device:

- FENG.01.01-IP.02-0358/23 „Development of breakthrough ABD technology for selective elimination of pro-inflammatory proteins from the blood of patients with chronic kidney disease“. To be implemented from June 2023 to May 2027. Total budget 33.75 million.

Panels of applicants with experts are currently underway; results of the competition are expected in late September/early October.

In addition, a project application PBO03a is currently being prepared and will be submitted to the SMART II competition organised by PARP. The deadline for submission of applications is 30 October 2023.

Nomination of lead candidates for projects PBO03g and PBO04

On 5 April 2023. The Company announced the selection of the molecule PBB-0091 as the lead candidate for preclinical and clinical studies in the PBO03g project. PBA-0091 will be developed as a novel immunotherapy targeting the GARP antigen for the treatment of cancer. PBA-0091 is in the form of a bifunctional fusion protein (BFP), i.e. a unique therapeutic format developed by Pure Biologics that is significantly more effective at killing cancer cells than conventional therapeutic antibodies. At the same time, reserve candidates have also been selected. Pure Biologics is developing PBA-0091 to meet all regulatory requirements for a Phase 0 clinical trial that will investigate early signs of therapeutic efficacy in head and neck cancer patients. The trial will commence at the end of 2023.

On 13 April 2023. The Company announced the selection of PBA-0405 as the lead candidate for preclinical and clinical studies in Project PBO04. PBA-0405 will be developed as a potential first-in-class immunotherapy for patients with cancers expressing the ROR-1 antigen, including leukaemias and solid tumours. PBA-0405 was selected on the basis of its ability to induce immune cell-mediated tumour cell killing, providing potentially significant therapeutic advantages over other ROR-1-targeted antibodies currently in clinical development. With the selection of PBA-0405, Pure Biologics has begun preparations to contract production of the molecule at a scale suitable for preclinical studies and further for Phase 0 and Phase 1 clinical trials. The company has begun preparations to obtain approval to initiate a Phase 0 clinical trial in 2023. The trial will be designed to test clinical efficacy following topical administration in humans and is expected to be completed in the second half of 2024. The company plans to initiate the phase 1 clinical trial in late 2024.

Submission of patent applications

In February this year, the Company signed a cooperation agreement for the preparation of patent applications with the Düsseldorf-based law firm MHPatent. The law firm has a broad spectrum of activities with specialisation in technical activities – patents, trademarks, licences.

On 5 June, the Company filed two patent applications with the European Patent Office (EPO) to obtain industrial property rights protection for the therapeutic molecules being developed in projects PBO03g and PBO04. Thus, the 20-year protection for both inventions, if the patents are granted, starts on 5 June 2023, referred to as the priority date.

The patent application for project PBO03g is entitled 'Anti-GARP/TGFβ1 antibodies and methods of use' and describes Pure Biologics' discovery of unique anti-GARP antibodies, as well as an innovative antibody format in the form of bifunctional molecules with an attached ULBP2 immunoligand. Thanks to the format developed by the Company, the molecule has a novel dual mechanism of action: (i) by activating immune cells, it induces the killing of cells with anti-GARP expression, both tumour and immunosuppressive Treg cells, and unlike the anti-GARP antibodies developed by competitors, (ii) it has the ability not only to inhibit the release of TGFβ1 from the

complex with GARP, but also to block the formation of the GARP/TGFβ1 complex, thereby reducing the immunosuppressive properties of the tumour microenvironment of tumours.

In contrast, the application for project PBO04 is entitled 'Anti-ROR1 antibodies and methods of use' and describes the unique anti-ROR1 antibodies discovered by the Pure Biologics team and their properties, most notably their ability to induce antibody-dependent cellular cytotoxicity (ADCC) against tumour cells expressing anti-ROR1. The biological activity demonstrated by the results of the studies and described in the patent application is many times greater than that of competing antibodies currently being tested in clinical trials.

Patent applications are an important milestone in the implementation of Pure Biologics' strategy, as they provide confirmation of the innovation of the products being developed within the Company's portfolio and, above all, represent the right assets to be commercialised in the future. The filing with the EPO makes it possible to obtain broad patent protection in selected European countries and, in subsequent steps, also to extend the exclusive right beyond the countries of Europe, including the markets of the USA, Canada and Asian countries.

Events, conferences, partnering

During the reporting period, the Company participated in biotechnology partnering conferences: BIO Europe Spring, held in Basel (Switzerland) from 20–22 March 2023, and BIO International Convention, held in Boston (USA) from 5–8 June 2023.

As part of these events, the Company held more than forty scheduled meetings with biotechnology and pharmaceutical industry representatives and investors. The company presented its project portfolio in order to find strategic partners, in particular for the PBO03g and PBO04 drug development projects.

In addition, the Company, represented by Pieter Spee, Chief Scientific Officer, participated in the Pharm Connect Congress held in Warsaw on 23–24 May 2023. Pure Biologics presented strategies for 'me-better' drug development and smart clinical development to representatives of the Polish pharmaceutical and biotechnology industry.

Signing of Term Sheet and subsequent Loan Agreement and Investment Agreement with ACRX Limited

On 17 March 2023, as part of the ongoing strategic options review process, the Issuer entered into a Term Sheet with ACRX Investments Limited, Nicosia ("ACRX"), to negotiate a potential transaction to determine the terms and conditions of ACRX's financing to the Company, and the terms of the parties' cooperation in connection with the financing provided.

As a result of the aforementioned negotiations, on 20 April 2023, an investment agreement was concluded between the Company and ACRX Investments Limited, setting out the obligations of the Parties with respect to the financing transaction, the principles of cooperation between the Parties during its execution, as well as the conclusion of a loan agreement.

Pursuant to the provisions of the Loan Agreement, the Investor granted the Company a loan in the amount of PLN 12,000 thousand [in words: twelve million zloty] for a period of two years from the date of its disbursement. Under the Investment Agreement, the Parties agreed on the mutual right to exercise the option to convert the Company's debt under the Loan into shares of a new issue of the Company. Interest on the Loan will be 10% per annum and will be converted into Converted Shares.

The loan was disbursed on 29 May 2023 once all of the following conditions were met:

- adoption by the General Meeting of a resolution to amend the Company's Articles of Association to include an authorisation for the Management Board to increase the share capital within the limits of the authorised capital, together with an authorisation to waive the pre-emptive rights of existing shareholders;
- the adoption by the General Meeting of the Company of a resolution on the issue of 154,272 registered series B subscription warrants with the exclusion of the pre-emptive right of existing shareholders, a conditional increase in the Company's share capital through the issue of 154,272 ordinary bearer shares with the exclusion of the pre-emptive right of existing shareholders; and
- adoption by the General Meeting of the Company of a resolution on the appointment to the Supervisory Board of the Company of a candidate indicated by the Investor.

The rights attached to the Warrants will be exercisable by the Investor by way of subscription for shares in the Company within one month of the Investor's subscription for the Converted Shares, but no later than 12 months from the date of the Investor's subscription for the Warrants if a private placement of the Converted Shares has not been made by that time.

During the term of the Investment Agreement, the Company may decide to carry out a public offering of the Company's shares of a new issue within the Company's authorised capital – if the Company's General Meeting passes a Resolution. Within 30 days after the registration of the increase of the share capital by shares issued under the SPO by the competent registry court, the Board of Directors of the Company will adopt the relevant resolution on the increase of the Company's share capital within the limits of the authorised capital as authorised by the Resolution, in order to offer the Converted Shares in a private placement to the Investor. If requested by the Company within 20 days of the Record Date, the Investor will be required to participate in the private placement and subscribe for the Converted Shares at an issue price equal to 90% of the issue price of the shares offered by the Company under the SPO, subject to the number of Converted Shares not exceeding 1/2 of the total shares allotted by the Company under the SPO. The Investment Agreement also provides for the same right of the Investor to request the Company, within 20 days of the Registration, to pass a Resolution to offer to the Investor in a private placement to subscribe for the Converted Shares at an issue price equal to the Investor Price, provided that the number of Converted Shares subscribed for by the Investor shall not exceed 1/2 of the total shares allotted by the Company in the SOP.

The Investment Agreement provides for contractual penalties, reserved in favour of the Company and the Investor, in the event of non-performance or improper performance of a given Party's obligations under the Investment Agreement, in an amount depending on the type of breached obligation of the Parties ranging from PLN 500 thousand to PLN 6,000 thousand. Payment of the contractual penalty does not exclude the Parties' right to pursue a claim for repair of the damage on general terms.

The Investment Agreement provides for an obligation on the part of the Investor to enter into a lock-up agreement with the brokerage house concerning the Converted Shares and the shares acquired as a result of the exercise of rights under the Warrants, limiting their transferability for a period of 12 months from the date of their acquisition. The aforementioned restriction will not apply if the Investor disposes of the Company's shares at a price of not less than PLN 50 per share.

The funds raised under the Loan Agreement will be used to finance operating costs in connection with the conduct of research and development work, including covering the Company's own contribution to supplement the grant funds of PLN 64.88 million, which were granted to the Company in connection with the:

- ABM's (Medical Research Agency) funding agreement for the PBO03 project, as reported by the Issuer in current report No. 15/2023 of 9 March 2023; and
- ABM's (Medical Research Agency) funding agreement for the PBO04 project, as reported by the Issuer in current report No. 4/2023 of 23 January 2023

and for the continuation of the Company's development strategy directed towards the parallel development of the PBO03 and PBO04 projects, through which the Company plans cost optimisations, primarily related to the conduct of phase 0 clinical trials.

The course of negotiations indicates that the Investor does not rule out increasing its capital commitment to the Company's development in order to meet its financial and capital needs in 2023 from the position of a strategic investor.

ACRX is a European transactional and distribution company in the TV rights market and an investor in areas such as new technologies, internet applications and biotechnology. ACRX is a major shareholder in one of the leading producers and publishers of computer games listed on the WSE.

Signature of agreement with MRA for funding of further phases of project PBO04 (Pure BIKE)

In January 2023, the Company entered into an agreement with the Medical Research Agency for the implementation and funding of the project „Phase 1 study of first-in-class bispecific ROR1xCD16 molecule in Patients with B-Cell Lymphoid Malignancies” in the framework of the competition for the development of targeted or personalised medicine based on cell therapies or protein products [ABM/2022/5].

The scope of the co-financed project includes advanced preclinical stages and the first phase of clinical trials (for haematological indications) of the PBO04 drug development project already conducted by the Issuer, including the development of the leading candidate PBO04 towards improving the effectiveness of treatment of patients suffering from haematological malignancies, the so-called B-cell Lymphoid Malignancies, including B-CLL and MCL.

The aim of the PBO04 project is to find an antibody-based drug candidate that acts as an immunotherapy strategy for the treatment of ROR1 receptor-expressing cancers. The PBO04 project, which is being developed in the Company as early as 2019, may offer significant competitive advantages over other ROR1-targeting molecules that have shown promising results in preclinical and clinical studies in recent years.

The total value of the project is PLN 48 897 223,25, and the amount of funding granted by MRA is PLN 32 439 513,93. Funds under the project may be spent in the years 2022–2026.

Signature of agreement with MRA for funding of further phases of project PBO03 (Pure Activator)

In January 2023, the Company entered into an agreement with the Medical Research Agency for the implementation and funding of the project „A phase 1 study to investigate the safety, tolerability and efficacy of bispecific compound in subjects with advanced solid tumours” in the framework of the competition for the development of targeted or personalised medicine based on cell therapies or protein products (ABM/2022/5).

The scope of the funded project includes the generation and verification in a phase 1 clinical trial of a highly innovative bifunctional fusion protein (BFP) with a specific mode of action resulting from the involvement of multiple targets. BFP, through binding to the GARP-TGF- β 1 complex, blocks the release of TGF- β 1 thereby alleviating immunosuppression and improving the anti-tumour immune

response in the tumour environment, and furthermore reduces the number of tumour and immunosuppressive cells through the NKG2D receptor.

The total value of the project is PLN 48 897 333,25, and the funding amount recommended by MRA is PLN 32 439 596,43. The project implementation deadline is 2022-2026.

Registration in the National Court Register of the capital increase from the issue of series G and H shares and amendments to the articles of association

In connection with the issue of series G and H shares taking place in December 2022, on January 13, 2023. District Court for Wrocław-Fabryczna in Wrocław, 6th Commercial Division of the National Court Register registered an increase in the Company's share capital by the amount of PLN 96,000 on the basis of the issue of 450,000 series G ordinary bearer shares and 510,000 series H ordinary bearer shares of the Company, each with a nominal value of PLN 0.10 carried out in accordance with Resolution of the Management Board No. 1/12/2022 of December 12, 2022 on increasing the Company's share capital within the limits of authorised capital.

Following the registration of the aforementioned amendments to the Articles of Association, the Company's share capital now amounts to PLN 321,400 [three hundred and twenty-one thousand four hundred zlotys] and is divided into 3,214,000 [three million two hundred and fourteen thousand] shares, with a nominal value of PLN 0.10 [ten groszes] each.

In connection with the registration of the share capital increase, an amendment to § 5.2 of the Company's Articles of Association was registered. The Company announced this by ESPI report 1/2023 dated January 13, 2023.

Registration in the National Depository for securities and listing of series G shares on the WSE

On January 23, 2023. The National Depository for Securities (NDS) issued a statement on the registration with the NDS of 450,000 series G bearer shares of the Company with a nominal value of PLN 0.10 each, marked with the ISIN code PLPRBLG00010, subject to their introduction to trading on the regulated market to which other shares of the Issuer marked with the aforementioned ISIN code were introduced.

According to the statement of the NDS, the registration was to take place within three days of the NDS's receipt of a decision on the introduction of the aforementioned shares to trading on the regulated market to which other shares of the Issuer bearing the aforementioned ISIN code had been introduced, but not earlier than the date indicated in that decision as the date of introduction of those shares to trading on that regulated market.

On January 24, 2023. The Management Board of the Warsaw Stock Exchange Inc., pursuant to Resolution No. 54/2023, stated that 450,000 series G ordinary bearer shares of the Company with a nominal value of PLN 0.10 [ten groszes] each were admitted to trading on the parallel market.

At the same time, the WSE Board decided to introduce 450,000 series G ordinary bearer shares of the Company to trading on the parallel market as of January 27, 2023, subject to the registration of these shares by the National Depository for Securities on January 27, 2023 and their designation with the ISIN code „PLPRBLG00010”.

Registration of H Shares in the NDS

On January 24, 2023. The National Depository for Securities (KDPW) issued a statement on the registration with the KDPW of 510,000 series H bearer shares of the Company with a nominal value of PLN 0.10 each, designated with the ISIN code PLPRBLG00051.

Registration of the H shares with the NDS took place on January 26, 2023. For the time being, the Company's Management Board will not apply for admission of the H shares to trading on a regulated market operated by the Warsaw Stock Exchange Inc.

Review of strategic options

On February 17, 2023, by ESPI message 14/2023, the Company announced that the Board of Directors of Pure Biologics S.A. had decided to initiate a review of the strategic options available to the Company to support the further development of its business.

The Company's Management Board has conducted analyses of strategic options in the areas of optimising running costs and sources of funding for key projects earmarked for further development. Given the circumstances, the Board assumed that the leading scenario would be to raise financing from a new issue of the Company's shares, with alternative forms of potential transaction (public or to an identified entity) and sources of capital (primarily in a geographical context) being reviewed.

The Board of Directors indicates that the raised amount of the loan from ACRX and the decision of the shareholders regarding the possibility to increase the share capital within the framework of the authorised capital have secured the sources of financing for the Company identified in current report no. 22/2023 and on 29 May 2023 the Board of Directors decided to complete the review of the Company's strategic options, as announced in current report no. 30/2023 dated 30 May 2023.

General Meeting of the Company

On May 25, 2023 at 12:00 p.m. in Wrocław, 48E Legnicka Street, the Annual General Meeting of the Company was held. The planned agenda of the Annual General Meeting includes consideration and adoption of corporate resolutions required in connection with the approval and closing of the 2022 financial year, adoption of resolutions constituting conditions precedent to the Loan and Investment Agreements with ACRX Investment described above, election of members of the Supervisory Board for a new term, as well as amendments to the Company's Articles of Association. The detailed agenda and resolutions adopted during the AGM can be found in ESPI announcements 26 and 27/2023 or on the Company's website.

Implementation of the first tranche of the second incentive programme

In connection with the implementation in the Company of the incentive programme introduced pursuant to Resolution No. 14 of the Company's Annual General Meeting of 21 June 2021, the Board of Directors on 31 May 2023 reviewed the fulfilment of the loyalty criterion and management objectives in relation to the Company's key personnel for the accounting period 01.01.2022 – 31.12.2022. The fulfilment of the loyalty criterion and the objectives of the executives was positively verified and the right to subscribe for subscription warrants in a total number of 39,000 was granted to the designated eligible persons with whom the relevant agreements had been previously concluded. The warrants were offered on 3 July 2023 and the offer was accepted in full on 14 July 2023. In turn, with regard to the members of the Management Board designated as eligible persons in this programme, the Supervisory Board of the Company verified the fulfilment of the loyalty criterion and the management objectives for the same accounting period on 30 June 2023. With regard to the members of the Management Board, Mr Petrus Spee and Mr Romuald Harwas, the fulfilment of the loyalty criterion and the management objectives was verified positively, and they were granted the right to subscribe for subscription warrants in the number of 4,000 for Mr Petrus Spee and 14,062 for Mr Romuald Harwas. The warrants were offered to the members of the Board of Directors on 1 August 2023 and the offer was accepted in full on 2 August 2023.

Appointment of the Supervisory Board and Management Board for the new term

Due to the expiry of the mandates of the Supervisory Board members, the Issuer's General Meeting adopted resolutions on May 25, 2023, appointing the following persons to the Issuer's Supervisory Board as of May 25, 2023:

- Mr Andrzej Trznadel,
- Mr Tadeusz Wesółowski,
- Ms Julia Bar,
- Mr Mariusz Czekala,
- Mr Paweł Wiśniewski.

At the same time, the General Meeting set the number of members of the Supervisory Board at 5.

The Supervisory Board, at its meeting on 26 May 2023, entrusted Mr Andrzej Trznadel with the function of Chairman of the Supervisory Board and Mr Paweł Wiśniewski with the function of Deputy Chairman of the Supervisory Board. At the same time, at the same meeting, the Supervisory Board of the Company decided to appoint to the Management Board Mr. Filip Jeleń as President of the Management Board, Mr. Romuald Harwas as Vice-President of the Management Board and Mr. Petrus Spee as Vice-President of the Management Board.

Significant contracts**Agreements in the area of in vivo preclinical studies PB004 with Gempharmatech (preclinical proof-of-concept study)**

On 1 February 2023, 10 May 2023 and 31 May 2023, Pure Biologics S.A. signed a series of contracts (internal numbers PB004/09/2022, PB004/02/2023, PB004/03/2023 respectively) with Gempharmatech (China). As part of the contract, Gempharmatech will perform panel safety studies of the drug candidate in project PB004 using a humanised CD34+NCG-hIL15 tumour mouse model. The studies will provide more complete information on the selected drug candidates and enable their further development.

Agreements in the area of preclinical in vivo studies PB003g with Gempharmatech (preclinical proof-of-concept study)

On 12.05.2023, 5.06.2023 and 7.06.2023, Pure Biologics S.A. signed a series of contracts (internal numbers PB003/32/2023, PB003/33/2023, PB003/34/2023, respectively) with Gempharmatech (China). Under the contract, Gempharmatech will perform panels of preclinical safety, tolerability and potency evaluation services of the drug candidate selected in project PB003g in a humanised xenograft mouse model (human tumour). The studies will provide more complete information on the selected drug candidates and enable their further development.

Agreement with WuXi Biologics (China) to produce recombinant drug candidates

29 May 2023. The company has entered into two agreements with WuXi Biologics in China. Under the order, WuXi Biologics will produce eight biological molecules under development in the company's projects (PB003 (1x afuc-IgG; 3x IgG-fusion), PB004 (4x afuc-IgG)) and perform stability studies. Additional planned studies extend the contract by a further \$605k (toxicology and drug substance development). The proteins produced will be used for the toxicology study planned in the projects, as well as for the phase 0 clinical study.

Contract with Truly Labs (Sweden) for pharmacokinetic studies of drug candidates in PB004 projects

21 July 2023. Pure Biologics has entered into agreement PB004/06/2023 with Truly Labs to conduct pharmacokinetic testing for the drug candidate in project PB004.

Contract with IVRS (Sweden) for a pilot drug candidate efficacy study in PB004

3 July 2023. Pure Biologics S.A. has entered into contract PB004/05/2023 with IVRS AB. The purpose of the work commissioned under the agreement is to test the efficacy of the drug candidate selected in project PB004. The model in the study is intended to mimic clinical conditions (stage A) and to test safety in the form of a localisation study (stage B). Conducting the study will provide more complete information on the profile of the drug candidate.

9. Identification of shareholders holding, directly or indirectly, significant blocks of shares, along with an indication of the number of shares held by these entities, their percentage share in the share capital, the number of votes resulting from them and their percentage share in the total number of votes at the general meeting

Table 1: Shareholding structure as of June 30, 2023 and as at the date of publication of the report

Shareholder	Number of shares	Number of votes at GM	Share in capital	Share of votes at GM
TFI Allianz Polska S.A.	320 798	320 798	9,98%	9,98%
Filip Jeleń	276 117	276 117	8,59%	8,59%
Augebit FIZ	189 720	189 720	5,90%	5,90%
Other	2 427 365	2 427 365	75,52%	75,52%
Total	3 214 000	3 214 000	100,00%	100,00%

* The real beneficiary of Augebit FIZ is Mr. Tadeusz Wesółowski, Deputy Chairman of the Supervisory Board of the Company.

10. Company shares held by members of the Management Board and the Supervisory Board

According to the Company's knowledge as of June 30, 2023 and as at the date of the preparation of the report, the managing and supervising persons held, directly or indirectly, the Company's shares in accordance with the table below:

Table 2: Shares held by managing and supervising persons as of June 30, 2023 and the date of the report

Akcjonariusz	Liczba akcji	Liczba głosów na WZ	Udział w kapitale	Udział w głosach na WZ
Filip Jeleń (President of the Management Board)	276 117	276 117	8,59%	8,59%
Romuald Harwas (Vice-President of the Management Board)	3 205	3 205	0,10%	0,10%
Petrus Spee (Vice-President of the Management Board)	1 000	1 000	0,03%	0,03%
Tadeusz Wesołowski (Deputy Chairman of the Supervisory Board) *	189 720	189 720	5,90%	5,90%
Andrzej Trznadel (Chairman of the Supervisory Board)	81 000	81 000	2,52%	2,52%
Total	551 042	551 042	17,15%	17,15%

* Indirectly through Augebit FIZ

11. Indication of any restrictions regarding the transfer of the ownership of the Issuer's securities

As at the date of preparation of this report, there are no contractual restrictions on the transfer of ownership of the Issuer's securities. However, attention should be paid to the issue of series H shares described in section III.8. of this report, which were not introduced to public trading on the WSE, which constitutes a certain limitation in the flexibility of their transferability in relation to other series that can be sold through the WSE.

12. Information on agreements known to the Company, including those concluded after the balance sheet date, which may result in future changes in the proportions of shares held by existing shareholders

Investment agreement z ACRX Limited

As a result of the aforementioned negotiations, on 20 April 2023, an investment agreement was concluded between the Company and ACRX Investments Limited, setting out the obligations of the Parties with respect to the financing transaction, the principles of cooperation between the Parties during its execution, as well as the conclusion of a loan agreement.

Pursuant to the terms of the agreement, the Company offered ACRX to subscribe for 154,272 registered subscription warrants, which will entitle ACRX to subscribe for 154,272 shares. The rights

under the Warrants will expire 2 years after their acquisition by ACRX, with ACRX being obliged to exercise the rights under the Warrants when the Company decides to conduct a public offering of the Company's new issue shares.

Incentive programme

On 21 June 2021, the General Meeting of the Company adopted a resolution on the establishment of a new Incentive Programme in the Company. The duration of the Incentive Scheme is the financial years 2021 and 2022 and the first half of the financial year 2023. Persons entitled to participate in the Incentive Scheme are the current members of the Company's Management Board and other persons deemed to be key to the Company's operations who are parties to an employment contract with the Company or any other contract under which the person provides work or services.

As part of this incentive programme, the Company has conditionally increased its share capital, under which it will issue up to 118,500 Series F ordinary bearer shares with a nominal value of PLN 0.10. In order to grant rights to the Shares, the Company will issue up to 118,500 series A registered subscription warrants, each entitling to acquire one Share. Right to take up Warrants allotted to Eligible Persons.

In connection with the implementation in the Company of the incentive programme introduced pursuant to Resolution No. 14 of the Company's Annual General Meeting of 21 June 2021, the Board of Directors on 31 May 2023 reviewed the fulfilment of the loyalty criterion and management objectives in relation to the Company's key personnel for the accounting period 01.01.2022 – 31.12.2022. The fulfilment of the loyalty criterion and the objectives of the executives was positively verified and the right to subscribe for subscription warrants in a total number of 39,000 was granted to the designated eligible persons with whom the relevant agreements had been previously concluded. The warrants were offered on 3 July 2023 and the offer was accepted in full on 14 July 2023. In turn, with regard to the members of the Management Board designated as eligible persons in this programme, the Supervisory Board of the Company verified the fulfilment of the loyalty criterion and the management objectives for the same accounting period on 30 June 2023. With regard to the members of the Management Board, Mr Petrus Spee and Mr Romuald Harwas, the fulfilment of the loyalty criterion and the management objectives was verified positively, and they were granted the right to subscribe for subscription warrants in the number of 4,000 for Mr Petrus Spee and 14,062 for Mr Romuald Harwas. The warrants were offered to the members of the Management Board on 1 August 2023 and the offer was accepted in full on 2 August 2023.

IV. BASIC ECONOMIC AND FINANCIAL FIGURES

1. Commentary on the current and projected financial situation.

A peculiarity of biotechnology companies is the deferral of the production process of a future potential medical device from the research process for that device, including clinical trials. The life cycle of a research project is much longer than in a manufacturing company, which means that the period between the establishment and evaluation of the project and its final commercialisation usually takes many years. In addition, each successive stage of project development involves higher operating costs than the earlier stage, culminating in the clinical trials and medical device certification stage.

The Company's financial situation as at the balance sheet date is difficult; a detailed description of the risk factors affecting this situation is described in sections IV.9 and IV.10. As at 30 June 2023, cash amounted to PLN 8,054 thousand. At the same time, funds of PLN 12,198 thousand were held in term deposits and treasury bonds.

During the first six months of 2023, the Company met its obligations on an ongoing basis and its cash position allowed it to maintain ongoing liquidity.

The primary sources of funding for the Company's activities to date have been grants from public funds and contributions from the founders and external investors. Further development of the Company will require incurring further financial expenditures related to subsequent stages of research work and the product commercialisation process. The Issuer's future revenues are strongly dependent on the commercialisation of research projects.

Net revenue from commercial services

In the commercial services revenue item of the standalone statement of profit and loss and other comprehensive income prepared by the Company, the value reported was PLN 30 thousand and is 8% of the volume recorded in the comparable period of 2022. The structure of sales was dominated by export sales, which accounted for 89.8% of the value of sales in the first half of 2023. Revenue from the sale of goods and services is a side activity of the company, which focuses on conducting R&D work.

There is no seasonality in the area of activity in which the Company operates.

Cost of services sold and gross profit from sales

The result on sales was shaped in accordance with the accounting principles adopted by the Company and currently in force, as described in detail in the Separate Financial Statements for 2022. The value of own costs of sold services amounted to PLN 5 thousand in the first six months of 2023, which generated a gross profit of PLN 25 thousand on sales. This gave a healthy gross margin on sales of over 83%.

Operating costs

The value of operating expenses charged to the result amounting to PLN 23 961 thousand in the period covered by this report (PLN 17 561 thousand in the comparable period of 2022, +36.4%) represents the aggregated costs incurred by the Company in all areas of business activity, i.e. R&D, contract research, administration and management costs. The main reason for the increase in operating costs is the intensification of R&D work, particularly the entry into the costly animal testing phase of projects PBO03g and PBO04.

Undesirable factors and beyond the Company's control are adverse macroeconomic conditions such as exploding inflation and the weakening of the Polish zloty. Cost levels are also affected by the increase in resources by highly specialised foreigners who must be contracted at the current stage of development of the Company's project portfolio. A significant impact on the increase in costs is the relocation to the new laboratory and office space. A significant accounting charge that does not result in a cash outlay is also the Incentive Programme, which in the first half of 2023 charged PLN 1,302k to operating costs.

In the structure of costs in the period covered by this report, 71% was expenditure on R&D projects for research work charged directly to the result. They amounted to PLN 17,062 thousand and, compared to the first half of 2022, when R&D costs amounted to PLN 9,609 thousand, increased by 78%. The driver of this increase is the conduct of costly pre-clinical studies and preparations for phase 0 clinical trials. Including the PLN 3 280 thousand not recognised in the result (advances, not meeting the cost accounting criteria), R&D expenditure in the Company in the reporting period exceeded PLN 20.3 million.

General and administrative expenses (PLN 6 894 thousand) accounted for 29% of total costs and were 12% (PLN 940 thousand lower than in the corresponding period of 2022). Despite the significant increase in space rental costs, this is the aggregate effect of the optimisation that the company has carried out in recent quarters.

There were major changes in the cost structure by type compared to previous periods. For the first time in the history of the Company, salaries and wages did not constitute the largest burden. In the reported period, almost half of the costs, i.e. 49.1% (PLN 11,772 thousand), were external services. This is an increase of 238% compared to H1 2022, when they amounted to £3,482k. The main drivers of the increase are analytical, pre-clinical and phase 0 study services and expert consultation services.

This is followed in the cost structure by salaries and wages (PLN 6,231 thousand) accounting for 26% of total costs. In this item, a decrease was recorded in relation to the first half of 2022 (PLN 7,609 thousand) by 18.1%.

Depreciation (PLN 2 980 000) came third in the cost structure in the reporting period, accounting for 12.4%. This item increased by 146% compared with the same period in 2022 when it amounted to PLN 1 212 000. The main reason for the increase is the recognition in the books of a long-term lease agreement for laboratory and office space in accordance with IFRS16 guidelines. This, at the same time, influenced a 94% decrease in the line item 'rents and leases, where there was a change from PLN 925k in H1 2022 to PLN 55k in the reported period.

Consumption of materials and energy (PLN 1,642k) accounted for only 6.85% of total costs in the first half of 2023 and was 36% lower than in the comparable period of 2022 (PLN 2,573k).

All of the above costs represent approximately 95% of operating expenses. All costs by type except third-party services and depreciation and amortisation decreased compared to the first half of 2022.

Revenue from subsidies

Under the heading of grant revenue in the first half of 2023. The Company reported PLN 9,777 thousand and this is 59.1% more than in the comparable period of 2022. The largest revenues in the reporting period were generated by projects: PB003 PureActivator accounting for 46.2% of PB004 – PureBike – 46.8% of grant revenue, and PB001 MultiBody – 5.9%. Grant income should increase in the coming year, as it is directly correlated to the costs of ongoing R&D work and these will increase as the work progresses and we enter further, more capital-intensive stages of individual projects.

It should also be borne in mind that the level of funding is being reduced from 80% to 60% of eligible costs as work progresses. This will not be without an impact on the level of this item in the coming quarters.

Project costs

In the first half of 2023. The Company has recognised PLN 17,062 thousand of project costs in the statement of profit and loss and other comprehensive income. Analysing the cost structure, the largest share (44% and 42.2%) of project costs in the period covered by this report are PBO03- Pure Activator and PBO04 - PureBike. Once again, the costs of unsubsidised projects appeared in the report. This item includes both the initial costs of the PBIO3 - UreTox project, described in detail in section V.7 of this report, as well as the costs of "pre-projects", i.e. R&D activities undertaken to identify the most promising candidates for grant applications submitted by the Company, which are described in section V.8.

Profit (loss) on operational activities

The loss from operations in the first half of 2023 amounting to PLN 15,610 thousand, is a result that determines the Company's aggregate activity in its two core business segments, i.e. commercial contract research and the implementation of innovative R&D projects. In the comparable period, the loss from operations amounted to PLN 10,980k. (+42.2% y/y)

When assessing and analysing this item in the P&L, it should be taken into account that the increasing scale, number and value of the R&D projects implemented by the Company, as adopted in its strategic objectives, will increase the level of the Company's own share included in the costs of the projects carried out. This will have a direct impact on the value of the operating loss generated, however, the Company's own share of the costs incurred in carrying out R&D projects is treated by the Company as an investment in projects with a potential above-average rate of return, should they be successfully completed and commercialised.

While the size of the result generated by the Company on the sale of contract research may mitigate the scale of this process, the proceeds from commercial activities are intended to essentially play a role in the Company's financial model to support the Company's own share of R&D projects. They are primarily intended to secure the functioning of the Company in its basic organisational infrastructure and as a legal entity. The main source of financing for these expenditures is and will be funds from capital raised through the issue of shares.

It should be noted that the value of the loss from operations in the first half of 2023 is an expected value, although its level due to the deteriorating macroeconomic situation and the Company's environment may surprise, the Board of Directors believes that this is a risk inherent in the business model of a highly innovative biotechnology company such as Pure Biologics. The Company's long-term financial model assumes that the growing R&D project segment will be financed in the coming years mainly from external capital raised.

Financial revenue and expenses

Financial income in the first half of 2023 amounted to PLN 323k. against PLN 10 thousand. in the corresponding period of the previous year. They comprised almost two thirds of interest income from deposits and one third of positive exchange rate differences.

Total financial expenses in the reported period amounted to PLN 1,672k. and consist of interest on leases and long-term contracts (PLN 1,548k) and interest on the ACRX Investments loan. The former figure is largely due to the accounting treatment of a long-term lease agreement for laboratory and office space in accordance with IFRS16 guidelines.

Net profit (loss)

The net loss in H1 2023 of PLN 16,959k is 41.15 higher than in the comparable period of 2022 (PLN 12,023k) and is mainly due to factors affecting the loss from operations and the results on financial activities.

Tangible assets

In this balance sheet item, amounting to PLN 36 286 000 (48.67% of total assets) as at the last day of the period covered by this report, the main component is property, plant and equipment of PLN 34 632 000. In the overwhelming majority (84%), these are assets used on the basis of a lease, rental agreement or similar.

The other key non-current asset item is the long-term receivables from third parties representing the guaranteed deposit paid under the above lease agreement.

Intangible assets in the reporting period amounted to PLN 384 thousand, representing 1% of long-term assets and 0.5% of total assets. The largest item of intangible assets as of 30 June 2023 was patents and licences – PLN 273k. Long-term financial assets represented a fraction (0.06%) of non-current assets.

The value of non-current assets increased by PLN 27,448 thousand (48.67%) compared to the beginning of the period covered by this report. This increase is due to the adoption of a long-term lease agreement for laboratory and office space, which is recognised in the company's books in accordance with IFRS16 guidelines. The company recognised a right-of-use asset for 10 years in the gross amount of PLN 28,780k.

Current assets

Current assets on 30 June 2023 amounted to £38,274k and represented 51.3% of the balance sheet total. They are 51% higher than at the beginning of the period covered by this report.

The largest item of current assets is trade and other receivables amounting to PLN 16 518 000. This item aggregates mainly subsidy receivables in the amount of PLN 9,811 thousand. This figure represents the amount of subsidy settlements that were incurred but still not settled as at the balance sheet date. Budget receivables (including VAT to be reimbursed) as of 30 June 2023 amounted to PLN 3,054 thousand. Of the total receivables from third parties, which amount to PLN 3,290 thousand, an amount of PLN 3,279 thousand represents the advance payment for Phase O clinical trials.

Cash and cash equivalents at the end of the reporting period amounted to PLN 8 054 thousand and short-term deposits and bonds to PLN 12 198 thousand.

Equity capital

The value of this balance sheet item as at 30 June 2023 amounted to PLN – 20,617 thousand and its increase in relation to those recorded at the end of last year is a direct result of the accumulation of losses from the period covered by this report, as well as the periods of issuance of series G and H shares.

Long-term liabilities

Non-current liabilities at the end of the reporting period amounted to PLN 38 987 thousand and are significantly (PLN 37 109 thousand, 1977%) higher than at the beginning of the period covered by this report. In the structure of liabilities, they now represent 52.3%. These liabilities represent, to a significant extent (PLN 28 595 000), the long-term part of instalments for fixed assets used on

the basis of a rental, lease or leasing agreement. The largest item among them is the aforementioned lease agreement for laboratory and office space.

In the non-current liabilities item, the loan from ACRX Investment is also of significant value (PLN 12,034k).

Also accumulated here in the amount of PLN 55,000. time-settled subsidies, i.e. relating to the Pureselect2 and PureApta technology platforms. Also shown are long-term provisions for employee benefits in the amount of PLN 39k.

Short-term liabilities

Short-term liabilities at the end of the reporting period amounted to PLN 14,957 thousand, representing 20.1% of the balance sheet total and 16.6% higher than at the beginning of the reporting period.

In the structure of liabilities, 50.9 per cent is accounted for by deferred grants (advances), 21.6 per cent by finance leases and 18.8 per cent by trade. The significant decrease in trade payables is mainly related to the settlement of payments related to the purchase of fixed assets as part of the project to complete the equipment in the company's new laboratory space. At the same time, the move to the new space generated higher costs and, consequently, higher lease, rental and leasing liabilities.

In the amount of PLN 728 thousand of other liabilities, PLN 482 thousand are payroll liabilities and PLN 229 thousand public-law liabilities.

2. Key financial and non-financial performance indicators.

Financial performance indicators

Table 4: Financial performance indicators of the Company

Index	Method of calculation	1H2023	31.12.2022	1H2022
Overall liquidity ratio	current assets/ current liabilities	2,56	1,88	3,29
Grant receivables turnover ratio (in days)	subsidy receivable/grant receipts x number of days in the period	180,6	254,3	100,4
Turnover ratio of trade payables (in days)	trade payables/operating costs x number of days in the period	26,6	79,8	26,0
Equity to fixed assets ratio	equity/ fixed assets	0,5	2,1	5,2
Overall debt ratio	total liabilities/total assets	0,72	0,45	0,32
Long-term debt ratio	long-term liabilities/total liabilities	0,52	0,06	0,05
Short-term debt ratio	short-term liabilities/total liabilities	0,20	0,39	0,26
Liabilities to equity ratio	total liabilities/ equity	2,6	0,8	0,5
Book value per share	equity/ number of shares at year end	6,4	8,1	13,2

Earnings per share (EPS) value	net profit/weighted average number of shares during the period	-5,4	-11,4	-5,3
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In the first half of the 2023 financial year, Pure Biologics S.A.'s liquidity situation remained stable. The overall liquidity ratio, which, due to the lack of inventories, is equivalent to the quick ratio during the accounting period, was at a comfortable level of 2.56 and is slightly higher than at the beginning of the reporting period.

Due to the insignificant volume of sales (PLN 30,000), the turnover rate of trade receivables was replaced by the turnover rate of grant receivables. In the past period, it amounted to 180.6 days and improved compared to the beginning of the reporting period. It illustrates the average duration of the settlement from the date of the company's application for reimbursement of costs until the receivables are settled by the subsidising institution.

The turnover rate of trade payables is 26.6 days and has improved since the beginning of the period covered by this report and is close to the level of the comparable period last year and remains at a fairly safe, low level. In the reimbursement system of grant settlement, the grantor institution requires payment of payables prior to submission of the reimbursement application. It is therefore in the Company's interest to settle its liabilities more quickly in order to be able to obtain refunds earlier and reduce its frozen working capital. Under the advance payment system, in which the Company has partially operated throughout the period covered by this report, the obligation to submit a settlement request is in most cases once every 90 days, and in the case of advances from ABM even 180 days. Therefore, the Company does not have such a vested interest in settling liabilities before their due date.

While the short-term debt ratio improved significantly (almost halving) from the beginning of the reporting period and remained at a similar level to the comparable period of 2022, the long-term and general debt ratios increased significantly. The increase in the long-term debt ratio is due to the recognition in the Company's books of a long-term liability for the lease of laboratory and office space in accordance with IFRS16.

Non-financial performance indicators

Due to the nature of Pure Biologics S.A.'s business, the key non-financial performance indicators are those relating to employee issues as shown in the tables below.

Table 5: Educational structure of employees.

Education						
	Total		Women		Men	
	number	share %	number	share %	number	share %
TOTAL	56		37		19	
Higher with an academic degree	32	57,1%	17	45,9%	15	78,9%
Higher	24	42,9%	20	54,1%	4	21,1%
Secondary	0	0,0%	0	0,0%	0	0,0%

Pure Biologics S.A. employs highly qualified professionals, more than 57% of whom hold a degree. Employees with tertiary and higher education degrees account for 100% of Pure Biologics S.A.'s workforce. The employment structure is dominated by women, whose share is 65.3%.

Table 6: Employment structure by length of service.

	Length of service					
	Total		Women		Men	
	number	share %	number	share %	number	share %
TOTAL	56		37		19	
less than one year	7	12,5%	5	13,5%	2	10,5%
1 to 3 years	12	21,4%	7	18,9%	5	26,3%
over 3 years	37	66,1%	25	67,6%	12	63,2%

The seniority structure of the workforce reflects the changes that have taken place in the Company over the last 12 months. During the reported period, the workforce decreased from 101 to 56 employees. This was the result of the evolution of the employment structure as project work progressed. More than 66% of employees have seniority of more than 3 years and only 12.5% joined the Company within the last year. The employment stability index, i.e. the number of people employed for more than 1 year, is 87.5% and is higher than the reading at the end of last June when it was 80.5%.

The overall turnover rate over the first half of the year was 26.4 per cent and, due to changes in the workforce, more than doubled compared to the first half of last year.

The level of indefinite contracts in the first half of 2023 was 91.1%, significantly better than the reading at the end of the comparable period, when it was 75.2%.

The average duration of recruitment processes (in weeks) in the analysis period of 2023 was 4 weeks and this is a reduction of approximately 4.6 weeks compared to the results of the first half of 2022. Due to structural changes, there were fewer of these recruitments.

The overall absenteeism rate for the first half of 2023 was 1.37%, up slightly from the reading for the first half of 2022 when it was 1.23%.

The accident absence rate is 0 and this positive trend has continued for many periods of time.

3. Description of the use of proceeds from the issue of securities.

At the end of 2022, the Company issued 450,000 G-series ordinary bearer shares with a nominal value of PLN 0.10 each and 510,000 H-series ordinary bearer shares with a nominal value of PLN 0.10. The issue price was PLN 20, as a result of which the Company raised capital in the amount of PLN 19,200 thousand. The capital increase was registered with the National Court Register on 13 January 2023. On 17 January 2023, the Company received the issue proceeds less the Brokerage commission. The funds raised from the issue in 2022 will be used, in line with the investment objectives, for own contributions to ongoing R&D projects and to cover unreimbursed costs of these projects.

4. Evaluation of the management of financial resources

The management of the Company's financial resources is the responsibility of the Management Board. In the Issuer's opinion, this is done in a rational and efficient manner. The Company's financial position at the time of the report is good. As at 30 June 2023, the value of cash on the Company's account was PLN 8,054 thousand, the value of short-term deposits was PLN 11,200 thousand and bonds was PLN 998 thousand.

Pure Biologics S.A. intends to continue to use the advance funding model for research and development work co-financed by the NCRD. This will increase the Company's financial security buffer. The Company meets its obligations on an ongoing basis and maintains a safe level of cash, although the Management Board believes that with increased expenditure on research and development work and no funding available until the end of the current year, it is at risk of losing its liquidity. The Issuer's future revenues are strongly dependent on the commercialisation of research projects.

5. Assessment of the feasibility of investment intentions

Pure Biologics S.A., in line with its business plans, intends to invest in research and development and physical infrastructure on an ongoing basis. The proceeds from the issue of shares and series G and H shares allow the planned investments, in particular the implementation of research and development projects already underway, to be carried out to a limited extent. The Company does not have sufficient working capital to finance its operations and research activities for a period of twelve months from the date of the report. In such a situation, depending on the scale of the projects, the Company will consider using alternative sources of financing.

PART III – STATEMENTS

V. STATEMENT OF THE MANAGEMENT BOARD OF PURE BIOLOGICS S.A. ON THE PREPARATION OF THE FINANCIAL STATEMENTS AND THE MANAGEMENT REPORT

The Board of Directors of Pure Biologics S.A. declares that, to the best of its knowledge, the semi-annual condensed financial statements for the period 01.01-30.06.2023 and the comparative data have been prepared in accordance with the applicable accounting principles and other regulations applicable to the Company, and that they give a true, fair and clear view of the Company's financial position and its financial result.

The Board of Directors of Pure Biologics S.A. also declares that the report on the Company's activities gives a true picture of the Company's situation, including a description of the main threats and risks.

Dr Filip Jan Jeleń
President of the Management
Board

Romuald Apollo Harwas
Vice-President of the
Management Board

Dr Petrus Johannes Louis Spee
Vice-President of the
Management Board