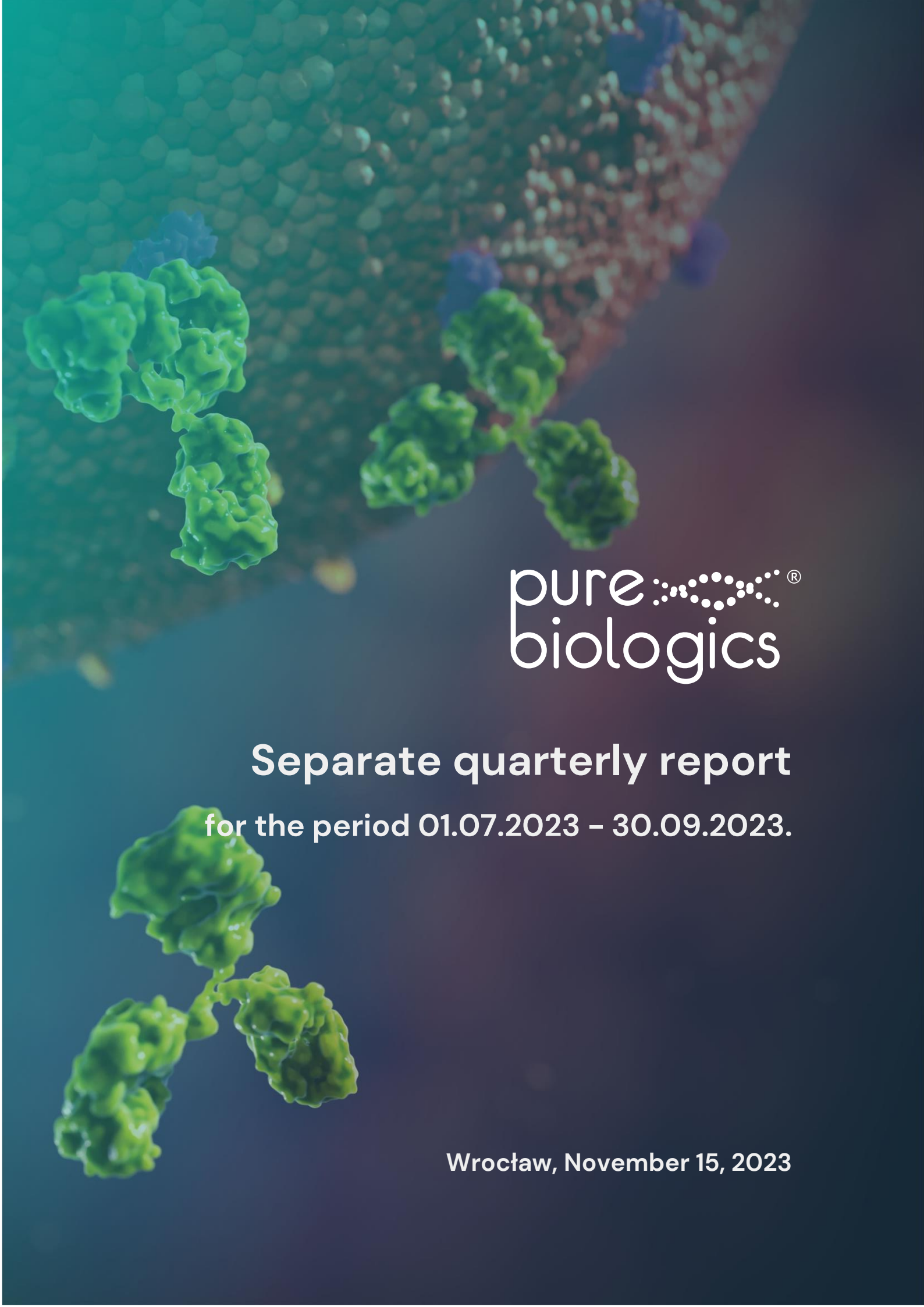

pure biologics®

Separate quarterly report

for the period 01.07.2023 – 30.09.2023.

Wrocław, November 15, 2023

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I. BASIC INFORMATION ABOUT THE ISSUER

1. Composition of the Management Board

As on 30 September 2023 and at the date of this report, the Board of Directors 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 Board of Directors did not change.

2. Composition of the Supervisory Board

As on 30 September 2023 and at the date of approval 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 Czekała - Member of the Supervisory Board.

The composition of the Supervisory Board did not change during the period covered by this report.

Audit Committee

As on 30 September 2023 and at the date of this report, the Audit Committee of the Supervisory Board consists of:

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

Mr Mariusz Czekała is a member of the Audit Committee who meets the requirements of the Act on Statutory Auditors to have knowledge and skills in accounting or auditing, while Ms Julia Bar has knowledge of the industry in which the Company operates. In addition, Julia Bar and Mariusz Czekała are independent members within the meaning of the Act on Statutory Auditors.

3. Organisational or capital links

On 1 December 2022, Pure Biologics S.A. established a wholly-owned subsidiary, Doto Medical Ltd., with its registered office in Wrocław, at: ul. Legnicka 48E, 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 has waived the preparation of consolidated financial statements for the nine months ended 30 September 2023.

4. Brief description of the company's activities

Subject of the Issuer's activity

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

Development of innovative drugs and therapies

The Company's core business is the development of new biological drugs and extracorporeal therapies based on its extensive expertise 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 Pure Biologics' strategy is 'smart drug development' (also presented as a 'Smart IO' approach). The company is developing drug candidates whose complex mechanism of action is likely to provide a competitive advantage over candidates developed by other companies targeting the same antigens that have already demonstrated therapeutic potential and safety in clinical trials. This means that the risks associated with developing drug candidates with a mechanism of action that is completely unvalidated clinically are reduced, while maintaining competitiveness through improvements to the existing mechanism of action that are expected to provide increased therapeutic efficacy. The Company's portfolio includes projects with significant advantages over competing solutions, with the projects under development 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 PB003G and PB004, Pure Biologics is focusing on the introduction of phase 0 clinical trials in its projects in order to obtain pharmacodynamic data (based on 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 trials, which will be based on active and multifaceted patient stratification, as opposed to the broad population-based studies practised in the classical approach. In addition, biomarkers validated in the phase 0

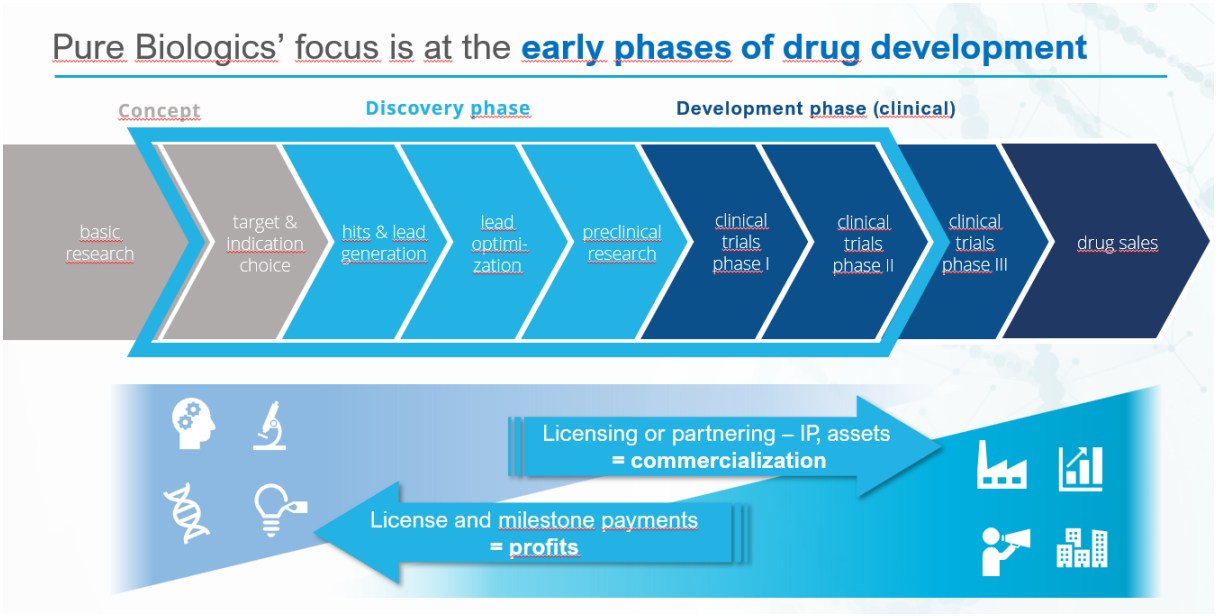
study will be included as additional study endpoints, in order to demonstrate therapeutic activity and clinical efficacy already in phase 1 clinical trials.

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, including those suffering from chronic kidney disease.

Within the first area (projects PB003A, PB003G and PB004), a new generation of antibodies is being developed in formats that improve their pharmacological properties. These molecules are expected to interact with immune cells in the tumour microenvironment to activate them to kill tumour cells, or to abolish tumour-induced immune blockade. 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 PureLibra library of sequences (ScFv antibody fragments), in addition to libraries licensed from Twist Bioscience.

The second business area (PB103) uses aptamers to create innovative therapeutic solutions - adsorbers that selectively remove pathogenic molecules from patients' blood for nephrology applications. 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 also conducts internal technology projects, including studies to improve aptamer stability and to investigate the safety of modified nucleotides.



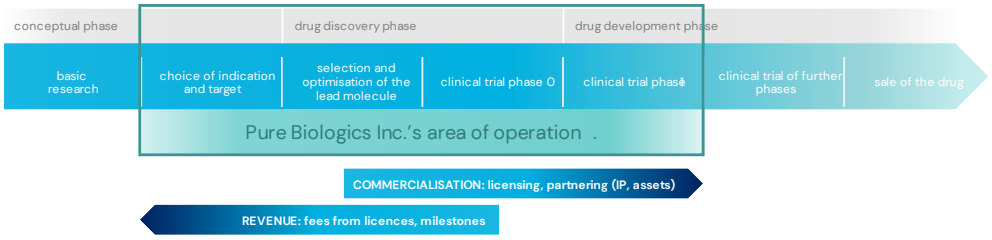


Figure 1: Phases of drug discovery and Pure Biologics S.A.'s area of activity. The company is active in the early stages of drug development.

Innovative R&D projects supported by grants

Pure Biologics actively uses public funds to support R&D activities in the company and has repeatedly successfully applied for funding for its projects at both the NCBR, the Medical Research Agency and the European Commission. Only in the period 2018-1Q2023, the Company has secured nearly PLN 175 million in funding for projects scheduled for 2018-2026.

Science and technology projects

The objective of the Company's science and technology projects is to continuously develop competencies based on proprietary solutions and maximise areas of IP and *know-how* utilisation. The realisation of this objective includes the testing of platforms developed by the Company, the exploration of the possibilities of their commercial applications beyond those arising from the Company's own drug and therapy development projects, and the exchange of knowledge and experience between recognised foreign scientific and research units and teams in Europe and worldwide. Collaborations carried out on research projects build international relationships and provide references for the research concepts, knowledge of Pure Biologics' scientists. Ensuring the replicability of the business model remains a priority for the Company. In parallel with the development and pursuit of commercialisation of the Company's main projects, activities are directed towards initiating further innovative programmes. The development of further projects will be dependent on securing non-dilutive funding, primarily in the form of grants.

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 offered, 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.

Human resources

The company has modern and well-equipped laboratory and office facilities with 53 employees, 52.8 per cent with doctoral degrees.

The company employs staff on the basis of employment contracts and also outsources 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: 92.4%, permanent contract level index: 98.11%.

In line with the announced plans 2023-1H2024, the team composition has been optimised, including staff reductions, as reflected in the overall turnover rate for 3Q2023 (49.64%).

There was no significant and disruptive employee absenteeism, with overall absenteeism of 1.99% in the period to the third quarter 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 an important 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*' (FIT).
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 the portfolio on a '*me-better*' concept, based on the development of original drugs and therapies based on molecular targets previously clinically validated, thereby significantly reducing the risks associated with clinical trial 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, which will 1) significantly increase project valuation in the context of subsequent commercialisation, and 2) more accurately assess the likelihood of success of costly Phase 2 and 3 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 positive results previously obtained by competitors in drug development programmes with a similar mechanism of action.

Unique expertise in the areas of antibody and aptamer selection and protein production and analysis.

Of the top ten best-selling drugs in the world, eight are protein drugs, including antibodies. To the knowledge of the Management Board based on publicly available information, the Issuer is the only commercial entity with proprietary antibody and aptamer selection technologies in Poland and one of the few entities working on these issues worldwide. Due to the degree of advancement of its own research and development projects, the Issuer has a real opportunity to strengthen its market position. The Issuer's customers include national and international biotechnology and pharmaceutical companies as well as research institutions and universities.

Research projects for immuno-oncology, a breakthrough in the fight against cancer.

The Company's own research projects focus on developing therapies and drugs to support the human immune system. This direction in the treatment of oncology patients has become the most important in the fight against cancer in recent years. Immuno-oncology therapies brought to market are rarely limited to the treatment of a single type of cancer, proving to be effective in at least several types of disease, which significantly increases their scope of application and the number of potential patients. The use of so-called 'combination therapies', which use a combination of two different therapies (either both from the field of immuno-oncology or combining immuno-oncology drugs with classical anti-cancer therapies, e.g. chemo- or radiotherapy), is also an important issue, further broadening the spectrum of indications for drugs of this type. Given the development of immuno-oncology in recent years, which has been systematically confirmed by partnering and licensing deals that dominate the pharmaceutical market in terms of value, the future positive results of the Company's research projects can be qualified among assets with significant profit potential.

Total control over the key discovery phase of drug development.

The Company's expertise allows it to carry out drug and therapeutic medical device development projects from the molecular target selection phase up to and including the in vitro testing phase, based entirely on its own scientific and technological resources. This ensures full independence in the sourcing (licensing) of drug candidates from other R&D entities or universities and from services provided by external companies up to the pre-clinical testing stage. This translates into control and confidentiality of the ongoing research at all stages, especially at its 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 numerous bio-molecules each time that bind a molecular target - antibodies and aptamers, respectively. From the broad pool of molecules generated, those variants with parameters best suited to the task at hand are selected and can be further optimised. Importantly, these platforms can work in parallel on multiple molecular targets.

II. DESCRIPTION OF THE ISSUER'S SIGNIFICANT ACHIEVEMENTS OR FAILURES DURING THE REPORTING PERIOD, TOGETHER WITH A DESCRIPTION OF THE MOST IMPORTANT FACTORS AND EVENTS, IN PARTICULAR OF AN UNTYPICAL NATURE, AFFECTING THE RESULTS ACHIEVED

1. Implementation of own R&D projects

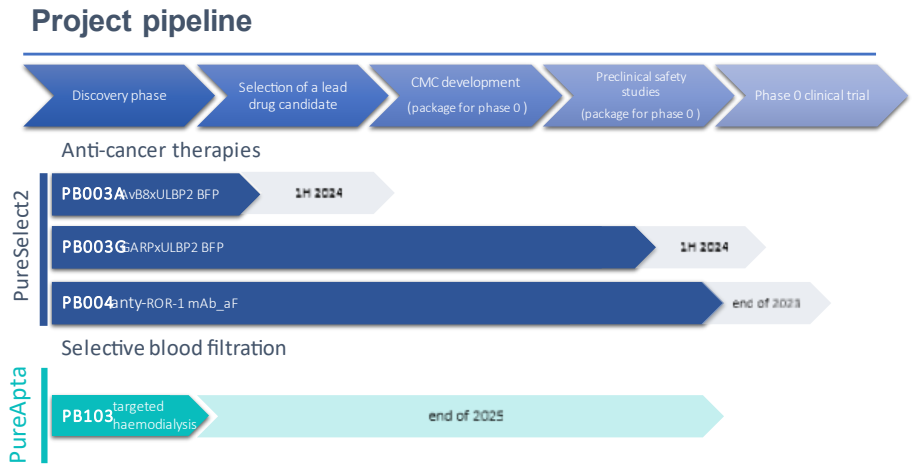


Figure 2: Status of the projects

Glossary

- ***ADCC*** (*antibody-dependent cell cytotoxicity*) - a biological mechanism in which a target cell (carrying the relevant antigen) is killed by an effector NK cell, under the influence of activation by an antibody recognising the antigen on the target cell.
- ***apheresis*** - a medical procedure in which the patient's blood is pumped through a device in which selected blood components (e.g. plasma fractions) are separated and the 'purified' blood thus returned to the patient's bloodstream. The type of filter inside the device determines which substances are removed.
- ***tumour-associated antigen*** (TAA) - a protein that is found on the surface of cancer cells. These antigens are unique to cancer cells or are present on them in much higher amounts than on healthy cells, making them important targets for anti-cancer therapies.
- ***aptamers*** - short, single-stranded oligonucleotides, chemically identical to DNA or RNA, having a high affinity for the selected molecular target due to their specific spatial structure. Due to their specificity and selectivity, they can be used as therapeutic or diagnostic molecules.
- ***autoantibodies*** - antibodies directed against the body's own cells and tissues. The presence of autoantibodies is characteristic of autoimmune diseases, in which such antibodies destroy healthy tissues, leading to severe symptoms and disease complications.

- ***antibody library*** - a pool of millions of random or semi-random protein sequences obtained by genetic and molecular engineering, from which new antibodies can be obtained by selection by phage presentation.
- ***molecular target*** - a macromolecule located on immune cells and/or tumour cells (antigen) that interacts with a drug to produce the desired therapeutic effect.
- ***chimeric antigen receptor*** (CAR) - a protein resulting from genetic engineering, called ch*imeric because of its* dual function of antigen binding and T-lymphocyte activation. CAR receptors are used to transform patient-derived T lymphocytes in a cellular immunotherapy called CAR-T. CAR-T therapy is used in the treatment of certain cancers, especially B-cell lymphomas and certain types of leukaemia.
- ***CMC*** - *chemistry, manufacturing, and controls* - a term used in the pharmaceutical industry and drug-related regulation that refers to processes and data related to three key areas: (1) *chemistry*: relates to the chemical characteristics of the drug, its composition, identification, chemical structure, and how the drug is manufactured and the processes used to produce the drug; (2) *manufacturing*: covers information related to the production of the drug, including the manufacturing process, manufacturing techniques and standards, quality control, and ensuring that the drug is produced according to specified quality standards; (3) *controls*: describes the quality control methods and procedures used during the manufacture of the medicine and how the quality of the product is monitored. These data must confirm that the medicine is safe, effective and complies with the quality standards. In the case of a new drug notification or an application for marketing authorisation of a drug, CMC information is necessary for regulatory authorities to assess the quality, compliance and safety of the drug.
- ***eIND*** (*exploratory investigational new drug*) - a term derived from US Food and Drug Administration (FDA) regulations, used to refer to a drug candidate that is in the early stages of development. In turn, an eIND *application* (eIND *application*), submitted to the FDA, allows sponsors to obtain approval for initial clinical trials (Phase 0), prior to submitting the actual IND application for Phase 1 approval.
- ***epitope*** - a fragment of a protein (antigen) characterised by its ability to interact directly and specifically with an antibody; binding of different epitopes by antibodies can result in different biological effects.
- ***immunoligand*** - a macromolecule of natural origin that activates selected cells of the immune system by binding to them in a specific manner.
- ***Immunosuppression*** - the weakening or suppression of the body's immune system. Some cancers create an immunosuppressive microenvironment, meaning that they can weaken or evade the body's immune system response, which in turn can contribute to their uncontrolled growth and spread. There are several mechanisms of immunosuppression that are exploited by tumour cells, including the secretion of immunosuppressive factors, the presence of suppressor cells in the tumour microenvironment, and the induction of changes in antigen expression.
- ***in silico*** - studies, analyses, simulations performed with the help of models or computer programmes.
- ***In vitro*** - (literally 'in glass') a term for experiments, tests or research conducted outside a living organism, under artificial laboratory conditions. *In vitro* research is performed on isolated cells, tissues or organs rather than on living organisms. In vitro testing is an important tool in biomedical research, pharmacology, molecular biology, microbiology and many other scientific fields, allowing the initial evaluation of potential drugs and the

understanding of biological mechanisms in a more controlled, safe and ethical manner prior to animal or human studies (*in vivo*).

- ***in vivo*** - experiments, tests or studies conducted on living organisms such as laboratory animals or humans. *In vivo* studies produce results that better reflect reality than *in vitro* (outside the organism) or *in silico* (computer simulations) studies, because the organism as a whole responds to stimuli (including drugs) in a more complex way.
- ***effector cells*** - cells of the immune system that, when activated, destroy pathogens or tumour cells (e.g. cytotoxic lymphocytes, NK cells).
- ***NK cells*** - '*natural killer*' cells - a group of immune system cells responsible for the body's innate immunity, including fighting cancer cells.
- ***cytostatic drugs*** - also known as chemotherapeutics, are a group of drugs used in the treatment of cancer. They aim to inhibit the division of cancer cells. Cytostatics can be used as monotherapy or in combination with other therapeutic approaches, such as surgery, radiotherapy or immunotherapy.
- ***regulatory T lymphocytes (Treg)*** - a population of T lymphocytes that play a key role in suppressing the body's immune response. Their main task is to maintain balance and prevent the immune system from overreacting to the body's own cells and tissues, as well as to foreign substances. Too few or dysfunctional regulatory T cells can lead to the development of autoimmune diseases or allergies. Conversely, too much Treg activity can impair the immune response against infections or tumours, a mechanism of active immunosuppression in cancer that negatively affects the efficacy of immunotherapy.
- ***aptamer selection,*** SELEX - a multi-step, cyclic process of discovering new aptamers from a pool of short random DNA or RNA fragments (aptamer libraries) to identify molecules that bind the selected molecular target.
- ***proliferation -*** the process of cell division whereby one cell divides into two or more new progenitor cells. In the case of cancer, tumour cells can exhibit uncontrolled proliferation, bypassing normal growth control mechanisms. Uncontrolled cell division is one of the hallmarks of cancer, making it capable of forming tumours and spreading to other parts of the body.
- ***phage presentation*** - an *in vitro* method for the discovery of antibodies specific to a selected antigen.
- ***afucosylated antibody*** - an antibody that has been modified to increase its potential to activate the immune system and, in particular, to induce antibody-dependent cytotoxicity (ADCC). The modification involves the removal of a fucose (sugar residue) from the antibody. The removal of fucose from antibodies can have a variety of effects, and one of the main goals of such modification is to increase the NK cell-dependent cytotoxic activity of the antibody.
- ***bispecific antibody*** - a new generation of antibody, a result of protein engineering, which has the ability to simultaneously bind two different antigens. One of the applications of bispecific antibodies is in anti-cancer therapy, as the simultaneous binding of antigens on the surface of tumour cells and effector cells allows the immune system to increase its activity against the tumour.
- ***specificity*** - the ability to selectively recognise and bind to a specific macromolecule ('key and lock' matching).

List of abbreviations

- **ABD** - *adjunctive blood detoxificataion*
- **ADCC -** *antibody-dependent cell cytotoxicity*
- **B-CLL** - *B-cell chronic lymphocytic leukaemia*
- **C5** - *complement protein 5*
- **CAR-T** - *chimeric antigen receptor*
- **CLL** - *chronic lymphocyte leukaemia*
- **CMC -** *chemistry, manufacturing, and controls*
- **CTL** - *cytotoxic T lymphocyte*
- **eIND** - *exploratory investigational new drug*
- **MABEL** - *minimal anticipated biological effect level*
- **MCL** - *mantle cell lymphoma*
- **MG** - *myasthenia gravis*
- **NGS** - *next generation sequencing*
- **NMO** - *Devic's syndrome; Neuromyelitis optica*
- **CKD** - *chronic kidney disease*
- **pcPoC** - *preclinical proof of concept*
- **scFv** - *single-chain variable fragment*
- **TAA** - *tumour-associated antigen*
- **TNBC** - triple negative breast cancer

Antibody-based immuno-oncology drug development projects

project name	therapeutic area	indication	active molecule
PB001	immuno-oncology	solid tumours, e.g. cancer of the colon and rectum (CRC)	bispecific antibody TIM3xTTA
PB003A	immuno-oncology	solid tumours, e.g. non-small cell lung cancer (NSCLC)	bifunctional fusion protein (antibody-immunoligand) anti-αVβ8
PB003G	immuno-oncology	solid tumours, e.g. non-small cell lung cancer (NSCLC)	bifunctional anti-GARP fusion protein (antibody-immunoligand) afucosylated anti-GARP antibody
PB004	immuno-oncology	haematological malignancies, solid tumours	afucosylated anti-ROR1 antibody

Figure 3: Antibody-based projects.

Drug development project PB001

Aim of the project

The PB001 project aimed to develop a first-in-class bispecific therapeutic antibody that simultaneously binds the TIM3 protein on immune cells and a tumour-associated antigen (TAA) on the surface of tumour cells - TIM3xTAA. Depletion of cytotoxic immune cells is a major obstacle to immune surveillance of tumours. TIM3 on the surface of cytotoxic T lymphocytes (CTL) and natural killer (NK) cells, plays a key role in the depletion phenomenon. By targeting TIM3, PB001 is designed to release the brakes that block CTL and NK cell activity in cancer patients. At the same time, PB001 was said to directly attack cancer cells, exposing them to the immune system and creating anchor points for cytotoxic cells to eliminate cancer cells more effectively.

Financing

The project was co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the grant agreement, the total cost of the project is PLN 32,037 thousand and the value of the grant is PLN 23,998 thousand. The cost eligibility period lasts until 31 December 2023. In August, the Company submitted the final information on the project to NCBR, which was accepted without objections with a date of 2 October 2023. Pure Biologics received a grant in the amount proportional to the completed work.

Project implementation and results during the reporting period

To assess the potential of the bispecific TIM3xTAA format under development to inhibit tumour growth, an in vivo study was performed in a humanised mouse model (Gempharmatech, China). Analysis of the results of the performed experiment showed no advantage of the bispecific TIM3xTAA antibody over anti-TIM3 monoclonal antibodies in clinical development. In addition, the discovery of a proprietary anti-TAA antibody to form a critical component of the TIM3xTAA bispecific antibody proved to be a challenge.

An analysis of the rationale for continuing the project, carried out in the third quarter, showed a lack of therapeutic potential for the TIM3xTAA format and thus an inability to meet the primary objectives of the PB001 project within the eligibility period of the funds granted by NCBR. Consequently, the Company decided to discontinue development of the bispecific antibody TIM3xTAA and subsequently submitted a final report to NCBR. The closure of the project took place after the NCBR approved the report. The Company is currently working to determine how to commercialise the know-how and assets developed during the development of the PB001 project, including the unique anti-TIM3 monoclonal antibody, PB001.TM14, to which the Company holds full rights. Additionally, the PB001.TM14 antibody has the potential for further therapeutic development as a monoclonal antibody for combination therapy with PD1 receptor blockers. However, given the initial design of the PB001 project and the magnitude of the proposed changes from the original project scope and schedule, it would not be possible to complete the project due to budgetary constraints.

The Company does not expect any further development of the PB001 project assets in the coming quarter, but will conduct a validity assessment of the patent application for the PB001.TM14 antibody.

Drug development project PB003A

Aim of the project

The aim of the PB003A project is to develop an anti-cancer drug specifically targeting integrin αVβ8, with significantly better properties than anti-αVβ8 antibodies currently in preclinical and early clinical trials (e.g. molecule PF-06940434, Pfizer). Integrin αVβ8 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 αVβ8 activity to reduce immunosuppression in the tumour environment, the aim of the PB003A project is to develop a much more aggressive drug candidate that will kill αVβ8-mediated Treg cells. Since αVβ8 is also expressed in cells of various tumour types (including lung, colorectal, head and neck and breast), PB003A will also directly induce the killing of tumour cells by cytotoxic lymphocytes, resulting in a much more effective anti-cancer therapy. To achieve this, drug candidate PB003A is being developed in the form of a so-called bifunctional fusion protein (BFP) therapeutic molecule, in which a conventional antibody will be fused to 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 show a qualitative advantage over conventional antibodies, but will also lead to the recruitment of significantly more cytotoxic cells. In addition, the company is working on alternative formats, including afucosylated, fully human anti-αVβ8 antibodies, which are significantly more effective in inducing immune cell-mediated killing of target cells than conventional antibodies. The aim of the PB003A project is to develop a lead candidate and to characterise it in in vitro and in vivo studies suitable for the release of the candidate into Phase 0 clinical trials. 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 phases of clinical trials 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 PB003A was originally part of project PB003, co-funded by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. Project PB003 involved the selection of antibodies against different molecular targets associated with the activity of the immunosuppressive protein TGFβ in the tumour microenvironment, to ultimately select the most promising drug candidate. The R&D work led to the division of the PB003 project into two separate projects, focused on different molecular targets (αVβ8/PB003A and GARP/PB003G). The first project to identify a lead drug candidate was PB003G, which thus received priority access to resources and NCBR funds, fulfilling the terms of the grant agreement.

Nevertheless, αVβ8 remains a promising molecular target for anti-cancer therapies, so Pure Biologics intends to continue the search for anti-αVβ8 antibodies. In November, Pure Biologics plans to apply for non-dilutive funding to support the implementation of project PB003A, as well as solicit private funding from strategic partners.

Project implementation and results during the reporting period

In the reported third quarter of 2023, the project's main activities focused on continuing the search for potential drug candidates - antibodies that can induce the killing of αVβ8-expressing tumour cells and immunosuppressive regulatory T cells.

In earlier selections by phage presentation, αVβ8 antigen-binding antibody sequences were obtained and produced in IgG1 antibody format as a first step in creating unique drug candidates. These candidates were tested for their potential to induce immune cell-mediated tumour cell killing, reflecting the intended mode of therapeutic action. Anti-αVβ8 antibodies were tested in a cancer cell killing screening assay using blood cells from healthy donors. 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 fusion protein (BFP) target format, as well as in the afucosylated antibody (af-IgG) format. These two therapeutic antibody formats were selected to significantly enhance the ability of αVβ8-targeted antibodies to 1) activate immune cells and 2) induce immune cell-mediated tumour cell death in cancer patients. During the third quarter, selected antibodies in af-IgG format were produced, and candidates in BFP format are currently being produced for further characterisation in in vitro and in vivo bioassays to confirm their biological activity and therapeutic potential. In addition, candidates will be subjected to a series of tests towards the assessment of manufacturing and quality characteristics (CMC), including those related to production yield, potential aggregation and stability in buffer and serum. In parallel, further selections were carried out by phage presentation to obtain αVβ8 antigen-binding antibody sequences using new antibody libraries and selection strategies to increase the likelihood of discovering optimal candidates possessing the profile of the target product. In the coming months, it is planned to analyse the obtained sequences using next-generation sequencing, followed by their production in IgG1 format and the study of binding to the molecular target.

While the PB003A project will continue the development of proprietary therapeutic molecules targeting αVβ8, due to strategic decisions taken by the Company, the Phase 0 study in solid tumour patients for the PB003A molecules has been postponed. In addition, Pure Biologics plans to apply in November for further funding for the PB003A project under the SMART2 (European Funds for the Modern Economy) pathway organised by PARP.

Drug development project PB003G

Aim of the project

The aim of project PB003G is to develop an anticancer drug that specifically binds the GARP-TGFβ1 protein complex, with significantly greater therapeutic efficacy than anti-GARP antibodies currently in early clinical development (e.g. molecules ABBV-151, Abbvie, HLX60, Henlius 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-TGFβ1 complex is highly expressed on Treg cells, but also on cells of various tumour types (including lung, colorectal, breast, head and neck) and plays a key role in immunosuppression.

While ABBV-151 aims to restore immune function by blocking the release of immunosuppressive TGFβ1 from the complex with GARP, DS-1055 recruits and activates NK cells to directly kill Treg and cancer cells. Project PB003G aims to develop a therapeutic molecule that will kill GARP-TGFβ1-expressing Treg and tumour cells much more effectively than competing molecules. To achieve

this, drug candidate PBA-0091 is being developed in the form of a so-called bifunctional fusion protein (BFP) therapeutic molecule, in which a traditional antibody will be fused to ULBP2, a natural immunoligand of the NKG2D receptor present on most cytotoxic NK and T cells in the tumour environment. This unique therapeutic format developed by Pure Biologics will not only show a qualitative advantage over conventional antibodies, it will also lead to the recruitment of significantly more cytotoxic cells capable of killing cancer cells. In addition, the Company has developed an afucosylated, fully human anti-GARP antibody, PBA-0111, which combines the blocking properties of ABBV-151 with the cell-killing potential of DS-1055.

The aim of the PB003G project is to identify the best candidate for a Phase 0 clinical trial with cancer patients. The implementation of a Phase 0 study as the first stage 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, expensive clinical trial phases, and 2) significantly increase the value of the project at an early stage of clinical development.

Financing

Project PB003G is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the grant agreement, the total budget of the project is PLN 39,905 thousand and the value of the grant is PLN 30,969 thousand. The period of cost eligibility lasts until 31 December 2023. The Company's own contribution in the amount of PLN 8,969 thousand is covered by equity.

In March 2023, Pure Biologics signed an agreement with the Medical Research Agency for the funding of the PB003G project entitled 'Phase 1 clinical trial to investigate the safety, tolerability and efficacy of a bispecific compound in patients with advanced solid tumours' for the PB003G molecule. The amount of funding is PLN 32,439 thousand, with a total project budget of PLN 48,897 thousand.

Project implementation and results during the reporting period

In the third quarter of 2023, the PB003G project focused on the preclinical development and production of drug candidate PBA-0091 and selected reserve candidates, for a phase 0 clinical trial in patients with solid tumours.

Previously, the Company announced the selection of PBA-0091 as the lead candidate targeting the GARP protein for cancer immunotherapy. This selection was based on a series of in vitro results using human cells, which showed that the PBA-0091 molecule was stable in serum and highly specific towards GARP and GARP-TGFβ1 in purified protein binding assays (biophysical assays) or cell surface proteins. The PBA-0091 molecule in in vitro assays also showed great potential to induce the killing of GARP and GARP-TGFβ1-expressing tumour cells and natural killer (NK) cell-mediated regulatory T (Treg) cells, reflecting the main intended mechanism of PBA-0091's anti-tumour effect in patients. In the third quarter of 2023, a series of in vivo animal studies were conducted to prove the therapeutic concept for PBA-0091 (proof-of-concept) by testing its tumour growth inhibition potential.

The first study was conducted in humanised mice with subcutaneously implanted tumours from human Raji cells expressing the GARP-TGFβ1 complex (Jackson Laboratory, USA). The molecule PBA-0091 did not induce significant inhibition of tumour growth. In contrast to PBA-0091, the

reserve candidate PBA-0111, which is an afucosylated human anti-GARP-TGFβ1 antibody developed by Pure Biologics, inhibited tumour growth by 39% in the highly challenging animal model used. This effect was highly statistically significant and significantly better than the tumour growth inhibition observed in mice treated with the DS-1055-like antibody (Daichii-Sankyo). DS-1055 is an anti-GARP antibody currently in phase 1 clinical trials and is considered a major competitor to the PB003G project. In a second proof-of-concept study using a humanised mouse model with subcutaneously implanted tumours from human HT-29 cell lines (Gempharmatech, China), molecule PBA-0091 again failed to demonstrate anti-tumour efficacy, while molecule PBA-0111 inhibited tumour growth 53% more effectively than the isotypic control (an afucosylated non-GARP-binding antibody).

A possible explanation for the discrepancy between the very good results obtained in in vitro studies in human cells and those obtained in in vivo studies in humanised mice is the results of a pharmacokinetics study performed to determine the half-life of PBA-0091 in Balb/C mice (TrulyLabs, Sweden). PBA-0091 showed a short half-life in the blood of mice, which most likely contributed to the lack of sufficient antitumour activity. Based on the results obtained with PBA-0091 in mouse studies, Pure Biologics will conduct further studies of PBA-0091 before deciding to invest in CMC development and studies to enable clinical development.

As expected, PBA-0111 showed a favourable pharmacokinetic profile, similar to other afucosylated IgG1 antibodies. Based on the positive results obtained for PBA-0111, Pure Biologics is exploring the possibility of testing PBA-0111 in a Phase 0 study, as well as further clinical development towards marketing authorisation. In one of the research centres conducting preclinical studies for the PBA-0111 molecule, a toxic effect was observed in the lungs of humanised mice with an implanted tumour. This effect only occurred after the first dose and was not observed after subsequent doses. In contrast, PBA-0111 toxicity was not observed in two other studies, which may suggest that it is not associated with human immune cells. The impact of the observed toxicity on the further development of the PBA-0111 molecule is currently being analysed in a series of preclinical studies, which will be completed in the first half of 2024. The Company is investigating the feasibility of including PBA-0111 in a Phase 0 clinical trial, which is further justified by the fact that Wuxi has produced a batch of PBA-0111 for safety testing and for a clinical trial involving at least 12 patients with head and neck cancer, soft tissue sarcoma and triple-negative breast cancer. In the Phase 0 study, the PBA-0111 molecule will be administered intratumourally, and a panel of biomarkers will be analysed to assess early signs of PBA-0111's anti-tumour activity in patients. Pure Biologics intends to initiate the open-label, multi-centre study in the first half of 2024 in the US. The study is fully in line with Pure Biologics' strategy to confirm the mechanism of therapeutic action in patients prior to investing in Phase 1-3 clinical development.

The objective of the PB003G project in the next quarter is to initiate safety studies to enable the application for clinical trial approval of the PBA-0111 molecule. A series of manufacturing and quality control (CMC) studies will also be conducted on the toxicology study batch and the clinical study batch. In addition, compatibility testing of the test molecule with the CIVO device for intramuscular injection in the Phase 0 study is planned for early 2024.

Drug development project PB004

Aim of the project

The aim of the PB004 project is to develop an anti-cancer drug based on an anti-ROR1 antibody with significantly improved therapeutic properties over Zilovertamab, an anti-ROR1 antibody that

has reached Phase III clinical development. ROR1 is a surface molecule that is expressed in a wide range of cancers, involved in the survival, proliferation and migration of cancer cells, while absent in most healthy tissues, making ROR1 an excellent therapeutic target. The PB004 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. Thus, 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 for licensing. The PB004 project occupies an important position in the Company's portfolio of highly innovative projects in the immuno-oncology therapeutics 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 was PLN 40,417 thousand and the granted co-financing amount is PLN 29,869 thousand. On 21 August 2022, the NCRD accepted the Company's proposed amendments to the project application, which included, among others, a change in format and a change from Phase 1 clinical trials to Phase 0 as the endpoint of the NCRD-funded project. The changes in scope are associated with a change 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 period of cost eligibility for the project ends on 31 December 2023. The project's own contribution of PLN 9 898 thousand is covered by the Issuer from equity.

In 2023, the Company signed an agreement with the Medical Research Agency for funding to continue the project in phase 1 clinical trials. The amount of funding is PLN 32,439 thousand, with a total project budget of PLN 48,897 thousand).

Project implementation and results during the reporting period

In Q3 2023, the activities of project PB004 focused on the CMC area and preclinical development of drug candidate PBA-0405, to support its clinical development 1) in phase 0 in patients with solid tumours, and 2) in phase 1 in patients with chronic B-cell malignancies.

The potential of PBA-0405 in the treatment of B-lymphocyte malignancies was demonstrated in a pilot study in mice by IVRS (Sweden). In mice with implanted tumour cells given PBA-0405, a 90% reduction in the number of ROR1-presenting tumour cells in the spleen and bone marrow was observed. This study is currently being continued to confirm the results obtained. Final results from the study are expected in November and will provide the rationale for the continued development pathway of PBA-0405 towards phase 1 clinical trials.

Pure Biologics has received the final report of a proof-of-concept study supporting the use of PBA-0405 in the treatment of solid tumours (Gempharmatech, China). In a group of humanised mice with subcutaneously implanted human JeKo-1 cells receiving PBA-0405, a statistically significant tumour growth inhibition of 46.58% was observed. Biomarker analysis showed increased levels of intracellular IFNɣ in NK cells in the tumour environment in the PBA-0405-treated group, but not in the control group, confirming that NK cell-dependent ADCC is the predominant therapeutic

mechanism of action of PBA-0405. Importantly, no elevated levels of intracellular IFNɣ in NK cells were observed in blood or spleen, indicating that the therapeutic mode of action of PBA-0405 is restricted to ROR1-expressing target cells, translating into a favourable safety profile for cancer treatment. Based on the conducted in vitro studies in human cells and the previously mentioned in vivo studies in humanised mice, IFNɣ will be included in a panel of pharmacodynamic biomarkers in clinical development. This will allow PBA-0405-induced immune cell activation to be monitored, starting in phase 0, which will begin at the end of this year.

A preclinical safety evaluation of PBA-0405, required for FDA regulatory approval of a Phase 0 clinical trial, was conducted in humanised tumour-injected mice (Gempharmatech, China). The study involved a single administration of three doses of PBA-0405, including a 100-fold higher dose than that planned for intratumoural microinjection in the phase 0 study. The study showed no significant signs of PBA-0405 toxicity, including clinical signs, changes in haematology, clinical biochemistry, cytokine levels, or changes in histopathology, compared to the control group. Furthermore, in order to justify the dose chosen for phase 0, the same mouse model was used to conduct a dose-response study, showing that in this model, maximum tumour growth inhibition for PBA-0405 was achieved at 10 mg/kg. Thus, the study confirms the safety of PBA-0405 and justifies its further clinical development in phase 0.

In the previous reporting period, drug candidate (drug substance) PBA-0405 was manufactured by Wuxi Biologics (China) for the Phase 0 clinical trial. During the third quarter, a batch of PBA-0405 was converted into a clinical trial drug product (drug product), which was then successfully tested for stability and activity, as well as compatibility with the CIVO device, which will be used for topical delivery of anti-cancer drugs in the Phase 0 trial. drug product), which was then successfully tested for stability, quality and activity, as well as compatibility with the CIVO device, which will be used for topical anticancer drug delivery in the phase 0 study. In addition, Pure Biologics and Presage Biosciences (USA) continued to complete the documentation needed to initiate the phase 0 clinical trial in patients with solid tumours, which will verify the mechanism of action of PBA-0405 in the complex human tumour microenvironment. The planned study will include at least 12 patients with head and neck cancer, soft tissue sarcoma and triple-negative breast cancer, and a panel of biomarkers will be used to investigate different signs of PBA-0405 activity in cancer patients. The open-label, multi-centre study will be conducted in the US, with clinical sites ready by the end of 2023. The study is fully in line with Pure Biologics' strategy to confirm the therapeutic mechanism of action of the molecule in humans before investing in Phase 1-3 clinical trials leading to marketing authorisation.

The goal for the PB004 project in the next quarter is to finalise the eIND dossier and submit an application to the FDA for Phase 0 clinical trial approval in early November. In addition, the project will continue to prepare for the development of the full CMC scope and PBA-0405 preclinical studies required for the Phase 0 clinical trial.

Aptamer-based therapeutic projects

project	therapeutic area	indication	product
PB002	neurology / rare diseases	Devic's syndrome (NMO)	aptamer selective adsorber
PB005	neurology/ rare diseases	myasthenia gravis	aptamer selective adsorber
PB103	nephrology	chronic kidney disease	aptamer selective adsorber

Figure 4: Aptamer-based projects.

Therapeutic project PB002

Aim of the project

The aim of the PB002 project was to develop a highly innovative targeted apheresis-based therapy for patients suffering from Neuromyelitis Optica (NMO) Syndrome. NMO is a potentially fatal neurological disease caused by autoantibodies that attack the spinal cord and optic nerve, leading to paralysis and blindness. It is characterised by varying severity of symptoms; periods of remission alternate with exacerbations, which often lead to hospitalisation and a significant increase in treatment costs. Therapeutic options for NMO patients during periods of exacerbation are non-selective and are associated with serious side effects. Consequently, there is still an unmet medical need for more effective NMO therapy with a simultaneously favourable safety profile and cost-effectiveness.

Financing

The project was co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. In May, the final information on the PB002 project was submitted to NCBR. On August 2, 2023 the National Centre for Research and Development, having analysed the information submitted by the Company, concluded 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 to be 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.

Project implementation and results during the reporting period

Due to the end of the project, no work was carried out under PB002 in the third quarter. However, the technology developed for the immobilisation of aptamers and their use for the selective removal of molecules from patients' blood was successfully used in the PB103 project.

Therapeutic project PB005 (AptaMG)

Aim of the project

Project PB005 aimed 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 abnormalities of neurotransmission at neuromuscular synapses. In the course of the disease, patients experience exacerbations that severely weaken the muscles of the limbs, thus affecting their daily life, as well as life-threatening myasthenic breakthroughs that cause respiratory failure. An exacerbation is considered a harbinger of a breakthrough and requires hospital treatment. One of the main factors responsible for the symptoms of the disease is the complement system; inhibition of complement protein 5 (C5) has been clinically proven to benefit patients in exacerbation. Pure Biologics intended in PB005 to develop a medical device to remove the C5 protein from a patient's blood, improving the apheresis procedure currently used in patients with severe MG symptoms.

Financing

The project was 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 granted co-financing is PLN 10,775 thousand. The planned period for the completion of eligible costs is 31 December 2023. In June, the final information on the implementation of the PB005 project was submitted to NCBR. The Company is currently awaiting a response from the intermediary institution.

Project implementation and results during the reporting period

Due to the planned termination of the project, no work was carried out under PB005 in Q3 2023. However, the developed technology for the immobilisation of aptamers and their use for the selective removal of molecules from patients' blood was successfully used in the PB103 project.

Therapeutic project PB103

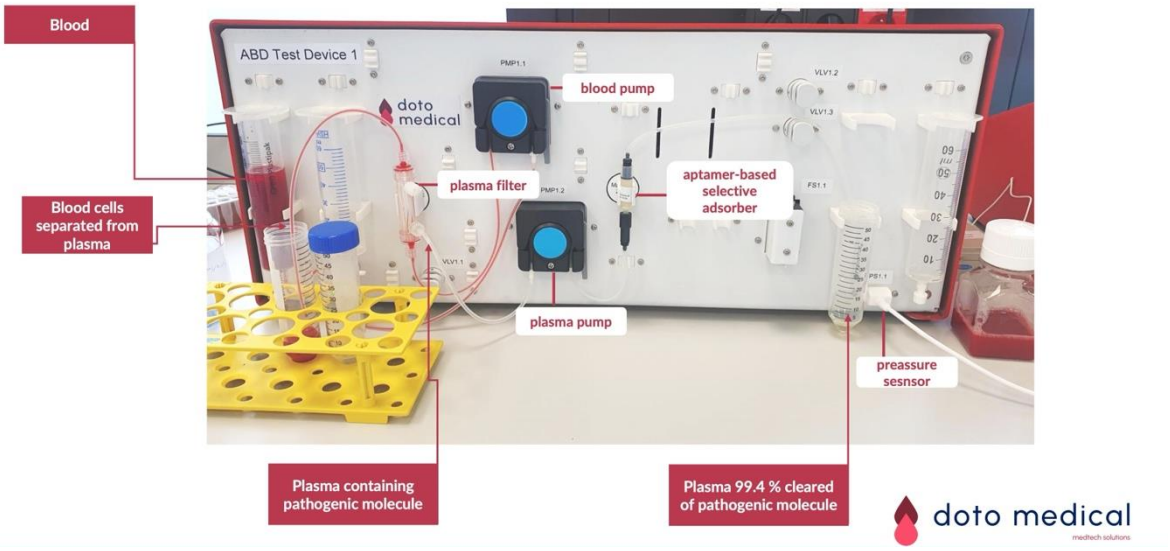


Figure 5: Functional prototype of an ABD device with aptamer filter.

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 kidney function, while the use of the adsorber being developed in project PB103b will reduce the risk of cardiovascular disease and mortality in patients with CKD.

With the progressive deterioration of kidney function, the body's water balance is disrupted in patients. Problems with urine production result in a sharp decline in the quality of life of patients who, while feeling constantly thirsty, can only consume a small amount of fluid, as excess fluid in the body can only be regulated by sweating and excretion with the stool. Consequently, there is an unmet medical need to develop therapies to prolong kidney function in patients with CKD. Underlying the deterioration of renal function is chronic inflammation. 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 nine to 12 times higher risk of premature 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. Consequently, there is an unmet medical need to develop therapies that would nullify vascular deterioration in haemodialysis patients. Certain proteins are present in much higher amounts in the blood of CKD patients with cardiovascular complications 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 disease progression and patient deterioration. 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 patients with MS. 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 patients with CKD are on dialysis, typically 3-4 times a week for an average of 5-10 years. In the US, treatment typically costs between $3,3 thousand and $10,4 thousand per month, with treatment of comorbidities raising the average price of care to as much as $14,4 thousand per month. In order to maximise PB103's chance of success in a market far more attractive than the niche markets targeted by the products developed under PB002 and PB005, Pure Biologics decided to focus its efforts entirely on the development of extracorporeal treatments under the PB103 project.

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 PB002 and PB005. 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 patients with CKD, 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 worth more than $105 billion globally in 2021.

Financing

The PB103 project 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 bear their own costs for this phase of the project.

During the course of development, the project was expanded and split into two sub-projects, PB103a and PB103b, addressing different complications in patients with CKD. 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 the PB103 project. The company plans to submit an application to the SMART 2 competition organised by PARP in November 2023.

Project implementation and results during the reporting period

In Q3 2023, the PB103 project focused on two main areas: 1) making functional improvements to the prototype ABD device, and 2) discovering aptamers that can be used in the ABD device to remove selected pathogenic molecules from the bloodstream of patients with chronic kidney disease (CKD).

Further development of the ABD device prototype focused on its technical aspects. As a result of the optimisation work, the components responsible for introducing blood into the device circuit and collecting plasma samples for analytical testing were improved. These improvements included the implementation of variable flow rates and pressures, as well as the ability to select sample sizes, thus increasing the functionality of the ABD device for its intended use in preclinical and clinical studies. In addition, the previously demonstrated functionality of the prototype ABD device, which efficiently and specifically captured the molecular target from the blood without compromising blood cell viability during multiple flow cycles through the device, was confirmed.

During the third quarter, sub-project PB103a discovered aptamers with high selectivity and strong affinity towards two pro-inflammatory cytokines identified as critical pathogens contributing to renal deterioration in patients with CKD. Aptamers with similar affinity to the human and porcine versions of one of the pro-inflammatory cytokines have been obtained, enabling preclinical studies of CKD in pigs using aptamers closely mirroring the action of aptamers that will be used in clinical trials in patients with CKD. To enable preclinical studies on the second of the pro-inflammatory cytokines, for which aptamers specific against the human version of the protein have already been obtained, it is planned to select aptamers targeting the porcine version of the protein.

Subproject PB103b developed aptamers directed against one of two proteins that have been identified as responsible for the increased risk of cardiovascular episodes in patients with CKD. As a result of the work carried out under the PB103b project, cross-reactivity of the two aptamers with human and porcine proteins was confirmed in Q3 2023, allowing their use in preclinical and clinical studies, significantly reducing project time and costs.

Laboratory work is currently focused on optimising the resulting aptamers and developing an adsorber that will selectively capture cytokines associated with chronic kidney disease. To achieve this, a pre-optimised lead aptamer of appropriate length and nucleolytic stability is used.

In Q3 2023, Doto Medical also partnered with a contract research organisation (CRO) to conduct a proof-of-concept study confirming the beneficial effect of removing identified pro-inflammatory cytokines from the blood on delaying kidney deterioration in CKD patients.

In the next stages, further development of the ABD device is planned with the introduction of a chamber that will allow the re-mixing of the cellular components of blood and plasma to re-obtain whole blood. This improved configuration of the device will therefore include an important step prior to the safe return of purified blood to the patient during an assisted dialysis procedure.

As part of the planned laboratory work, the newly discovered aptamers will be subjected to initial functionality tests for molecular target capture using early prototype adsorbers. The leading aptamers will be successively shortened to a minimum length that guarantees their functionality. This is an important aspect to reduce the cost of manufacturing the final product in the future. The shortened aptamers will then be optimised to be resistant to the degrading action of nucleases naturally found in human blood. The high nucleolytic stability of the 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 the assisted dialysis procedure.

In collaboration with the CRO, a suitable animal model of kidney disease will also be developed in the near future to investigate the effect of prolonging residual kidney function in response to blocking or removing selected pathogenic proteins from the blood.

Consortium science and technology projects

Project PB013 (ALTERCAR)

Aim of the project

The aim of the project is to pilot the development of a new cell therapy using T lymphocytes with an inserted chimeric antigen receptor (CAR-T) against newly selected molecular targets overrepresented in selected leukaemias and lymphomas. The Polish-Norwegian consortium will conduct research from selection of new targets, through selection of antibody fragments (scFv) binding these targets and development of a CAR receptor equipped with the selected binding molecule, to animal studies demonstrating the efficacy of the new therapy, which will be applicable to 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 and the allocated amount of EU funding is PLN 6,573 thousand. The budget for the stages implemented by the Company is PLN 413 thousand. (total cost), and the granted amount of co-financing 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 1 January 2021, and the planned completion of the project is 31 December 2023.

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.

Project implementation and results during the reporting period

During the third quarter, work took place on the side of the partners, who carried out 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 financed by the Norwegian Financial Mechanism 2014-2021. The total value of the project for the consortium is PLN 6,571 thousand and the allocated amount of EU funding is PLN 6,508 thousand. The budget of the project stages implemented by the Company is PLN 158 thousand (total cost), and the granted amount of co-financing is PLN 95 thousand. The Company covers its own contribution to the project in the amount of PLN 63 thousand from equity. The project has been implemented as part of the consortium since 1 October 2020, and the planned completion of the project is 30 September 2023.

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.

Project implementation and results during the reporting period

During the third quarter, work took place on the partners' side, which continued to work on the mechanism of action of selected cytostatic drugs and the preparation of growth factor conjugates with these drugs. Pure Biologics' possible further participation in the project will depend on the results obtained by the Consortium partners.

2. Operational events

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 section 1 above. In addition to the events mentioned in the aforementioned section, the activities in the business development and corporate areas of the Company, which are described below, may be of significance for the 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 secure new grants for 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.01.01-IP.02-001/23), two of which were related to drug development, while the third is a technological project to optimise the discovery process of therapeutic antibodies at Pure Biologics. Doto Medical Ltd. submitted a proposal for the development of a therapeutic medical device in the same competition.

On 19 October, PARP announced a list of projects recommended for co-financing, which did not include any of the Company's aforementioned projects.

In November 2023, the Company plans to submit proposals for four projects in the competition of the Polish Agency for Enterprise Development (SMART II, FENG), three of which relate to drug development (PB003A, PB105 and PB106), while the fourth is a technology project to optimise the discovery process of therapeutic antibodies at Pure Biologics (PI012).

Doto Medical Ltd. plans to submit an application in the same competition for the development of a therapeutic medical device in project PB103a.

Events, conferences, partnering

In the period immediately following the reporting period, the Company took an active part in the following events:

- 5 October 2023 - Presentation for analysts, Poland
- 11-13 October, 2023 - BIO Japan 2023, Yokohama, Japan
- 21-22 October, 2023 - Książęca Street 13 Conference, Warsaw, Poland
- 23-25 October, 2023 - mBank Healthcare Days Conference, Warsaw, Poland
- 6-8 November, 2023 - BIO Europe, Munich, Germany

The BIO conferences (Yokohama, Munich) were particularly important events. BIO Japan is the world's largest partnering conference for the Japan, Korea and East Asia area. BIO Europe, on the other hand, is the largest event of its kind in Europe and one of the largest in the world. As part of these events, the Company held dozens of scheduled in-person meetings with biotechnology and pharmaceutical industry representatives and investors. The company presented its project portfolio to find strategic partners for the PB003G and PB004 drug development projects.

In addition, on 15 October 2023, representatives of the Company participated in the Longterm - Książęca Street 13 conference and the mBank Healthcare Days conference in Warsaw, during which they introduced investors to the Company's business profile, discussed more broadly the results of the in vivo studies and the clinical development path of projects PB003G and PB004 and the related prospects.

3. Corporate events

Implementation of the second incentive programme

In connection with the implementation at the Company of the incentive programme introduced pursuant to Resolution No. 14 of the Company's Annual General Meeting of 21 June 2021, on 31 May 2023 the Board of Directors verified the fulfilment of the loyalty criterion and the 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 management objectives was verified positively 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.

On 15 September 2023, the Board of Directors verified the fulfilment of the loyalty criterion and the management objectives in relation to the Company's key personnel for the accounting period 01.01.2023 - 30.06.2023. The fulfilment of the loyalty criterion and the management objectives was verified positively and the right to subscribe for subscription warrants in a total number of 34,500 was granted to the designated eligible persons with whom the relevant agreements had previously been concluded. The warrants were offered on 4 October 2023 and the offer was accepted in full on 5 October 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 28 September 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 acquire subscription warrants in the number of 16,000 for Mr Petrus Spee and 6,250 for Mr Romuald Harwas. The warrants were offered to the members of the Management Board on 4 October 2023 and the offer was accepted in full on 5 October 2023.

Adoption by the company's board of directors of a resolution to increase the company's share capital

On 13 September 2023 the Company's Management Board adopted a resolution on increasing the Company's share capital within the limits of the authorised capital by way of issuing new I-series bearer shares through a public offering, excluding pre-emptive rights of the existing shareholders, amending the Company's Articles of Association, dematerialising I-series shares and rights to I-series shares and applying for admission of these shares and rights to shares to trading on a regulated market ["Issue Resolution"]. Pursuant to the Issue Resolution, the Company's share capital will be increased by up to PLN 171,000 [one hundred and seventy one thousand zloty] shall be affected by way of the issue of up to 1,710,000 [one million seven hundred and ten thousand] ordinary I-series bearer shares with a nominal value of PLN 0.10 [ten groszy] each ["I-Series Shares"].

The Issue Resolution was adopted by the Company's Management Board upon the Supervisory Board's consent to deprive the Company's shareholders of pre-emptive rights to I-Series Shares. I-Series Shares will be offered by the Company for subscription under the open subscription procedure referred to in Article 431 § 2(3) of the Code of Commercial Companies, taking into account Article 440 § 3 of the Code of Commercial Companies, under a public offering within the meaning of Article 2(d) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market and repealing Directive 2003/71/EC. The public offering of the I-Series Shares will be made by the Company on the basis of a prospectus for which the Company intends to apply for approval by the Financial Supervision Authority without delay ["Prospectus"]. The Prospectus, once approved by the Polish Financial Supervision Authority, will be the sole legally binding offering document containing information about the Company and the I-Series Shares, as well as their admission and introduction to trading on the regulated market operated by the Warsaw Stock Exchange. The approval of the Prospectus by the Polish Financial Supervision Authority cannot be construed as an endorsement of the securities offered in the offer or admitted to trading on the regulated market.

4. Analysis of the actual and potential impact of the conflict in Ukraine on the Company's operations

The occurrence of the armed conflict in Ukraine had an indirect and limited impact on Pure Biologics Inc.'s financial position in Q3 2023. The Company does not cooperate with entities registered in Ukraine, Russia and Belarus, nor does it provide services to or procure from contractors from the above countries. The Company is also not directly affected by risks related to the availability of employees coming from Ukraine and sanctions imposed on private individuals of Russian and Belarusian citizens, as well as financial institutions from the aforementioned countries. However, macroeconomic mechanisms such as exchange rates, inflation or interest rate increases affected the macroeconomic situation in Poland, and this certainly affects the Company's results. This mainly concerns interest rate increases and inflation. These risks are described in more detail in what is presented in the "Financial Risk Management" section of the interim report for H1 2023.

The Company's Management Board is analysing the situation related to the armed conflict in Ukraine on an ongoing basis and does not rule out that possible new conditions and developments may significantly affect Pure Biologics S.A.'s business. Possible disruptions include: an increase in the cost of conducting R&D work as a result of inflationary and wage pressures, interrupted or disrupted supply chains in, which may result in restrictions on the availability of reagents, particularly those imported from Asia, disruptions in the process of work continuity, disruptions in the supply of electricity, including an increase in energy costs, cyber attacks on IT resources resulting in data leakage, risks arising from the availability of employees, particularly the exodus of foreign workers.

III. SELECTED FINANCIAL DATA

The selected financial data presented in the report has been translated into euro as follows:

1) Items relating to the statement of profit and loss and other comprehensive income, the cash flow statement were converted at an exchange rate representing the arithmetic average of the exchange rates announced by the National Bank of Poland on the last day of each month:

- For the period 01.01.2023 - 30.09.2023: PLN 4.5773
- For the period 01.01.2022 - 30.09.2022 PLN 4.7787

2) Items in 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, this rate was:

- as of 30.09.2023: PLN 4.6356
- as at 31.12.2022: PLN 4.6899

	For the period 01.01.2023 - 30.09.2023	For the period 01.01.2022 - 30.09.2022	For the period 01.01.2023 - 30.09.2023	For the period 01.01.2022 - 30.09.2022
	PLN thousand	PLN thousand	EUR thousand	EUR thousand
Operating income	16 598	9 702	3 626	2 030
Total operating expenses	36 967	27 088	8 076	5 668
Operating profit (loss)	(21 860)	(17 327)	(4 776)	(3 626)
Profit (loss) before tax	(24 556)	(18 443)	(5 365)	(3 859)
Net profit (loss)	(24 556)	(18 443)	(5 365)	(3 859)
Weighted average number of shares	3 168 286	2 254 000	3 168 286	2 254 000
Earnings (loss) per ordinary share (in PLN/EUR)	**(7,75)**	**(8,18)**	**(1,69)**	**(1,71)**
Net cash flow from operating activities	(19 779)	(12 290)	(4 321)	(2 572)
Net cash flow from investing activities	763	23 303	167	4 876
Net cash flow from financing activities	23 385	(1 517)	5 109	(317)
Total net cash flow	4 369	9 496	955	1 987

	As on 30.09.2023	As on 31.12.2022	As on 30.09.2023	As on 31.12.2022
	PLN thousand	PLN thousand	EUR thousand	EUR thousand
Total assets/liabilities	65 177	33 009	14 060	7 038
Non-current assets	34 901	8 838	7 529	1 884
Current assets	30 276	24 171	6 531	5 154
Equity	13 020	18 297	2 809	3 901
Liabilities and provisions for liabilities	52 158	14 712	11 252	3 137
Long-term liabilities	38 416	1 877	8 287	400
Short-term liabilities	13 742	12 834	2 964	2 737
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)	**4,05**	**8,12**	**0,87**	**1,73**

IV. ABBREVIATED INTERIM FINANCIAL STATEMENTS

The Abbreviated Interim Financial Statements for the three months ended 30 September 2023, prepared in accordance with International Financial Reporting Standards as endorsed by the European Union, are attached hereto.

V. COMMENTARY ON THE FINANCIAL RESULTS

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 a 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 clinical trials and certification.

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. of the Separate Semi-Annual Report for the period ended 30.06.2023. As on 30 June 2023, cash amounted to PLN 6,629 thousand. At the same time, funds to the value of PLN 3,993 thousand were held in term deposits and treasury bonds.

During the third quarter of 2023, the Company met its obligations on an ongoing basis and its cash position allowed it to maintain its current 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.

1. Commentary to separate statements of profit or loss and other comprehensive income

Revenue from commercial services

In the commercial services revenue line of the stand-alone statement of profit or loss and other comprehensive income prepared as on 30 September 2023, the Company reported a value of PLN 56 thousand for the third quarter of 2023 and PLN 83 thousand cumulatively after three quarters. This is a respective 21% and 13% of the volumes recorded in the comparable period of 2022. The sales structure was dominated by export sales, which accounted for 100% of the sales value in the third quarter of 2023 and 96% cumulatively. Revenues from the sale of goods and services are a side activity of the company, which focuses on conducting R&D work.

There is no seasonality in the business area in which the Company operates.

Cost of services sold and gross profit on sales

The result from sales was shaped in accordance with the accounting principles adopted by the Company and currently in force, described in detail in the Separate Financial Statements for 2022. The value of own costs of services sold amounted in Q3 of 2023. PLN 14 thousand, which generated a gross profit of PLN 42 thousand on sales. This gave a healthy gross margin on sales of over 74%. This margin was generated 100% on overseas sales. On a year-to-date basis after three quarters of 2023, the cost of sales amounted to PLN 19 thousand which made it possible to generate PLN 67 thousand of gross profit on sales.

Operating costs

The value of operating expenses charged to the result amounting to PLN 13,006 thousand in the period covered by this report (PLN 9,572 thousand in the comparable period., +36.5% and 36,967, +36.5% y-o-y for 9 months) represents the aggregate 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 the PB003g and PB004 projects.

Undesirable factors and beyond the Company's control are adverse macroeconomic conditions such as exploding inflation and the weakening of the Polish zloty. Costs 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 cost increases is the relocation to 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 1,302 thousand to operating expenses.

In the structure of costs in the period covered by this report, 86% was expenditure on R&D projects in the field of research work charged directly to the result. They amounted to PLN 11,177 thousand in Q3 2023 and PLN 28,239 thousand cumulatively. Compared to Q2 2022, when R&D costs amounted to PLN 7,304 thousand, they have increased by 53%. 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), the Company's R&D expenses in Q3 2023 exceeded PLN 31.5 million.

General and administrative expenses (PLN 1,814 thousand) accounted for 13.9% of total costs in the reported period and were 17% (PLN 362 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 the company has carried out in recent quarters.

There were major changes in the cost structure by type compared to previous periods. Once again (for the first time after Q2), salaries and wages were not the largest burden in the Company's history. In the reported period, well over half of the costs, i.e. 65.5% (PLN 8,519 thousand), were external services. This is more than threefold increase compared to the same period in 2022, when they amounted to PLN 2 092 thousand. The main drivers of the increase are analytical services, pre-clinical and Phase 0 studies and expert consultancy services.

Next in the cost structure are salaries and wages (PLN 1,878 thousand) accounting for 14.4% of total costs. In this item, a decrease in relation to the third quarter of 2022 (PLN 4,087 thousand) by PLN 2,199 thousand, i.e. almost 54%, was recorded.

Depreciation and amortisation (PLN 1,391 thousand) came third in the cost structure in the reporting period, accounting for 10.7%. This item increased by 126% compared with the same period in 2022

when it amounted to PLN 614 thousand. 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 item 'rents and leases', where a change was recorded from PLN 487 thousand in Q3 2022 to PLN 27 thousand in the reported period.

Consumption of materials and energy (PLN 641 thousand) accounted for only 4.93% of total costs in the reported quarter of 2023 and was 52.7% lower than in the comparable period of 2022 (PLN 1,353 thousand).

All the costs listed above account for more than 95% of operating expenses. All costs by type except third-party services and depreciation and amortisation decreased compared to the comparable period of 2022.

Grant income

Under the heading of grant revenue in the third quarter of 2023, the Company reported PLN 6,735 thousand and this is more than twice (+130.9%) more than in the comparable period of 2022. The entire revenue in the period covered by the report was generated by projects: PB004 - PureBike - 59% of grant revenue, and PB003 PureActivator accounting for 41%. Analysing the sources of grant revenue, in the reporting period 85.3% (PLN 5,747 thousand) of the grant came from NCBR and 14.7% (PLN 988 thousand) from ABM.

Project costs

In the third quarter of 2023, the Company recognised PLN 11,177 thousand of project costs in the statement of profit and loss and other comprehensive income. When analysing the cost structure, PB003-Pure Activator and PB004-PureBike account for the largest share (44% and 42.2%) of project costs in the period covered by this report. Once again, unsubsidised project costs have appeared in the report. This item includes both the preliminary costs of the PB103 - UreTox project, described in detail in Section II 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.

Operating profit (loss)

The loss from operating activities in the reported period of 2023, amounting to PLN 13,006 thousand, is the result of determining the Company's aggregate activity in two main business segments, i.e. commercial contract research and implementation of innovative R&D projects. In the comparable period, the loss from operations amounted to PLN 9,527 thousand. (+36.5% year-on-year).

When assessing and analysing this item in the P&L, one should take into account the fact, that the growing scale and value of the R&D projects implemented by the Company, as assumed 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 generated loss on operations, however, the Company's own share in the costs of R&D projects is treated by it as an investment in projects with a potential above-average rate of return in the event of their positive completion and commercialisation.

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 essentially intended to play a supporting role in the Company's financial model for its own participation in R&D projects.

They are primarily intended to secure the operation of the Company's core organisational infrastructure and as a legal entity. The main source of funding for these expenditures is and will continue to be funds from capital raised through the issue of shares.

It should be noted that the value of the loss from operations in the third quarter 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.

Net profit (loss)

The net loss in Q3 2023 of PLN 7,597 thousand is 18.3% higher than in the comparable period of 2022 (PLN 6,420 thousand) and is mainly due to factors affecting the loss from operations and results from financing activities.

2. Commentary to separate statement of financial position

Non-current assets

In this balance sheet item, amounting to PLN 34,901 thousand (53.5% 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 33,262 thousand. The overwhelming majority (85%) of these are assets used under a rental, lease or similar agreement.

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

Intangible assets during the reporting period amounted to PLN 369 thousand, representing 1% of non-current assets and 0.5% of total assets. The largest item of intangible assets as on 30 September 2023 was patents and licences of PLN 269 thousand. Non-current financial assets represented a fraction (0.06%) of non-current assets.

The value of non-current assets almost tripled (by PLN 26,063 thousand) compared to the beginning of 2023. 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 28,780 thousand.

Current assets

Current assets as on 30 September 2023 amounted to PLN 30,276 thousand and represented 46.5% of the balance sheet total. They are 21% lower than at the beginning of the period covered by this report.

The largest item of current assets was trade and other receivables amounting to PLN 17,506 thousand. This item aggregates mainly subsidy receivables in the amount of PLN 10,157 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) amounted to PLN 3,782 thousand as on 30 September 2023. Of the total receivables from third parties, which amount to PLN 3,295 thousand, an amount of PLN 3,279 thousand represents the advance payment for Phase 0 clinical trials.

Cash and cash equivalents at the end of the reporting period amounted to PLN 6,629 thousand and short-term deposits and bonds to PLN 3,993 thousand.

Equity

The value of this balance sheet item as on 30 September 2023 amounted to PLN 13,020 thousand and its reduction from that recorded at the end of Q2 2022 and 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 comparable periods and losses from previous years.

Long-term liabilities

Long-term liabilities at the end of the reporting period amounted to PLN 38,416 thousand and are slightly (PLN 571 thousand) lower than at the beginning of the period covered by this report. However, they are significantly (PLN 36,539 thousand, 1994%) higher than at the beginning of 2023. In the structure of liabilities, they currently represent 58.9%. These liabilities represent, to a significant extent (PLN 26,002 thousand), the long-term part of the instalments for fixed assets used on the basis of rental, lease and leasing agreements. 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 also represents a significant value (PLN 12,330 thousand).

Also accumulated here, in the amount of PLN 45 thousand, time-settled subsidies, i.e. relating to the Pureselect2 and PureApta technology platforms. Long-term provisions for employee benefits in the amount of PLN 39 thousand are also shown.

Short-term liabilities

Short-term liabilities at the end of the reporting period amounted to PLN 13,742 thousand, representing 21.1% of the balance sheet total and 8.1% lower than at the beginning of the reporting period.

In the structure of liabilities, 45.9% are deferred grants (advances), 23.7% are trade receivables and 22.0% are finance leases.

Of the PLN 657 thousand of other liabilities, PLN 393 thousand are payroll liabilities and PLN 248 thousand are public-law liabilities.

VI. OPINION ON THE FEASIBILITY OF ACHIEVING THE PUBLISHED RESULT FORECASTS FOR A GIVEN YEAR IN THE LIGHT OF THE RESULTS PRESENTED IN THIS QUARTERLY REPORT

The company does not publish financial forecasts.

VII. INDICATION OF SIGNIFICANT PROCEEDINGS PENDING BEFORE A COURT, AN AUTHORITY COMPETENT TO CONDUCT ARBITRATION PROCEEDINGS OR A PUBLIC ADMINISTRATION BODY

In the period covered by this report, the Company was not a party to any proceedings pending before a court, an authority competent to conduct arbitration proceedings or a public administration authority concerning the Issuer's liabilities or receivables.

VIII. INFORMATION ABOUT THE CONCLUSION BY THE ISSUER OF ONE OR MORE TRANSACTIONS WITH RELATED PARTIES, IF SUCH TRANSACTIONS WERE CONCLUDED ON CONDITIONS OTHER THAN MARKET CONDITIONS

During the reporting period, there were no non-arm's length transactions with related parties.

IX. DESCRIPTION OF THE ORGANISATION OF THE GROUP, INDICATING THE ENTITIES SUBJECT TO CONSOLIDATION

On 1 December 2022, Pure Biologics Inc. established a wholly-owned subsidiary, Doto Medical Ltd, with its registered office in Wrocław, at: Legnicka 48E 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 has waived the preparation of consolidated financial statements for the nine months ended 30 September 2023.

X. INFORMATION ON THE GRANTING OF CREDIT OR LOAN GUARANTEES BY THE ISSUER OR ITS SUBSIDIARY

The Issuer did not grant any loans, credits or guarantees during the reporting period.

XI. ISSUER'S SHAREHOLDING STRUCTURE

The table below sets out (in numbers and percentages) information on the structure of the Company's share capital and the structure of the total number of votes at the Company's AGM as at the balance sheet date and the date of publication of this report.

Table 1: Shareholding structure as at 30.09.2023. and as at the report publication date

Shareholder	Number of shares	Number of votes at the GM	Share in capital	Share of votes at the 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 beneficial owner of Augebit FIZ is Mr Tadeusz Wesołowski, Vice Chairman of the Company's Supervisory Board.

To the best of the Company's knowledge, as at the balance sheet date and the date of the report, the managing and supervising persons held directly or indirectly shares in the Company as shown in the table below:

Table 2: Shares held by management and supervisory personnel as at 30.09.2023 and the date of the report

Shareholder	Number of shares	Number of votes at the GM	Share in capital	Share of votes at the GM
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 (Vice-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%**

To the Company's knowledge, there were no changes in the shareholding during the reported period.

XII. INDICATION OF FACTORS WHICH, IN THE ISSUER'S OPINION, WILL AFFECT ITS RESULTS IN THE PERSPECTIVE OF AT LEAST THE NEXT QUARTER

Looking ahead to at least the next quarter, performance will mainly depend on the following factors:

- the rate of progress in the various R&D programmes relating primarily to more advanced projects,
- the effectiveness of clearing funding applications for ongoing R&D programmes and final applications submitted,
- the resolution of applications for new grants and subsidies that the Company has submitted over the past quarters,
- progress in the search for potential partners from biotechnology and pharmaceutical companies for selected early-stage programmes that could provide synergies for the Issuer's business.

Other factors have been identified and discussed in sections II and V of this report

XIII. SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

After the period covered by this report, up to the date of publication, there have been no significant events affecting the Company's operations.

XIV. STATEMENT OF THE MANAGEMENT BOARD CONCERNING THE INFORMATION CONTAINED IN THIS REPORT

The Management Board of Pure Biologics Inc. declares that, to the best of its knowledge, the condensed financial statements of the Company included in the report for the third quarter of 2023 and the comparable data have been prepared in accordance with the regulations applicable to the Company, and that the information concerning the Company's activities during the period covered by the report presents a true picture of the development and achievements and the situation of Pure Biologics Inc.

Filip Jan Jeleń	Romuald Apollo Harwas	Petrus Johannes Louis Spee
President of the Management Board	Vice-President of the Management Board	Vice-President of the Management Board

Wrocław, 15 November 2023.