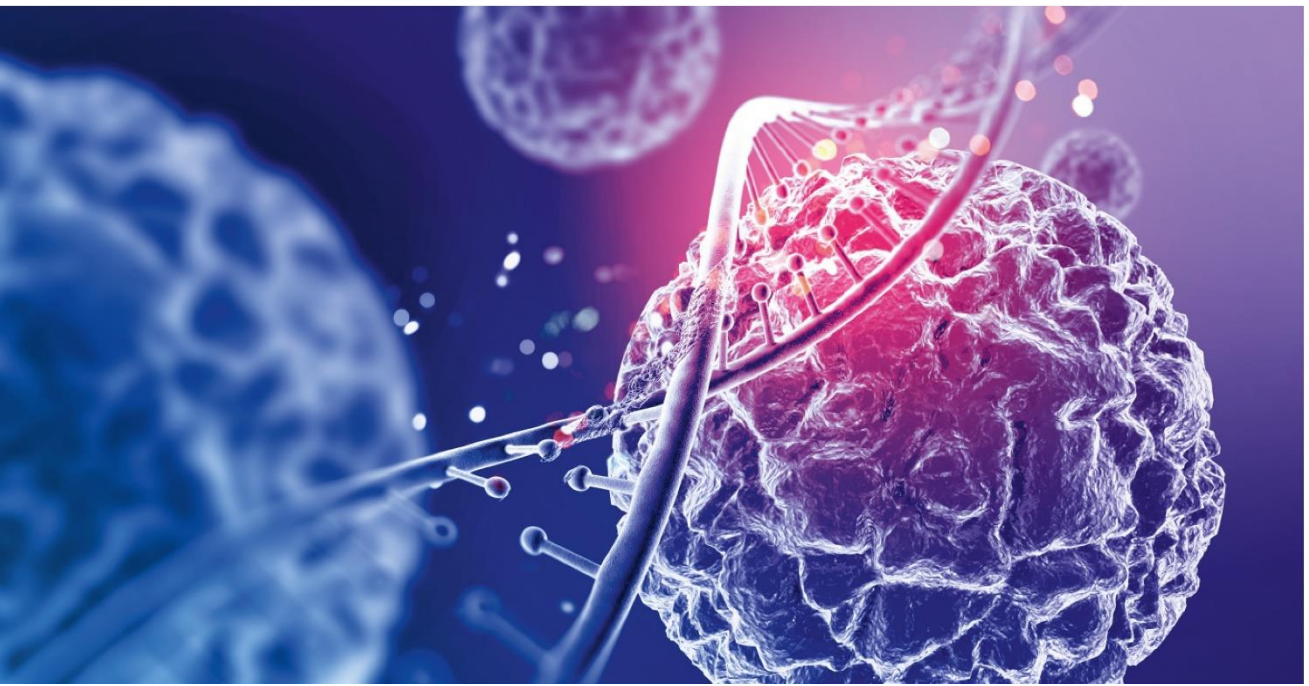
pure biologics®

SEPARATE QUARTERLY REPORT

FOR THE PERIOD 01.07.2022 - 30.09.2022

Wroclaw, November 15, 2022



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I. BASIC INFORMATION ABOUT THE ISSUER

1. Members of the Management Board

As on 30 September 2022 and as on the day of the issue of this report, the Board consists of:

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

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

2. Members of the Supervisory Body

As on 30 September 2022 and as on the date of this report, the Supervisory Body consists of:

1. Mr. Andrzej Trznadel - Chairman of the Supervisory Body,
2. Mr. Tadeusz Wesołowski - Deputy Chairman of the Supervisory Body,
3. Ms. Julia Bar - Member of the Supervisory Body,
4. Mr. Andrzej Kierzkowski - Member of the Supervisory Body,
5. Mr. Mariusz Czekała - Member of the Supervisory Body.

During the period covered by this report, the composition of the Supervisory Body did not change.

Audit Commitee

As on 30 September 2022 and as on the date of this report, the Audit Committee of the Supervisory Body cosists of:

1. Mr. Mariusz Czekała – Chairman of the Audit Committee,
2. Ms. Julia Bar – Member of the Audit Committee,
3. Mr. Andrzej Trznadel – Member of the Audit Committee.

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

3. Brief description of the Company's activities

Subject of the Issuer’s activity

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

Fig. 1: Scope of activity of the Company.

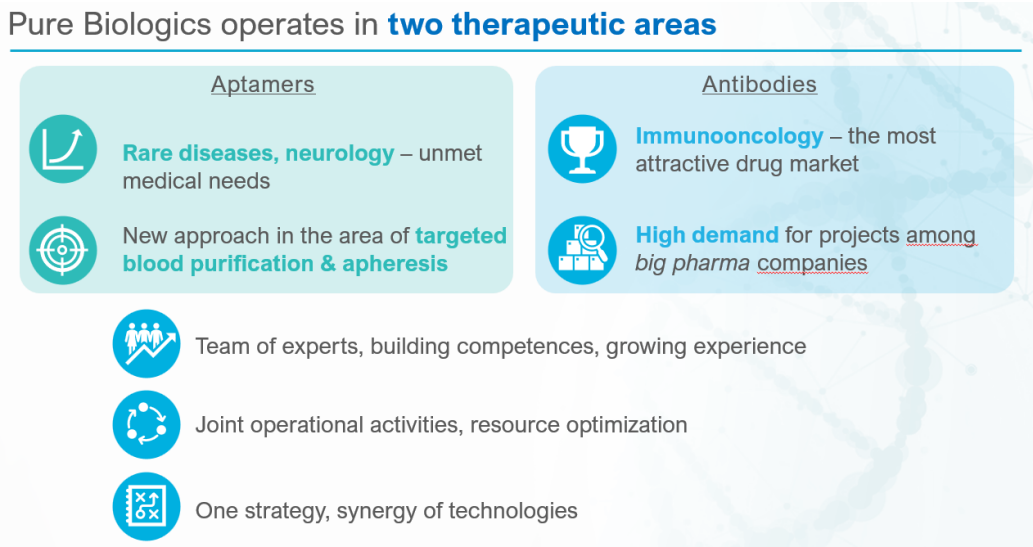
Innvovative segment	Contract research segment
Own R&D projects – innovative biomedical solutions • Biopharmaceuticals • Therapeutic medical devices • Diagnostic particles	Contract research for pharmaceutical companies • Gaining experience • Cooperation with big pharmaceutical companies – both polish and foreign

Development of innovative drugs and therapies

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

The work focuses on the study of molecules (proteins and nucleic acids, i.e. aptamers) and their use in specific environments and conditions. The Company targets projects that develop active molecules that are first-in-class in the category of drugs and therapeutic solutions. This translates into minimising the risk that competitors achieve positive results in development programmes for drugs with an identical or highly similar mechanism of action earlier.

Fig. 2: Scope of activity of the Company.



The Company's in-house Business Intelligence Team monitors the thematic areas of research conducted by other entities and the results obtained by them, based on publicly available information and industry knowledge.

Research and development programmes

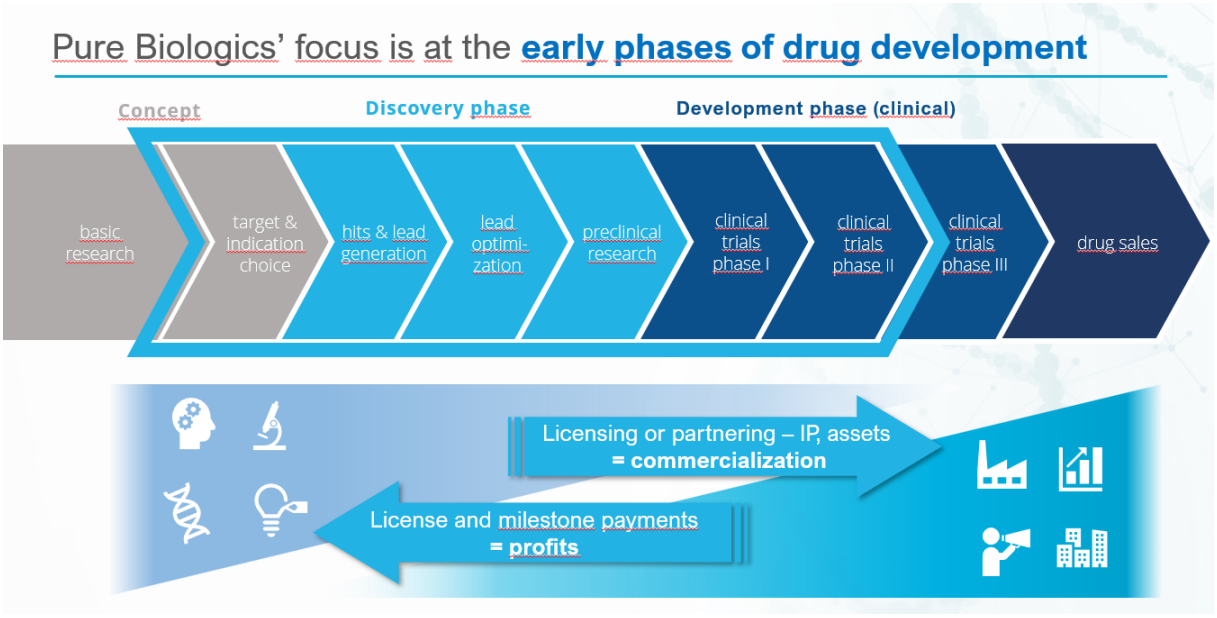
Pure Biologics' activities focus on two areas: 1) development of advanced antibody-based cancer immunotherapy drugs; 2) the use of aptamers for the development of innovative anticancer drugs and

medical devices to selectively remove pathogenic molecules from the blood of patients with inflammatory diseases. All projects in Pure Biologics' portfolio have in common the aspect of modulating the function of the immune system in order to achieve a therapeutic effect..

The first area (PB001, PB003 i PB004 projects) develops next-generation antibodies - bispecific antibodies, bifunctional molecules and molecular target binding molecules with novel formats to improve their pharmacokinetic properties. These molecules are supposed to interact with immune cells in the tumour microenvironment in order to activate them to kill tumour cells, or to lift the immune blockade induced by the tumour. For the discovery of molecular target binding sequences used in the design of next-generation antibodies, the Company uses its proprietary PureSelect2 technology platform, as well as its own sequence library (ScFv antibody fragments) PureLibra, in addition to libraries licensed from Twist Biopharma.

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

Fig. 3: Phases of drug discovery and Pure Biologics' area of activity.



Innovative R&D projects supported by grants

Pure Biologics actively uses public funds to support R&D activities in companies and has repeatedly successfully applied for funding for its projects at both the NCBR and the European Commission. Only in the period 2018-2019, the Company obtained nearly PLN 106 million in funding for the implementation of projects scheduled for 2018-2023.

Science and technology projects

The objective of the scientific and technological projects carried out by the Company is the continuous development of competencies based on proprietary solutions and maximising the areas of IP and know-how utilisation. The implementation of this objective includes testing platforms developed by the Company, exploring the possibilities of their commercial applications beyond those arising from the Company's own drug and therapy development projects, and exchanging knowledge and experience between recognised foreign scientific and research units and teams in Europe and worldwide. The collaboration carried out on research projects builds international relationships and provides references for the research concepts and subject matter expertise of Pure Biologics' scientists. Following the initial commercialisation of the Company's major projects, these activities form the basis for initiating and developing further ultra-innovative programmes in the future.

Contract research

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

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

Human resources, infrastructure facilities and standards to commercialize R&D projects

The company has modern and well-equipped laboratory and office facilities in which it employs 81 scientific staff, 40.5% with a doctoral degree (a total of 86 specialists serving the scientific and research segment directly).

The Company employs staff on the basis of employment contracts and also outsources activities on the basis of civil law contracts. As on 30 September 2022 the Company employed 101 people (96,275 FTE).

In the third quarter, the Company continued its balanced human resources management policy, whereby the size of its research team is maintained and the focus is on retaining current staff within the Company's structures (employment stability rate of 79.2%, general turnover rate at the end of September 2022 14.85%). 99% of the staff have a university degree or higher with an academic degree, and nearly 40% have a doctoral degree. The staffing structure is predominantly female (65.3%).

There was no significant and disruptive employee absenteeism, with overall absenteeism of 1.25% and no accident absenteeism in the period to the third quarter.

Competitive advantage

Focus on first-in-class drugs.

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

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

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

Pure Biologics' focus is on demonstrating early signs of therapeutic efficacy in clinical trial phases 0 and 1 through appropriate patient selection, use of biomarkers, etc., which 1) will significantly increase the valuation of the project in the context of its subsequent commercialisation and 2) allows a more accurate assessment of the probability of success of the costly phases 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 previous positive results obtained by competitors in drug development programmes with a similar mechanism of action.

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

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

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

The Company's own research projects focus on searching for drugs and therapies supporting human immune system. This direction of research in cancer treatment in recent years became the most important in cancer control. Immunooncologic treatments brought into the market are rarely limited to one tumour type, turning out to be efficient in at least several types of illnesses. Therefore it broadens

their range of application and number of potential patients. An important issue is also the use of so-called combination therapies, in which two different treatments are used (both of the immunooncology field or a treatment consisting in combining immunooncologic drug with classical anti-cancer therapy, for example chemo- or radiotherapy), which additionally broadens the range of indications for use of this type of drugs. Taking into account the immunooncology's development in recent years, systematically confirmed by partnering and licensing transactions which, in value terms, dominated the pharmaceutical market, one can qualify the future positive results of the Company's research projects among assets with significant profit potential.

Research projects on rare diseases' treatment.

The second medical area of Company's interest are rare diseases, also known as orphan diseases. These conditions are mostly genetically dependent, occurring in the population fewer than five out of ten thousand cases (lower than 0,5‰), in most cases appearing in child's age. There are over six thousand diseases of this type worldwide, and the total number of patients is estimated at over 6% of the European population, i.e. over 30 million people. These diseases vary in etiology, symptoms and effects, but they are usually associated with (i) heavy course and high mortality, (ii) low public awareness, often among medical staff, and (iii) a significant shortage of effective therapies - so far, only about 5% of these diseases have been treated. Due to the social impact and the cost of care, there is significant social, administrative and institutional support for the development of new treatments for rare diseases.

Total control over the key discovery phase of drug development.

Company's competence allow it the execution of projects of drug and medical device development from the phase of choosing the molecular target to the phase of in vitro tests inclusive, entirely basing on its own scientific and technological resources. This ensures full independence in obtaining (licensing) drug candidates from other R&D entities or universities, and from services provided by third parties to the pre-clinical phase. This translates into control and confidentiality of the studies carried out at all stages, in particular at their initial, most sensitive stage. Providing funding, including funding from the NCBR, to carry out research into the above projects up to the first phase of clinical research (pre-clinical studies are commissioned by specialized entities of CRO type), makes the projects to be commercialized only when their value is high.

The first Polish entity focusing on the innovative biological drugs development.

The Issuer, as the first entity in Poland, started investments into new, innovative, i.e. non-generic and non-biosimilar, biological drugs that is drugs with macromolecule as an active particle, e.g. antibody or aptamer. The experience of the research team, gathered in recent years in a wide range of renowned research groups in Europe and worldwide, the business know-how and the secure and attractive operating model developed, allow the Company to develop its business, which is now among the leading trends in global pharmaceuticals.

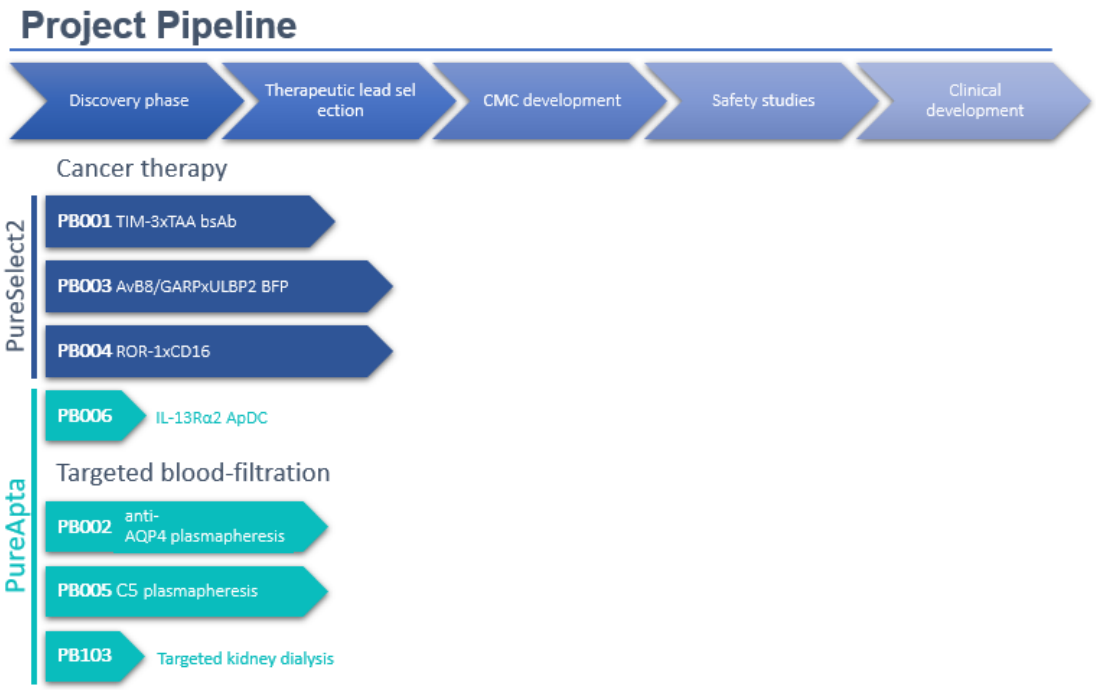
Possibility to generate large numbers of new leading particles with self-designed technology platforms.

The technological platforms PureSelect2 (former PureSelect) and PureApta developed by the Company, allow it each time to generate numerous bioparticles binding molecular target – adequately antibodies and aptamers – by using in vitro techniques (without animals' immunisation) and therefore relatively quickly and at low cost. From the generated wide particle pool, those variants are selected that have the parameters best suited to the task ahead and can be further optimized. Importantly, these platforms can work in parallel on a number of molecular targets and significantly reduce the early phase of the project (the so-called hit generation phase).

II. DESCRIPTION OF SIGNIFICANT COMPANY'S ACCOMPLISHMENTS OR FAILURES IN THE REPORTED PERIOD ALONG WITH THE DESCRIPTION OF THE MOST IMPORTANT FACTORS AND EVENTS, UNTYPICAL IN PARTICULAR, INFLUENCING THE RESULTS

1. Execution of own R&D projects

Rys. 4: Status of projects



Glossary

- *apheresis* – a medical procedure in which patient's blood is pumped through an extracorporeal device in which, like in dialysis, selected blood components are separated and thus the "purified" blood returns to the patient's bloodstream. The kind of removed substances depends on the filter used inside the device.
- *aptamers* – short oligonucleotides, fragments made of the same material as DNA, having a high affinity for the chosen molecular target. In many ways they resemble antibodies and can be used as therapeutic and diagnostic particles.
- *antibodies' library* – a pool of millions of random or partially random protein sequences obtained by genetic and molecular engineering, from which it is possible to obtain new antibodies by phage selection.

- *molecular target* – a macromolecule located on cells of the immune system and/or tumour cells that interacts with the drug, causing the desired therapeutic effect.
- *affinity chromatography* – a method of purifying biological molecules, such as proteins, from complex mixtures (e.g. human blood) which uses the phenomenon of specific interaction between specific molecules.
- *epitope* – a protein fragment characterised by its ability to interact directly and specifically with an antibody; binding of different epitopes by antibodies may 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.
- *effector cells* – general term for those cells of the immune system which, upon activation, destroy pathogens or neoplastic cells (e.g. lymphocytes, NK cells).
- *NK cells* – 'natural killer' cells – a group of cells of the immune system that are responsible for innate immunity of the body, including fighting cancer cells.
- *cellular expression system* – antibodies' production system in cultures of mammalian cells.
- *lymphocytes* – cells of immune system with various functions, e.g. some subpopulations are responsible for the destruction of pathogens or cancer cells.
- *overexpression in the mammalian expression system* – process that uses mammalian cells to produce large amounts of recombinant protein, e.g. molecular target.
- *nuclease* – naturally occurring enzymes that degrade DNA or RNA molecules, also used in genetic engineering. Their presence in body fluids can degrade aptamers.
- *RT-PCR* (ang. real-time polymerase chain reaction) – a method for the simultaneous multiplication of DNA or RNA molecules along with the measurement of the amount of the resulting product in real time, used in molecular biology to assess the amount of DNA or RNA in a sample.
- *aptamers' selection, SELEX* – a multi-stage cyclic process of acquiring new active aptamers, i.e. obtaining active molecules from a wide pool of short random fragments of DNA or RNA that can bind a selected molecular target.
- *phage selection* – a use of pool of genetically modified bacterial viruses (phages) to obtain a new protein sequence – antibody protoplasts – binding a selected molecular target.
- *specificity* – the ability to selectively recognize and bind to a specific macromolecule (matching on the 'key and lock' principle).
- *TNBC* – Triple Negative Breast Cancer cells characterized by a lack of receptor for the hormones: estrogen and progesterone, and one of the endothelial receptors.
- *expressive vector* – gene carrier, artificially introduced into the cell, from which the production of the protein takes place.

Antibody-based immuno-oncology drug development projects

Fig. 5: Antibody-based projects

Project name	Therapeutic area	Indication	Active molecule
PB001 MultiBody	immunooncology	colorectal cancer (CRC)	bispecific antibody
PB003 PureActivator	immunooncology	non-small-cell lung carcinoma (NSCLC)	bimodal fusion protein (antibody-immunoligand)
PB004 PureBIKE	immunooncology	triple negative breast cancer (TNBC)	bispecific antibody

PB001 Drug development project (MultiBody)

Aim of the project

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

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the co-financing agreement, the total cost of the project is PLN 32,037 thousand, and the value of the grant is PLN 23,998 thousand. The Company's own contribution in the amount of PLN 8,002 thousand is covered by the Company from the capital obtained as part of the issued shares.

Implementation and results of the project in the reported period

In the third quarter of 2022, Project PB001 focused on further validation of the mechanism of action of bispecific molecule TIM3xTAA. Development of tools to evaluate the biological activity of bispecific TIM3xTAA antibodies using model molecules continued. Immune cell activation assays were developed, in which the effect of bispecific protein on the activation of T lymphocytes and NK cells was investigated by examining the secretion of cytokine IFNɣ. The results obtained for T cells showed insufficient immune

cell activation relative to experimental assumptions. Due to the ambiguity of the results obtained with primary T cells, further attempts to optimise functional assays will be carried out on NK cells, which also express surface TIM3 antigen.

The inconclusive results that were obtained in the functional assays determined the need to develop additional control molecules to validate the cell-based assays, as well as to assess the activity of the bispecific antibody under development. The production process of the designed molecules has started; according to the schedule, the new control molecules should be included in the trials in the fourth quarter of this year.

In addition, work continued during the reporting period to acquire unique protein TIM3 binding sequences. 47 sequences obtained using Twist Biopharma libraries and the in-house scFv fragment library were commissioned for production in IgG1 format with the Fc end silenced. At the beginning of the fourth quarter, the manufactured molecules will undergo validation, which will include biophysical assays (BLI), cell surface target binding assays (flow cytometry) and biological activity analyses in functional assays such as a reporter assay for inhibition of phosphatidylserine binding to the TIM3 receptor and functional assays based on peripheral blood mononuclear cells (PBMCs). These tests aim to assess the suitability of the molecules for human therapy and the feasibility of preclinical animal studies.

Pure Biologics has so far failed to obtain working molecules for a second molecular target presented on tumour-associated antigen (TAA) cells due to selection failures and recent negative results for a molecule based on a bacterial-derived binding sequence. For this reason, Pure Biologics is currently developing a set of new control molecules that will allow possible modification of the molecular targets in PB001. In addition, the current level of knowledge of the biology of the second molecular target, which has developed significantly compared to the start of the Project, further confirms the validity of the new direction of development of PB001 molecule.

PB003 Drug development project (PureActivator)

Aim of the project

The PB003 (PureActivator) project is developing a dual-action anti-cancer therapy that 1) eliminates the number of immuno-suppressive regulatory T cells (Treg) in the tumour microenvironment and 2) recruits cytotoxic immune-cells to directly kill tumour cells. The accumulation of regulatory T (Treg) cells in the tumour microenvironment is associated with an unfavourable prognosis in various types of solid tumours. Integrin αVβ8 and GARP complex are highly expressed on various tumour cells, as well as on activated regulatory T cells (Tregs) where they contribute to immuno-suppression in the tumour environment. Therapeutic antibodies typically use the CD16 receptor on the surface of NK cells to trigger tumour-killing. However, CD16-positive NK cells are scarcely found in solid tumours, contributing to the low efficacy of molecules targeting the CD16 receptor. The PB003 project aims to develop a bifunctional therapeutic antibody (BFP) that specifically recognises αVβ8 or GARP. In addition, the molecule will bind to ULBP2, a natural ligand for the NKG2D receptor, which activates NK cells and is expressed on virtually all cytotoxic NK and T cells present in the tumour environment. The molecule being developed in the PB003 project has the potential to be a breakthrough therapy for the treatment of solid tumours and can be used in most cancer indications. Pure Biologics plans to take the development of the drug

candidate through the first phases of clinical trials, after which it will commercialise the project by making the molecule available for licensing.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the co-financing agreement, the total cost of the project is PLN 39,905 thousand, and the value of the grant is PLN 30,969 thousand. The Company's own contribution amounts to PLN 8,969 thousand the Company intends to cover this from the capital raised through the conducted share issues.

Implementation and results of the project in the reported period

In the third quarter of 2022, Project PB003 continued to validate model bifunctional molecules based on molecular target binding sequences known from the literature. A study was initiated to achieve preclinical proof-of-concept in vivo using the model molecules. In addition, the development of bifunctional antibodies containing unique binding sequences was ongoing during the reporting period.

Model anti-αVβ8 molecules, produced in the previous reporting period and validated in vitro, were transferred to The Jackson Laboratory (USA) for in vivo testing. In a study using genetically modified human FcRn (neonatal Fc receptor) mice, Pure Biologics expects to obtain pharmacokinetic data, including the half-life of the molecule in the blood. Preliminary results of the study will be known by the end of October and final results in November 2022.

Model molecules directed against a second molecular target, the GARP-TGFβ1 complex, were also produced. Two variants of anti-GARP-TGFβ1 model monoclonal antibodies were obtained, as well as two variants of anti-GARP-TGFβ1 bifunctional molecules, differing in their ability to induce antibody-dependent cellular cytotoxicity (ADCC) through modification of the Fc fragment. These molecules have been validated in biophysical and cellular assays for their ability to bind molecular targets, as well as in functional assays for biological activity. BFP molecules, compared to monoclonal antibodies, have been shown to cause greater increases in markers CD107, INFy and TNFα, indicative of NK cell activation in response to binding of the molecule. Furthermore, in NK cell cytotoxicity assays, model bifunctional antibodies directed against GARP-TGFβ1 activated NK cells isolated from donor blood, thereby inducing death of cells overexpressing GARP as well as the GARP-TGFβ1 complex, but not of cells without antigen expression. Bifunctional molecules therefore show a greater ability to activate immune cells to kill cancer cells than reference monoclonal antibodies currently in clinical development. A preclinical proof-of-concept study in mouse tumour models is planned for the fourth quarter of 2022.

In parallel with studies of the mechanism of action and activity of model molecules, intensive work continued on the development of proprietary therapeutic molecules anti-αVβ8 and anti-GARP-TGFβ1, using licensed Twist Biopharma libraries. In the past quarter, the Company conducted in vitro studies of its own anti-αVβ8 and anti-GARP-TGFβ1 antibodies. Sixty anti-GARP-TGFβ1 antibodies in IgG format were produced and validated in in vitro assays, from which seven antibodies were selected based on binding profiles to the complex and its individual components, as well as functional assays, and are now being produced in the bifunctional target molecule format. For molecular target αVβ8, 34 antibodies in IgG format have been produced and are currently being verified in in vitro assays.

Optimisation of in vitro functional assays to test the mechanism of action of the molecules under development, i.e. the ability to reactivate the immune system, also continued in the third quarter. Based on antibody-dependent NK cell cytotoxicity (ADCC) and Treg cell inhibition tests, lead molecules will be selected for further preclinical development. Immunohistochemical studies have also been initiated to confirm the expression of molecular targets on selected tumour types. This will allow us to propose

inclusion criteria for patients in the clinical trial and to stratify them based on the number of Treg cells infiltrating the tumour, as well as the expression of proteins on tumour cells.

PB004 Drug development project (PureBIKE)

Aim of the project

The objective of the PB004 (PureBIKE) project is to develop an anti-cancer drug based on an anti-ROR1 antibody with significantly improved therapeutic properties compared to competing antibodies currently in early-stage clinical development. PB004 will be a long-acting bispecific killer engager (BiKE) molecule designed to inhibit tumour cell proliferation and migration, as well as induce tumour cell death through natural killer (NK) cell activation and initiation of antibody-dependant cellular cytotoxicity (ADCC) process. The drug under development may have high potential in treating patients with ROR1-expressing tumours, including triple negative breast cancer (TNBC), a particularly aggressive breast cancer subtype, but also ovarian, lung, gastric, prostate cancer and chronic lymphocytic leukaemia. Pure Biologics plans to take the drug to phase one clinical trials when the project will be made available for outlicensing. The PB004 project constitutes an important position in the pipeline of the Company's highly innovative drug-development projects in the segment of immuno-oncology therapies.

Financing

The project is co-funded by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. On 21 August 2022, NCBR accepted the Company's proposed amendments to the project application, which included changing the format from BIKE (bispecific killer engager) to a long-acting BIKE molecule and changing the Phase 1 clinical trial to Phase 0 as the endpoint of the NCBR-funded project. The scope changes are associated with a change in the total project budget (from PLN 40.42m to PLN 38.62m) and the amount of funding (from PLN 29.87m to PLN 28.79m). The introduction of Phase 0 into the clinical development of the PB004 molecule will result in a significant increase in the value of the project and positively impact on its commercial potential by obtaining pharmacodynamic data and indications of anti-cancer efficacy early in clinical development. This can be achieved earlier than Phase 1 and at a significantly lower cost, as reflected by the change in the project budget. The implementation of a Phase 0 study as the first step in the clinical development of immuno-oncology projects is in line with Pure Biologics' 'smart clinical development' strategy of acquiring pharmacodynamic data early in development to 1) support planning and reduce the risk of failure of later, expensive clinical milestones; and 2) significantly increase the value of projects in early clinical development.

The planned period of cost eligibility for the project is 31 December 2023. The Issuer intends to cover its own contribution to the project in the amount of PLN 9,800 thousand from its own capitals.

Implementation and results of the project in the reported period

In the reported third quarter of 2022, the main project activities focused on 1) narrowing down the number of potential formats of long-acting BiKE molecules to two final ones based on stability, ease of production and immune cell cytotoxicity induction potential (ADCC); and 2) continuing the selection of proprietary molecules that bind target antigens.

Previously, PB004 project conducted the first in vivo pharmacokinetic study using model molecules and genetically engineered mice with the human neonatal Fc receptor (FcRn), which determines the half-life of IgG antibodies and albumin in blood. Using genetically modified mice, Pure Biologics has obtained

half-life data for different formats with better translation to clinical conditions. Data from the Jackson laboratory confirmed that long-acting BiKE has a longer half-life than that observed for the conventional BiKE molecule, confirming the validity of the approach taken in the project PB004. The project is preparing for an in vivo preclinical proof-of-concept study in which the final format of the long-acting BiKE molecule will be selected.

During the reported period, further selections of proprietary molecules anty-ROR1 and anty-CD16a were carried out using various libraries of ScFv fragments, leading to a total of 55 promising CD16a- and anti-ROR1-binding sequences. Following molecular target binding assays, 27 anti-CD16a and 43 anti-ROR1 antibodies were selected and will be further tested using functional assays, which will ultimately allow the selection of the lead molecule. Preliminary results indicate that the selected CD16a-binding molecules can induce ADCC in a similar manner to the model molecule. The data obtained for the most favourable format of the model molecule, will be confirmed using proprietary antigen-binding sequences to generate the lead molecule. This work also includes a comparison with an afucosylated IgG1 antibody optimised to provide the best induction of ADCC.

To test the biological activity of selected molecules, in collaboration with the Ludwik Hirszfeld Institute of Immunology and Experimental Therapy of the Polish Academy of Sciences, the expression of the molecular target ROR1 in cells from patients with chronic lymphocytic leukaemia (CLL) was confirmed, and a tumour cell proliferation inhibition assay was developed. Further functional assays are planned as part of the collaboration, including ADCC and ADCP (antibody-dependent phagocytosis). In addition to functional assays, experiments have also been performed to assess the ease of production and stability of molecules, including in human and animal serum, narrowing the number of potential formats to two, which will be used to develop proprietary therapeutic molecules with unique molecular target binding sequences.

In the next quarter, in vitro testing of model molecules will continue in Project PB004, culminating in an in vivo proof-of-concept study in a mouse tumour model, planned for early 2023. Development of proprietary therapeutic molecules will also continue. In addition, the project is being prepared for preclinical evaluation in the coming year.

Aptamer-based therapeutic projects

Fig. 6: Aptamer-based projects

Project name	Therapeutic area	Indication	Product / active molecule
PB002 AptaPheresis	neurology/rare diseases	Neuromyelitis Optica (NMO)	biomolecular filter with aptamer
PB005 AptaMG	neurology/rare diseases	Myasthenia Gravis	biomolecular filter with aptamer
PB006 AptaMLN	oncology	melanoma	aptamer-drug conjugate

PB103 UreToxApta	urology	chronic kidney disease	biomolecular filter with aptamer

PB002 therapeutic project (AptaPheresis)

Aim of the project

The PB002 (AptaPheresis) project aims to develop a highly innovative targeted apheresis therapy for the treatment of patients suffering from Neuromyelitis Optica (NMO). NMO is a potential fatal neurological disease caused by auto-immune antibodies that target the spinal cord and optic nerves, leading to severe paralyses of limbs and blindness. It is characterised by varying severity of symptoms; periods of remission alter with exacerbations, which often lead to hospitalisation and a significant increase in treatment costs. Therapeutic options for NMO patients during exacerbation periods are non-selective and are associated with serious side effects. Therefore, there is still an unmet medical need for more efficient NMO treatments, with an improved safety profile and cost-efficient.

Under project PB002, Pure Biologics is developing a medical procedure in which auto-antibodies against aquaporin-4, a pathogenic factor in NMO, are selectively removed from patients' bloodstreams. PB002 is a medical device that will capture auto-antibodies using highly specific aptamers developed using proprietary PureApta technology. PB002 has the potential to significantly improve care of the estimated 300,000 NMO patients world-wide, while reducing treatment costs.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) under the Intelligent Development 2014-2020 programme. According to the co-financing agreement, the total cost of the project is PLN 14,282 thousand and the value of the grant is PLN 10,542 thousand. The Company intends to cover its own contribution of PLN 3,740 thousand from the conducted share issue.

Implementation and results of the project in the reported period

During the last reported period, work continued on the prototype of a medical device, an aptamer adsorber for the capture of autoantibodies against aquaporin-4 (AQP4). The adsorber prototype is currently being tested in ex vivo studies using rat serum. The next milestone of the project is to test the adsorber prototype in in vivo studies in an animal model.

In the course of the experimental work carried out, there was a need to correct the operation of the test apparatus and to redesign and carry out molecular target binding tests by cold-mobilised aptamers on the bed. Ex vivo experiments in a dynamic system, i.e. during the flow of serum through a column with immobilised aptamer, showed that the binding of the molecular target from rat serum was over 80%. Thus, it was confirmed that the aptamer bed fulfils the necessary requirements and can be used to build a target adsorber with a volume of 1 ml, which will then be used for in vivo studies on an animal model.

At the same time, during the last reporting period, the Company completed the implementation of a Quality Management System based on the requirements of ISO 13485:2016 PN-EN ISO 13485 - Medical devices Quality management systems - Requirements for regulatory purposes and Good Laboratory Practice (GLP), including activities related to Quality Assurance and Quality Control. Thus, one of the

milestones of phase 4 of the project has been achieved. The key objective of the implemented system is to meet normative requirements and applicable legislation by achieving quality objectives within the project implementation.

Work on prototyping the column using the lead molecule is scheduled to continue for the upcoming reporting period. A batch of prototype adsorbers with a target column volume (1 ml) will be produced, and column quality control is planned as the next step. Subsequently, the prototype adsorbers will be tested in ex vivo studies using rat serum containing the molecular target. Ex vivo and quality tests will verify the functionality of the prototypes, which in the next step will be tested in vivo on an animal model.

The Beneficiary has initiated a tender procedure in which a Subcontractor for an in vivo study involving selective apheresis on a rat model will be selected. The in vivo study is scheduled to start in December this year and be completed in January 2023.

PB005 therapeutic project (AptaMG)

Aim of the project

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

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) as part of the Intelligent Development 2014-2020 programme. According to the grant agreement, the total cost of the project is PLN 14,730k, and the awarded funding is PLN 10,775k. The planned period for the completion of eligible costs is 31 December 2023. The Company intends to cover its own contribution in the amount of PLN 3,958 thousand from equity capital.

Implementation and results of the project in the reported period

Milestone 4 of the project is the development of a laboratory prototype medical device (aptamer adsorber) that will capture >80% of the molecular target (C5 protein) from human plasma under laboratory conditions and from the blood of animals subjected to the selective plasmapheresis procedure in vivo studies.

In the previous reporting period, it was confirmed that the aptamers obtained in the project have very good binding parameters for the human C5 protein. The cold-mobilised particles on the deposit bind between 82-98% of the native molecular target from human serum, depending on the experimental setup used. In order to test the adsorber prototype in vivo on an animal model, it is necessary to obtain aptamers that exhibit so-called interspecies reactivity, i.e. that bind native C5 protein from animal serum. To this end, experiments were conducted to test whether selected aptamers bind C5 protein from rat, rabbit, pig and domestic coffee serum. The experiments showed that the selected molecules had no affinity for the C5 protein from serum of the listed species.

Due to the high homology of the human C5 protein with the monkey counterpart, the interaction of aptamers with the monkey C5 protein was tested. Using biophysical techniques (SPR), aptamers were confirmed to interact with recombinant monkey C5 protein. Experiments using macaque serum were also initiated.

Aptamers that demonstrate binding of the C5 protein from animal serum will subsequently be optimised to achieve appropriate stability parameters in human and animal plasma. These steps are necessary to proceed to the next step, i.e. testing of the prototype adsorber in ex vivo experiments, followed by in vivo studies on an animal model.

PB006 Drug development project (AptaMLN)

Aim of the project

The aim of the PB006 project is to develop a targeted chemotherapy, in the form of a drug-conjugated aptamer targeting IL-13Rα2, for safe and efficient treatment of melanoma. Traditional chemotherapeutics effectively kill cancer cells, but the doses needed to eradicate the tumour cause unacceptable side effects in patients. Immunotherapies in the form of monoclonal antibodies work well in subsets of patients. Unfortunately, in most patients suppression of tumour-killing immune cells in the tumour micro-environment hampers therapeutic efficacy of such therapies. PB006 will specifically recognize the molecular target of IL-13Rα2 displayed on the surface of tumour cells. After the receptor binds the conjugate, the entire complex will be taken-up by the cell, after which the drug will be released and kill the tumour cell. Thus, PB006 will allow targeted delivery of highly toxic molecules specifically to cancer cells, thereby by-passing immuno-suppression and reducing side-effects in comparison with conventional chemotherapies. To increase the chance of achieving therapeutic efficacy of PB006, a companion diagnostic test will be developed in parallel to identify patients whose tumour cells express IL-13Rα2. Cancer types eligible for PB006, based on reported expression of IL-13Rα2, includes melanoma, glioma, and colon cancer. PB006 therefore shows great potential, both therapeutically and commercially.

Financing

The PB006 project is a collaboration between Pure Biologics and the Polish Centre for Technology Development (PORT, Wroclaw, Poland). The total value of the project is PLN 2 354 thousand, and the granted amount of EU funding is PLN 2 072 thousand. The budget of the stages of the project implemented by the Company amounts to PLN 1,412 thousand (total cost), and the granted amount of co-financing is PLN 1,129 thousand. In February this year, the funding granted by the National Research and Development Fund for the phases implemented by the Company ended and PORT decided not to

continue with the project. In September, the Company obtained information that the final report had been accepted by NCBR and the project settled. The results obtained during the project will serve as the foundation for a new project, for which grant funding is currently being sought.

Implementation and results of the project in the reported period

During the reporting period, experiments to determine the cytotoxicity and genotoxicity of selected chemically modified nucleosides used in PureApta™ technology were completed. This is necessary to determine the safety profile of aptamers containing modified nucleotides. The modifications used not only increase the stability of aptamers in nuclease-rich environments (e.g. blood), but also increase their affinity for molecular targets and thus the likelihood of selection success. A total of five modifications were tested. The results showed that none of the tested modifications were cytotoxic or genotoxic, as tested by two methods.

A fifth selection campaign against IL-13Rα2 was completed in the third quarter, but did not yield the expected results in terms of a specific aptamer. After analysing the experiments carried out so far and developing a new selection strategy, a sixth selection campaign was launched with a recombinant protein as the molecular target. However, the results of monitoring the progress of selection did not show a narrowing of the oligonucleotide pool, which was confirmed by biophysical methods. Due to unsatisfactory results, selection was discontinued.

An in-depth in silico analysis of the potential reasons for selection failure is currently underway. Once the results of the analysis are available, the project assumptions will be re-evaluated.

PB103 therapeutic project (UreTox)

Aim of the project

Project PB103 (UreTox) aims to develop an innovative product that significantly improves the haemodialysis efficiency of patients suffering from chronic kidney disease (CKD). Renal failure leads to the accumulation of uremic toxins in the patient's blood, some of which are not removed during haemodialysis, causing loss of residual kidney function and serious cardiovascular complications, which are often the direct cause of premature death in patients. Patients live an average of 25 years less than healthy individuals, with 15-20% of patients dying within the first year of diagnosis.

The product under development will be in the form of an adsorber that, with the help of aptamers, will specifically capture uremic toxins responsible for complications of chronic kidney disease and which are not effectively removed by traditional haemodialysis. The adsorber will be used as an adjunct to haemodialysis, performed on a given patient up to four times a week, significantly increasing its effectiveness and thereby improving the clinical prognosis of patients suffering from PChN. The disease is estimated to affect approximately 700 million people worldwide. Furthermore, according to current projections, PChN will become the fifth leading cause of death worldwide by 2040. Currently, more than 2 million people worldwide undergo dialysis or kidney transplantation, but this figure may represent only 10% of those who actually need treatment. Project PB103 is implemented using patented PureApta™ technology.

Financing

Project PB103 is being carried out in partnership with the Dutch company Relitech Besloten Vennootschap. 3 June 2022. The companies have signed a collaboration agreement covering the first phase of the project, in which Pure Biologics will select aptamers for the first 2 molecular targets and Relitech will develop a prototype device based on a model aptamer and conduct a proof-of-concept experiment on animals. The estimated cost of the stage on Pure Biologics' side, which will be covered by equity, is PLN 450,000. In subsequent stages, the Companies plan to develop a device based on selected aptamers and its preclinical and clinical development. Grant funding is being actively sought for Project PB103.

Implementation and results of the project in the reported period

In Q3 2022, Project PB103 completed the in silico structural analysis of the molecular targets and developed a selection strategy that will yield at least two aptamers specific for two different uremic toxins. Two selection campaigns were carried out with satisfactory initial results in that the pool of molecular target binding sequences was significantly narrowed. Samples were subjected to next-generation sequencing and subsequent bioinformatics analysis, which allowed the identification of 15 sequences potentially binding the first, and 16 sequences potentially binding the second molecular target. The selected sequences will then be subjected to biochemical and biophysical testing to investigate their specificity and binding strengths.

During this reported period, work continued on the development and optimisation of methods for the detection and quantification of molecular targets in human serum and selected animal sera, which will be required for in vitro and ex vivo testing.

In addition, Relitech, a partner in Project PB103, has initiated the development of the device and conducted initial tests using a test configuration of the prototype. The aim of the tests is to analyse potential technical limitations early on, and to develop and test various solutions to identified problems.

Collaborative science and technology projects

PB013 project (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 introduced chimeric antigen receptor (CAR-T) against newly selected molecular targets overrepresented in selected leukaemias and lymphomas. The Polish-Norwegian consortium will conduct research from the selection of new targets, through the selection of antibody fragments (scFv) that bind these targets and the development of the CAR receptor equipped with a selected binding molecule, to animal studies demonstrating the effectiveness of the new therapy, which will be used in patients resistant to standard treatment (Rituximab, CD19-CAR T).

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) as part of the "Applied Research" program financed by the Norwegian Financial Mechanism 2014-2021. The total

value of the project for the consortium is PLN 6 655 thousand, and the granted amount of EU funding is PLN 6 573 thousand. The budget of the project stages implemented by the Company is PLN 413 thousand (total cost), and the amount of co-financing granted is PLN 330 thousand. The own contribution of the project in the amount of PLN 83 thousand is covered by the Company from the capital obtained as part of the issued shares. The project has been implemented as part of the consortium since January 1, 2021, and the planned completion of the project is December 31, 2023.

The Consortium

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

Implementation and results of the project in the reported period

In the first half of 2022, sequences in Pure Biologics' ScFv antibody fragment format binding the molecular target were selected and then submitted to partners for further testing. In the third quarter of 2022, further steps are planned for the selection of the optimal binding sequence that can be used for CAR receptor engineering. To this end, the selected sequences will be produced in IgG1 format and then subjected to 'epitope binning' tests using biophysical methods (BLI, SPR). The aim of the tests, which are planned for 2022/23, will be to select 2 sequences that bind different epitopes of the target protein.

PB014 project (DualDrug)

Aim of the project

The aim of the project is to develop a human growth factor protein conjugate with two different cytostatic drug molecules. This type of therapeutic molecule, preferentially internalized by the cells of selected neoplasms, is designed to effectively eliminate these cells by virtue of the strong synergistic effect of two cytotoxic drugs. The cooperation with the University of Wrocław and the University Hospital in Oslo will allow the consortium members' expertise to be combined to develop a new drug candidate faster and more likely up to the stage of animal testing.

Financing

The project is co-financed by the National Centre for Research and Development (NCBR) as part of the "Applied Research" program financed by the Norwegian Financial Mechanism 2014-2021. The total value of the project for the consortium is PLN 6 571 thousand, and the granted 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 amount of co-financing granted is PLN 95 thousand. The own contribution of the project in the amount of PLN 63 thousand is covered by the Company from the capital obtained as part of the issued shares. The project has been implemented as part of the consortium since October,1 2021, and the planned completion of the project is September, 30 2023.

Implementation and results of the project in the reported period

In the third quarter of 2022, the Issuer carried out the first mid-scale protein production trials under industrial conditions in a bacterial system. In the coming weeks, the actual production and purification of the protein for the synthesis of the protein-drug conjugate will be carried out.

2. Operating events of the Company

The first in vivo study in Project PB003

In Q3 2022, Project PB003 entered the in vivo phase of studies to determine the pharmacokinetic (PK) and pharmacodynamic (PD) properties of the bifunctional molecules under development. On 19 September, a PK study using human FcRn receptor transgenic mice administered model PB003 molecules. Data are currently being analysed and final results are expected in November. The PD study is in the process of planning and contracting.

Signing of annex to the grant agreement PB004 PureBike - NCRD approval for Phase 0 studies

On 19 September 2022. The Company became aware that the National Centre for Research and Development had signed an addendum to the grant agreement for Project No. POIR.01.01.01-00-0209/19 [PB004 PureBike], which formally updates the scope of research and the project schedule.

The update of the experimental pathway results in modifications made by the Company to the substantive assumptions of the project, which were developed in accordance with the recommendations of the expert of the National Centre for Research and Development [NCBR] positively evaluating the 2021 research progress report.

Changes to the project include, among others, a reduction in subcontracting work, resulting in a reduction in project implementation costs by a total of PLN 1 800 000 [including the Company's own contribution of PLN 720 000] and a reduction in the implementation time of selected tasks. The total cost of the project after the changes amounts to PLN 38,617,125 [formerly PLN 40,417,125] and the amount of funding is PLN 28,789,080 [formerly PLN 29,869,080].

The revision of the remaining work to be carried out in the project was based on the results obtained during the Company's own research, as well as on changes in the project's business environment and ongoing competitive analysis. The annexed changes do not affect the main objectives of the project.

Among the design changes, the most significant is the decision to conduct a Phase 0 clinical trial, in which patients will be injected directly into the tumour with microdoses of the drug candidate, which will allow confirmation of the mechanism of action of the PB004 molecule in the complex tumour microenvironment and predict the potential efficacy of the drug candidate in anti-cancer therapy. The Phase 0 results will provide the Company with valuable data from the point of view of further drug development, such as pharmacodynamic and pharmacokinetic data and biomarker analysis. This will provide a significant competitive advantage at an earlier stage of the project, at a lower cost..

Actions taken to secure new grants and subsidies

Pure Biologics is actively involved in obtaining grants to continue current and new projects. In September 2022, three grant applications were submitted to the Medical Research Agency competition for the development of targeted or personalised medicine based on cell therapies or protein products (ABM/2022/5):

- " Phase 1 clinical trial to investigate the safety, tolerability and efficacy of a bispecific compound in patients with advanced solid tumours" - a follow-on project to project PB003 after a phase 0 clinical trial;
- „Phase 1 clinical trial of the first-in-class bispecific molecule ROR1xCD16 in patients with B-cell lymphoid malignancies" - a follow-on project to project PB004 after a phase 0 clinical trial;
- Application for a phase 1 clinical trial of a protein-toxin conjugate in which the protein is a multispecific antibody that binds 4 cancer-related antigens. The as yet undisclosed project will potentially be the subject of a licence acquired by Pure Biologics from a third party.

The total budget of each project was PLN 50 million, of which the funding body will potentially cover costs of between PLN 30.8 and 33.1 million.

In October, the National Cancer Institute's 'Clinical and Translational Exploratory/Developmental Studies (R21)' competition, organised by the US government agency NIH (National Institutes of Health), saw Pure Biologics submit funding applications for two new projects to conduct proof-of-concept phases for multispecific molecules interacting with previously undisclosed molecular targets. The projects have budgets of $278,000 and $288,000 and are 100% funded.

Grant applications are currently being prepared for a competition for the development of targeted or personalised medicine based on nucleic acid-based medicinal products (ABM/2022/6), to be announced by the Medical Research Agency at the end of November.

Contract research

During the reported period, the Company carried out a number of contracted research activities in the field of R&D support for a French client, Neurophoenix SAS (NPX). Neurophoenix is a biotechnology company that is developing polypeptide drug candidates - PTEN inhibitors that unlock neuronal repair in optic neuropathies and several other neuronal diseases. The collaboration between Pure Biologics and Neurophoenix has been ongoing for several years, and during this time the work carried out by the Company has enabled the development of efficient expression of NPX polypeptides in microbial systems and supported the identification of therapeutic candidates. Pure Biologics is currently assisting in formulation screening to support the development of Neuropheoenix formulations towards clinical trials. During the reported period, work was also completed for a UK/Croatian client.

Patents and protection of intellectual property

On 2 September 2022, Pure Biologics filed an application (PL442186) for a further extension of patent protection for the proprietary PureApta™ platform. The developed solution extends and complements a method for the synthesis and purification of modified oligonucleotides patented in Europe and the US (patents EP3350195 and US10450673). Thanks to the solutions developed in Platform PureApta™, it is possible to achieve even higher stability of the aptamers obtained.

Events, conferences, partnering

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

- 11 October, 2022 – EU-Japan Biotech & Pharma Partnering Conference 2022, Osaka, Japan
- 12-14 October, 2022 – BIO Japan 2022, Yokohama, Japan
- 24-26 October, 2022 – BIO Europe, Lipsk, Germany

Particularly relevant events were BIO Japan, which 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. During the events, Pure Biologics' representatives held dozens of personal meetings with representatives of the pharmaceutical industry as well as the investment industry. The Company presented its project portfolio, focusing in particular on antibody drug candidates.

Moreover, on 15th of October, 2022, representatives of the Company took part in the Longterm - KsiążęcaStreet11 conference in Warsaw, during which they familiarised investors with the Company's business profile, the projects it is conducting and the related prospects.

Measures to create a new laboratory and office complex

In Q3 2022, construction and arrangement work continued in connection with the preparation and commissioning of the Company's new laboratory and office complex. Emphasis was placed on electrical, sanitary and building automation installation work. All approaches for power and electrical sockets were prepared, the entire plumbing, central heating and all ventilation point extraction connections were distributed. An innovative and completely safe carbon dioxide distribution system secured by a gas detection system was developed with the participation of designers from the various branches, which will supply the laboratory area with the gas necessary for cell culture. In cooperation with the Landlord (Owner and Manager of the complex), contractors were selected for areas such as carbon dioxide installation, carpets, kitchen and furniture fittings. Work also continued with the consultants for the various trades (electrical and low current installations, building area and sanitary installations), and investor supervision of the documentation and progress of the work was carried out through cyclical weekly meetings and site visits.

In addition to the work strictly related to the construction area of the project, during the reporting period the project team focused its efforts on market verification and the selection of suppliers for the equipment (so-called critical apparatus) and laboratory furniture required to launch the new premises. Based on the market reconnaissance carried out, it was decided to rent or purchase more than 30 items of laboratory equipment from 11 different suppliers. The value of planned purchases for this year is approximately PLN 3.3 million.

Development of the Company's research and development infrastructure

Activities in the area of research infrastructure included the development and issuing of further ISO 13485-compliant quality documents, such as Sample Management and Equipment Logs. At the same time, a series of internal audits were initiated to verify the degree of training and adherence to the issued documents by laboratory staff, the laboratory maintenance department, the human resources department and the quality department. The audit identified two non-conformities in the laboratory area due to the lack of appropriate procedures in accordance with ISO 13485, and identified substantive points in the documents issued that required revision.

Another area of increased activity in Q3 2022 was the preparation of the Company's resources for the relocation process to the new premises. A detailed plan for the move was developed, minimising the amount of time that individual laboratory rooms would be out of service. A schedule was prepared that took into account the logistical movements of both offices and laboratories, as well as scheduled service visits that included the de-installation and reinstallation of individual equipment in the new space. A service company specialising in the transport of optics, laboratory equipment and precision analytical equipment was selected. The selection was based on price, the provision of vehicles with anti-vibration load compartments, sufficiently high third-party liability insurance, length of existence in the market and a history of orders.

At the same time, the collection of tenders for services related to the maintenance of the new laboratory - supply of technical gases, cleaning, hazardous waste disposal, maintenance and building automation has begun.

Activities in the area of building key scientific competencies in the Company related to entering the next development phases of R&D projects

In the first half of 2022, Pure Biologics initiated activities to recruit a highly qualified manager with a medical background from the European market for the position of Chief Medical Officer, with experience in clinical drug development projects with significant international pharmaceutical companies. This is an important element in the implementation of the Company's strategy in the area of building key competencies necessary at further stages of the development of clinical research projects and in the process of commercialisation and acquisition of business partners in the big pharma industry. In the process of recruiting a candidate for the position of Medical Director, the Company is supported by a professional life science recruitment agency specialising in creating business relationships between experienced experts and managers and pharmaceutical companies in Europe.

3. Corporate events

Changes in the Company's shareholding structure

As a result of the merger of TFI Allianz Polska S.A. with Aviva Investors Poland TFI S.A., in which TFI Allianz Polska S.A. was the acquiring company and Aviva Investors Poland TFI S.A. was the acquired company, the level of involvement of the Funds managed by TFI Allianz Polska S.A. in the total number of votes at the general meeting of the Company changed. The Funds held 302,298 shares in the Company, representing 13.41% of the Company's share capital, entitling them to 302,298 votes, which

represented 13.41% of the total number of votes at the Company's general meeting. The merger took place on 1 July 2022.

4. Analysis of the actual and potential impact of the COVID-19 pandemic on the Company's operations

Due to the ongoing pandemic, there were still global factors that were having some effect on the execution of some R&D work in the company's projects, particularly in relation to supply chains. There were no apparent disruptions or delays resulting from this, although the accumulation of a number of individual factors gave rise to an undesirable element of disruption.

To smooth the way the company operated, no additional safety procedures were put in place. Employees had access to diagnostic tests, which made it possible to quickly identify cases of disease and limit their spread. There was no major COVID-19-related downtime in R&D activities although other potential risks were partially realised, which are described in more detail in the 2021 annual report.

5. 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 the financial situation of Pure Biologics S.A. in the third quarter of 2022. The Company does not cooperate with entities registered in Ukraine, Russia and Belarus, nor does it provide services to or procure from counterparties 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 has an impact on 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 2022.

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

III. SELECTED FINANCIAL DATA

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

1) Items relating to the statement of profit or loss and other total income, the cash flow statement and the statement of changes in equity were converted at an exchange rate representing the arithmetic average of the exchange rates published by the National Bank of Poland:

- For period between 01.01.2022 and 30.09.2022: PLN 4,7787
- For period between 01.01.2021 and 30.09.2021: PLN 4,6880

2) The balance sheet items were converted according to the average exchange rate announced by the National Bank of Poland, in force on the balance sheet date; this exchange rate amounted to:

- As on 30.09.2022: PLN 4,8698
- As on 31.12.2021: PLN 4,5994

	Period of 9 months ended 30.09.2022	**Period of 9 months ended 30.09.2021**	**Period of 9 months ended 30.09.2022**	**Period of 9 months ended 30.09.2021**
	PLN thousand	PLN thousand	EUR thousand	EUR thousand
Operating revenues	9 702	10 237	2 030	2 184
Total operating costs	27 088	20 923	5 668	4 463
Operating profit (loss)	(17 327)	(10 684)	(3 626)	(2 279)
Profit (loss) before tax	(18 443)	(11 072)	(3 859)	(2 362)
Net profit (loss)	(18 443)	(11 072)	(3 859)	(2 362)
Net cash flows form operating activities	(12 290)	(18 479)	(2 572)	(3 942)
Net cash flows from investment activities	23 303	(586)	4 876	(125)
Net cash flows from financial activities	(1 517)	49 303	(317)	10 517
Total net cash flows	9 496	30 237	1 987	6 450

	As on 30.09.2022	**As on 31.12.2021**	**As on 30.09.2022**	**As on 31.12.2021**
	PLN thousand	PLN thousand	EUR thousand	EUR thousand
Total assets / liabilities	30 260	47 190	6 214	10 260
Tangible assets	5 400	4 175	1 109	908
Current assets	24 860	43 015	5 105	9 352
Equity capital	24 344	39 486	4 999	8 585
Liabilities and provisions for liabilities	5 916	7 704	1 215	1 675
Long-term liabilities	1 822	2 155	374	468
Short-term liabilities	4 094	5 549	841	1 206
Weighted average number of ordinary shares	2 254 000	2 210 044	2 254 000	2 210 044
Profit (loss) per ordinary share (in PLN / EUR)	**(8,18)**	**(5,01)**	**(1,71)**	**(1,07)**
Number of shares at the end of the period	2 254 000	2 254 000	2 254 000	2 254 000
Book value per share (in PLN / EUR)	**10,80**	**17,87**	**2,22**	**3,88**

IV. ABBREVIATED INTERIM FINANCIAL STATEMENT

The Abbreviated Interim Financial Statements for the three-month period ended 30 September 2022, prepared in accordance with International Financial Reporting Standards as adopted by the European Union, are attached hereto.

V. COMMENT ON FINANCIAL RESULTS

1. Comment on the separate statement of profit and loss and other total income

Revenue from commercial services

In the commercial services revenue item of the stand-alone statement of profit or loss and other comprehensive income prepared again under IAS/IFRS for Q3 2022. The Company reported a value of PLN 263 thousand. in the reported quarter and PLN 639 thousand cumulatively. In the comparable period, i.e. Q3 last year, PLN 82k was recorded. (PLN 150 thousand cumulatively). In the period covered by the report, the company focused on conducting R&D work, although this does not mean that the company completely abandoned commercial activities, as exemplified by contracts executed in Q3 of this year. These include contracted research work in the field of R&D support for a client from France, which is conducting R&D work on a protein preparation for therapeutic applications.

Cost of services sold and gross profit from sales

The result on sales was shaped in accordance with the accounting principles adopted by the Company and currently in force, described in detail in the Separate Financial Statements for 2021. The value of own costs of services sold amounted to PLN 47 thousand in Q3 of 2022, which made it possible to generate PLN 216 thousand of gross profit on sales. This gave a healthy gross margin on sales of over 82%. This margin was generated mainly on foreign sales.

Operating costs

The value of operating expenses amounting to PLN 9,527 thousand in the period covered by this report (PLN 7,255. in the comparable period, +31.3% and 27,088, +29.5% 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. It does not include capitalised R&D costs, which did not occur during the reported period. There are many complex reasons for the increase in operating costs. The main expected and foreseen factors are the intensification of R&D, moving individual projects to further, increasingly capital-intensive phases of development, e.g. pre-clinical studies in project PB004 and PB003. Undesirable factors and beyond the Company's control are unfavourable macroeconomic conditions such as exploding inflation and the significant weakening of the Polish zloty. Costs are also

affected by the expansion of infrastructure facilities (preparation for relocation to a new location), the increase in human resources, in particular by highly specialised foreigners who must be contracted at the current stage of the Company's portfolio development. A significant accounting charge that does not result in a cash expense is also the Incentive Programme, which in the third quarter of 2022 charged PLN 1,112 thousand to operating expenses. This is PLN 546 thousand more than in the corresponding period of 2021.

In the structure of costs in the period covered by this report, 77% (PLN 7,304 thousand) was expenditure on R&D projects for research work charged directly to profit. The costs of general management and sales accounted for 23% (PLN 2 176 000). Such a significant change in costs (almost double the increase in G&A costs compared to the same period in 2021) has several reasons; the Board of Directors was expanded to include Mr Peter Spee, G&A costs are charged to the 2nd incentive programme, which was priced more expensively than the previous one and is aimed at management, so it has a greater impact on this item than the previous programme; we bear the effects of inflation, as well as the lack of programmes in the early stages of development, which means that the cost of resources not working on currently ongoing projects is charged to G&A costs.

In the structure of costs by type, the largest item, 42.8%, is salaries (PLN 4 078 000), an increase of 30.3% compared with the same period last year. Cumulatively, after 9 months, salaries amounted to PLN 11 687 000, an increase of 26.8% year on year. Aggregated with social security and other employee benefits, this item accounts for 49.7% of operating expenses. This structure is similar both in the comparable period of 2021 and on a year-to-date basis. This is followed in the cost structure by: third-party services (22.0%, PLN 2,092 thousand in Q3 2022 and 20.6%, 5,574 on a year-to-date basis). In the comparable periods of 2021, this was 11.8% and 9.7% respectively. This swap is expected, and is driven by higher project spending by external service providers as work on projects shifts to phases requiring external, specialised subcontractors and the use of external experts. The largest decrease in the cost structure was recorded in depreciation and amortisation, which accounted for 6.44% of total costs (PLN 614k) in the period covered by this report and is a decrease of 2.8pp compared to the comparable period of 2021. The structure of other costs by type did not change much compared to the comparable period and ranged from -1.5pp to +0.6pp.

Revenue from subsidies

Under the heading of grant revenue in Q3 2022. The Company reported PLN 2,917 thousand and this is 4.8 per cent less than in the comparable period of 2021. The largest revenues in the reporting period were generated by projects: PB003 PureActivator project accounting for 41,4%, PB004 – PureBike – 27,3% subsidy income, and PB005 AptaMG – 16,3%. Grant income should increase in the coming year, as it is directly correlated to the costs of ongoing R&D work and these will increase as the work progresses and the individual projects enter further, more capital-intensive stages. It should also be borne in mind that the level of co-financing as the work progresses is reduced from 80% to 60% of eligible costs. This will not be insignificant to the level of this item in the coming quarters.

Project costs

Project costs include both the eligible and non-eligible parts of the costs of running individual research programmes. In the third quarter of 2022. The Company recognised PLN 7,304 thousand of project costs in the statement of profit or loss and other comprehensive income. Analysing the cost structure, the

largest share (36.3%) of project costs in the period covered by this report is accounted for PB003 – PureActivator. Five major key projects generated 95.0% of total project costs in the first half of 2022. This is the second time that unsubsidised project costs have appeared in the report, following the H1 2022 report. This item includes both the initial project costs of the PB103 project – UreTox, described in detail in point II.1 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.

Profit (loss) on operating activities

The loss from operations in the third quarter of 2022, amounting to PLN 6 420 thousand, is the result of determining the Company's aggregate activity in its two core business segments, i.e. commercial contract research and the implementation of innovative R&D projects. In the comparable period, the loss from operations amounted to PLN 4 276. Its increase of 50.2% y-o-y, with a comparable level of total revenue (PLN 3,179k in Q3 2022 vs. PLN 3,148k in Q3 2021) was mainly due to the cost factors described above.

When assessing and analysing this item in the P&L, it should be taken into account that the increasing scale, number and value of the R&D projects implemented by the Company, as 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 directly affect the value of the operating loss generated, however, the Company's own share of the costs incurred in carrying out R&D projects is treated by the Company as an investment in projects with a potential above-average rate of return, should they be successfully completed and commercialised.

While the size of the result generated by the Company on the sale of contract research may mitigate the scale of this process, the proceeds from commercial activities are essentially intended to play a role in the Company's financial model to support the Company's own share of R&D projects. In the first instance, they are intended to safeguard the functioning of the Company in its basic organisational infrastructure and as a legal entity. The main source of funding for these expenditures is, and will continue to be, 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 2022 is an expected value, although its level due to the deteriorating macroeconomic situation and the Company's environment may come as a surprise, the Board 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 segment of R&D projects in the coming years will be financed mainly by external capital raised.

Net profit (loss)

The net loss in Q3 2022, amounting to PLN 6 420 thousand, is mainly due to factors affecting the loss from operations and the results on financing activities. The results on financing activities were mainly shaped by the costs of interest on leasing contracts for laboratory equipment used in the Company's activities.

2. Commentary on the separate statement of financial position

Fixed assets

In this balance sheet item, amounting to PLN 5 400 thousand as on the last day of the period covered by this report (17.8% of total assets), the main component is property, plant and equipment PLN 4 917 thousand. The overwhelming majority (91.0%) of these are used on a rental, leasing basis for highly advanced laboratory equipment used for R&D projects. This item increased by 42.5% (PLN 1 466 thousand) compared to the beginning of 2022. The main growth factor responsible for the PLN 1 257 thousand increase in this item is the purchase of machinery and equipment to supplement the machinery stock due to the relocation to the new laboratories in the last quarter of this year.

The second key item of non-current assets is intangible assets. During the reporting period, they amounted to PLN 473 thousand, representing 8.8% of non-current assets and 1.6% of total assets. The largest item of intangible assets as on 30 September 2022 was costs of completed development work patents and licences (PLN 270 thousand, 34.5%). Non-current financial assets being shares in ProAnimali Sp. z o.o. accounted for a fraction (0.3%) of non-current assets.

Current assets

Current assets as on 30 September 2022 amounted to PLN 24 860 thousand and accounted for 82.2% of the balance sheet total. These are down 42% from the beginning of the period covered by this report.

The largest item of current assets was cash and cash equivalents - PLN 15 674 thousand. The second significant item is trade and other receivables amounting to PLN 8 041 thousand. This item mainly aggregates grant receivables in the amount of PLN 5 246 thousand. This figure represents the amount of grant settlements that have been incurred but are still unaccounted for at the balance sheet date. Budget receivables (including VAT to be refunded) on 30 September 2022 amounted to PLN 910 thousand. Of the total trade receivables of PLN 1 854 thousand, PLN 1 422 thousand represents a cash deposit paid as security under the lease agreement for new laboratory space.

Equity

The value of this balance sheet item as on 30 September 2022 amounted to - PLN 24 344 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

Non-current liabilities at the end of the reported period amounted to PLN 1 822 thousand and are by PLN 378 thousand (2.1%) lower than at the beginning of the period covered by this report. In the structure of liabilities, they represent only 6.0%. This structure does not deviate from the level at the beginning of the period (5.1%). These liabilities represent, to a significant extent (PLN 1 696 thousand), the long-term portion of instalments on fixed assets used on the basis of a lease, rental or leasing agreement. Also accumulated under this heading in the amount of PLN 83 thousand are time-sensitive subsidies, i.e. relating to the technology platforms Pureselect2 and PureApta. Long-term provisions for employee benefits in the amount of PLN 42 thousand were also shown.

Short-term liabilities

Current liabilities at the end of the reporting period amounted to PLN 4 094 thousand and represent 13.5% of the balance sheet total and are 64.2% lower than at the beginning of the reporting period,

when they amounted to PLN 8 262 thousand. and by PLN 10 208 thousand (71.4%) lower than at the end of the corresponding period in 2021. The main reason for this was the settlement and crediting to income of advances for grants settled in time.

In the structure of liabilities, 25.2% are accounted for by deferred grants (advances), 14.9% by finance leases, 29.8.2% by trade and 28.6% by other liabilities. This is where accrued but unpaid wages and government taxes are aggregated. The significant increase in trade payables is mainly related to the purchase of fixed assets as part of the project to complete the equipment in the company's new laboratory space. These liabilities have been settled at the date of publication of this report.

VI. POSITION ON THE POSSIBILITY OF THE PUBLISHED PERFORMANCE FORECASTS FOR 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 body, concerning the liabilities or receivables of the Issuer.

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 period covered by this report, there were no transactions with related parties on terms other than market terms.

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

The company does not form a capital group.

X. INFORMATION ON CREDIT OR LOAN SURETIES OR GUARANTEES GRANTED BY THE ISSUER OR ITS SUBSIDIARY

During the period covered by this report, the Issuer did not grant any loans, credits or guarantees.

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.

Shareholder	Number of shares	Number of votes at AGM	Share in capital	Share of votes at AGM
TFI Allianz Polska S.A.	302 298	302 298	13,41%	13,41%
Filip Jeleń	257 817	257 817	11,44%	11,44%
Maciej Mazurek	160 104	160 104	7,10%	7,10%
Augebit FIZ	153 220	153 220	6,80%	6,80%
Piotr Jakimowicz	146 576	146 576	6,50%	6,50%
Andrzej Trznadel	81 000	81 000	3,59%	3,59%
Other	1 152 985	1 152 985	51,15%	51,15%
Total	**2 254 000**	**2 254 000**	**100,00%**	**100,00%**

To the best of the Company's knowledge, as of 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 on 30.09.2022 and the date of the report

Shareholder	Number of shares	Number of votes at AGM	Share in capital	Share of votes at AGM
Filip Jeleń (President of the Board)	257 817	257 817	11,44%	11,44%
Romuald Harwas (Vice-President of the Board)	3 205	3 205	0,14%	0,14%
Petrus Spee (Vice-President of the Board)	1 000	1 000	0,04%	0,04%
Tadeusz Wesołowski (Vice-Chairman of the Supervisory Board)***	153 220	153 220	6,80%	6,80%
Andrzej Trznadel (Chairman of the Supervisory Board)	81 000	81 000	3,59%	3,59%
Andrzej Kierzkowski (Member of the Supervisory Board)	26 221	26 221	1,16%	1,16%
Total	**522 463**	**522 463**	**23,18%**	**23,18%**

*** Actual beneficiary Augebit FIZ.

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 depend mainly on the following factors:

- the rate of progress in the various R&D programmes, which primarily concern more advanced projects,

- the effectiveness of the clearance of applications for funding for ongoing R&D programmes and final applications submitted,
- the outcome of applications for new grants and subsidies that the Company has submitted over recent 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 operations.

Other factors are 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

Pure Biologics' Management Board declares that, to the best of its knowledge, the condensed financial statements of the Company included in the report for the third quarter of 2022 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 Pure Biologics' development, achievements and situation.

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 2022