Ministry
of Digital Transformation
of Ukraine

UKRAINIAN GLOBAL
INNOVATION STRATEGY

# SECTOR STRATEGY: BIOTECH

(BIOTECHNOLOGIES)

UKRAINIAN GLOBAL INNOVATION STRATEGY UNTIL 2030

# ЗМІСТ

# ABBREVIATIONS AND DEFINITIONS

## KEY DEFINITIONS

| | |
|---|---|
| STRATEGY | Ukrainian Global Innovation Strategy until 2030 |
| BIOTECH | Biotechnologies |

## ABBREVIATIONS

| | |
|---|---|
| Agr | Agriculture |
| AI | Artificial intelligence |
| DNA | Deoxyribonucleic acid |
| EU | European Union |
| GMP | Good manufacturing practice |
| GDP | Gross domestic product |
| HEI | Higher educational institution |
| IP | Intellectual property |
| mAb | Monoclonal antibody |
| PCR | Polymerase chain reaction |
| R&D | Research and development |
| SME | Small and medium enterprises |
| SME | Small and medium enterprises |
| SW | Software |
| USA | United States of America |
| VR | Virtual Reality |
| WHO | World Health Organization |

# STRATEGY SUMMARY: BIOTECH

# UKRAINE CAN BECOME A LEADER IN THE GLOBAL BIOTECH INDUSTRY BY DEVELOPING INNOVATIVE SOLUTIONS AND EXPORTING BIOPHARMACEUTICAL PRODUCTS

The Ukrainian Global Innovation Strategy until 2030 defines the development of the biotechnology as one of the strategic goals, the achievement of which will strengthen the innovation ecosystem and realize Ukraine's innovation potential.

## UKRAINE'S FUTURE ROLE IN THE GLOBAL BIOTECH INDUSTRY

### EXPORTS OF UKRAINIAN BIOPHARMACEUTICAL PRODUCTS

The strong potential of the biopharmaceutical industry allows Ukraine to become an important player in the manufacturing of innovative medicines. Enhancing government support and the increased demand for biotech solutions, e.g. regenerative medicine and mental health solutions will contribute to Ukraine’s potential and its access to international markets

### CREATING BIOTECHNOLOGY CLUSTERS

The formation of specialised biotechnology clusters will support the development of innovative solutions and will strengthen competitiveness. Such R&D centers will bring together Ukrainian and international biotech startups, businesses, research institutions and universities, which will allow them to share experiences, attract investments and commercialize scientific developments

### INCREASING BIOFUEL PRODUCTION

The use of biotechnologies, such as fermentation, biosynthesis and pyrolysis, has a favourable impact on increasing biofuel production. Ukraine has the potential to become a leading supplier of bioethanol and biodiesel to EU countries that are switching to renewable energy

### DEVELOPING BIOINFORMATICS

Expanding biobanks of genetic material and plant crops and enhancing the development and use of SW for biological research, namely the analysis of RNA, DNA, and protein structures will become an important development area for Ukraine’s biotechnology. The development of tools for big data visualisation and modelling of biological processes will accelerate the implementation in the fields of medicine, pharmaceuticals and agrobiotechnology

# UKRAINE HAS STRONG SCIENTIFIC POTENTIAL IN BIOTECHNOLOGY, BUT NEEDS TO STRENGTHEN STATE SUPPORT AND HARMONIZE LEGISLATION

## STRENGTHS

- Free access to natural resources and biodiversity in Ukraine contributes to effective R&D activities
- Developed pharmaceutical industry in Ukraine, which serves as the basis for further implementation of new innovative solutions in the biopharmaceutical area.
- Availability of highly qualified specialists, developed research infrastructure and higher education institutions that prepare personnel for the sector

## WEAKNESSES

- Insufficient financial, scientific and technical support from the state, as well as the lack of close interaction between all stakeholders in the technological ecosystem
- Instability of government policy and frequent changes in the legislative regulation of the sector in Ukraine. Imperfect IP rights protection
- Insufficient experience in the development and commercialization of biological technologies slows down the launch of innovative products

## OPPORTUNITIES

- Ukraine's integration into the EU and harmonization of legislation will facilitate the export of Ukrainian biotechnology products to international markets. Improving legislation on technology transfer and co-financing with Ukrainian and foreign institutions
- Strong IT in Ukraine may contribute to the development of algorithms and software for biological data analysis
- Establishing public-private partnerships in BioTech for financing innovation projects and boosting startups development

## THREATS

- Weak patenting system and innovations commercialization in Ukraine
- The war in Ukraine creates a high risk of doing business and may lead to increased political and economic instability
- The outflow of human capital, in particular scientists and researchers, may hinder the active development of BioTech

# IMPLEMENTATION OF THE BIOTECH DEVELOPMENT STRATEGY IN UKRAINE REQUIRES HARMONIZATION OF LEGISLATION, FINANCING AND INFRASTRUCTURE SUPPORT

## IMPLEMENTING THE STRATEGY OF THE BIOTECH SECTOR INVOLVES A NUMBER OF TASKS:

### REGULATORY

- Harmonizing legislation with EU norms to ensure compliance of Ukrainian BioTech products with international standards
- Reducing the time for registration of BioTech products and introducing transparent procedures for clinical trials
- Developing a regulatory framework for PPPs in the BioTech sector

### ECONOMIC

- R&D financing through government programs aimed at developing biopharmaceutical production
- Introducing state guarantee mechanisms for attracting foreign investment in Ukraine's BioTech sector
- Development of investment and grant programmes for biotechnology companies and start-ups

### INFRASTRUCTURAL

- Modernizing laboratory equipment in research institutions engaged in BioTech research
- Establishment of centers and rules for collective use of equipment for business and the scientific community, after the infrastructure

1

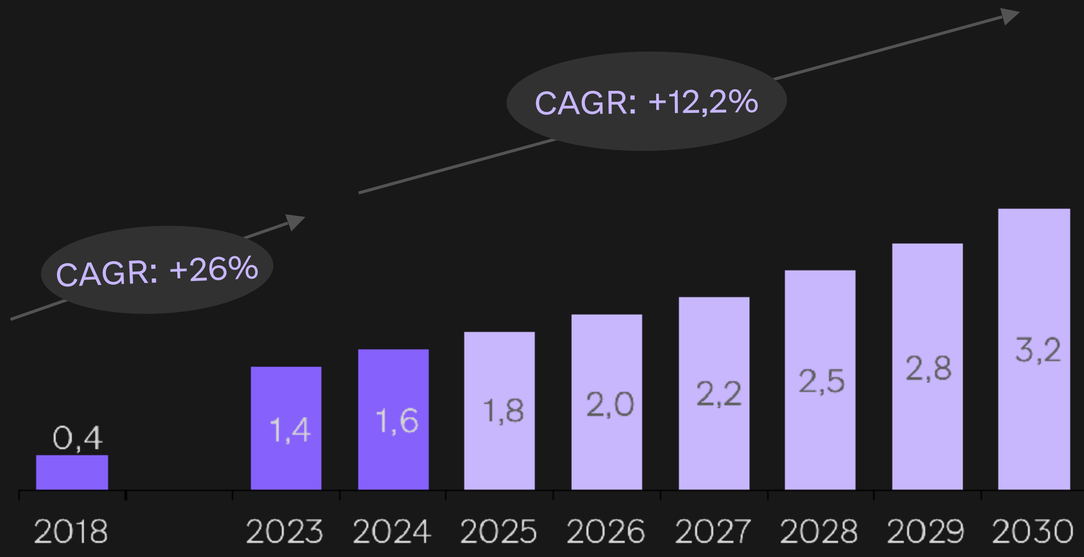
# SECTOR STRATEGY: BIOTECH

# 1.1 GLOBAL BIOTECH SECTOR OVERVIEW

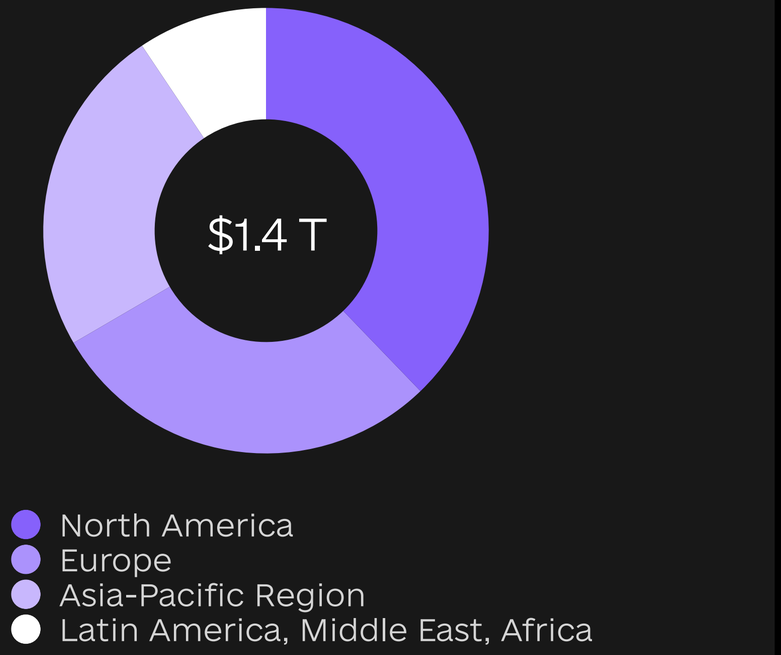
# THE GLOBAL BIOTECHNOLOGY MARKET IS REPORTING STEADY GROWTH DUE TO PUBLIC FOCUS ON ESG ASPECTS AND THE IMPACT OF THE PANDEMIC

The global biotechnology market responds to changes in the world and society. In 2018, the biotechnology market was projected to reach a size of only $0.6 trillion by 2025, growing at a 9,5% CAGR during 2019-2025. However, the COVID-19 pandemic and growing attention to ESG aspects became powerful catalysts for the industry, triggering its accelerated growth. These factors have stimulated investment in BioTech, increased demand for innovative solutions in medicine, AgriTech, and environmental projects, thus creating conditions for doubling the market by 2030.

## DYNAMICS OF THE GLOBAL BIOTECHNOLOGY MARKET, $ TRILLION



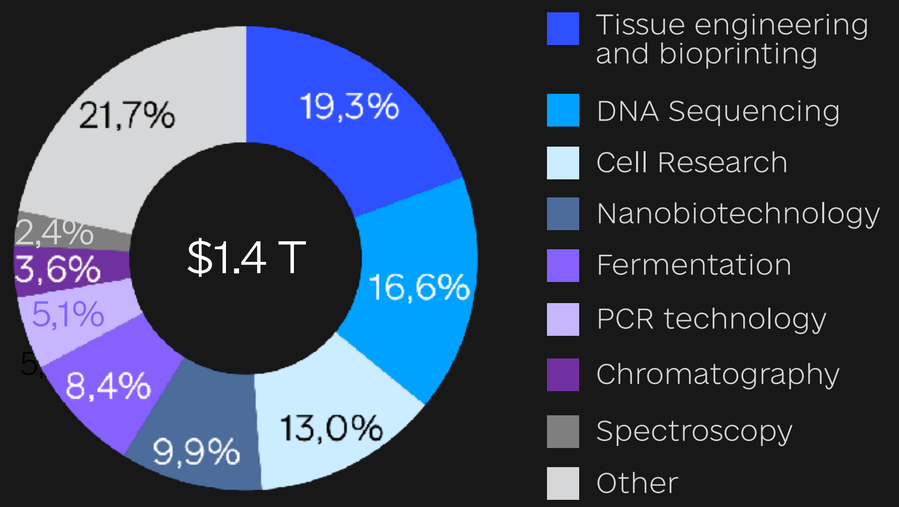

## GLOBAL BIOTECH MARKET BY REGION, 2023



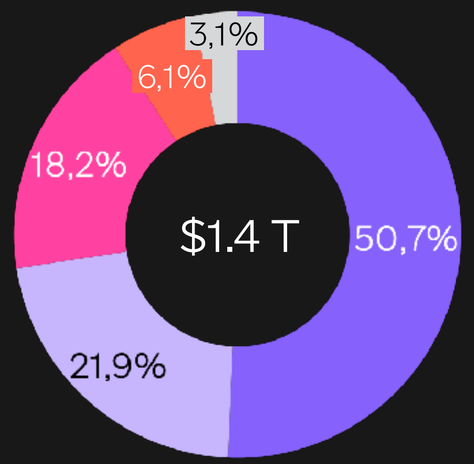
# IN 2023, HEALTHCARE SECTOR AND BIOTECHNOLOGIES, WHICH WERE ACTIVELY APPLIED IN THIS AREA, CONTINUED DOMINATION ON THE GLOBAL BIOTECH MARKET

## SEGMENTATION OF THE GLOBAL INNOVATIVE TECHNOLOGY MARKET[1]

### BY TECHNOLOGY




### BY APPLICATION AREA




| | CAGR 2021-2023 |
|---|---|
| Healthcare | +4,5% |
| Industrial processing | +11,7% |
| Agriculture | +1,0% |
| Bioinformatics | +4,6% |
| Other | -25,4% |

- Biotechnology innovations such as biosensors, VR applications, bioprinting, gene editing, etc. are expected to transform the global biotechnology market
- The versatility of tissue engineering and regeneration technologies, including their widespread use in the healthcare industry, will help maintain the market's dominant status during 2020-2023

- Despite the continuing dominance of the healthcare sector, the industrial processing sector has shown the fastest CAGR of 11.7% during 2021-2023. This growth is driven by the need to develop more eco-friendly solutions in the context of the sustainable development trend
- In addition to these sectors, biotechnology has applications in the defence industry, in particular, for biodefence, criminology and other strategic sectors

[1]Includes the use of biotechnology to create new products, processes and solutions

# BIOTECHNOLOGY ALLOWS TO IMPROVE HEALTHCARE TREATMENTS AND INCREASE AGRICULTURAL PRODUCTIVITY

## BIOTECH SEGMENTS BY APPLICATION AREA

### HEALTHCARE

Using biotechnology to improve the diagnosis, treatment and prevention of diseases

| | |
|---|---|
| 💉 BIOPRODUCTS | antibodies, growth hormones, vaccines, enzymes, blood plasma |
| 🧬 GENE THERAPY | correction of genetic defects using CRISPR, ZFN, TALEN and other methods |
| 🧬 CELL THERAPY | using stem cells for tissue regeneration |
| 🫀 BIOMATERIALS | bioprinting of organs for transplantation, production of tissues for wound treatment and orthopedic surgeries |
| 💊 CLINICAL TRIAL | organ-on-a-chip models, genetically modified organisms, computer modeling for clinical trials |
| 👤 PERSONALIZED MEDICINE | selection of treatment based on the patient's genetic profile |

### AGRICULTURE

Using biotechnology to improve plant yields and quality, as well as to adapt to climatic and environmental changes

| | |
|---|---|
| 🌾 GENETICALLY-MODIFIED CROPS | developing new crops enriched with nutrients (proteins, vitamins, etc.) and resistant to pests and diseases |
| 🦠 BIOFERTILIZERS | using microorganisms that improve the absorption of nutrients by plants |
| 🍼 BIOPESTICIDES | biological pest control agents |

# APPLICATION OF BIOTECHNOLOGY ALLOWS TO PERSONALIZE BIOLOGICAL INFORMATION AND CREATE ENVIRONMENTAL SOLUTIONS IN INDUSTRY

## BIOTECH SEGMENTS BY APPLICATION AREA

### BIOINFORMATICS

Individualized approach to the analysis and interpretation of genetic and biological data, as well as research of new biotechnological solutions

| | |
|---|---|
| 🧬 ANALYSIS AND RESEARCH | genome sequencing, identification of genes, their functions and mutations, analysis of proteins and their functions |
| 🗄️ DATABASES | collection and storage of genetic information, as well as development of SW for biodata analysis |
| 🔬 VR FOR DRUG DESIGN AND MOLECULAR VISUALIZATION | modeling potential new molecules, prediction of drug-protein interactions |
| 👤 PERSONALIZED MEDICINE | genetic tests for medical purposes, development of personalized medicines, food intolerance tests, gene therapy |

### INDUSTRIAL PROCESSING

Creating eco-friendly and sustainable solutions through the use of biological materials and biotechnology

| | |
|---|---|
| ⛽ BIOFUEL | production of biogas, bioethanol and biodiesel from agricultural crops |
| 🦠 BIOPOLYMERS | developing biodegradable plastics from crops and bacteria |
| 🌱 BIOREMEDIATION | using bacteria, fungi and plants to clean up contaminated environments (i.e. soil, water, air). |
| 🧪 INDUSTRIAL FERMENTATION | developing active substances from biological materials for detergents, paper production, etc. |

# KEY BIOTECH TRENDS THAT CREATE INNOVATIVE SOLUTIONS FOR MEDICINE, GENETICS AND THE DEVELOPMENT OF LIVING SYSTEMS

## KEY TRENDS IN THE GLOBAL BIOTECH MARKET

### ARTIFICIAL INTELLIGENCE

Using artificial intelligence in biotechnology helps to analyze large amounts of data, automate research and develop new methods of treatment and diagnosis

### GENOME EDITING

A technology that allows changing the genetic structure of organisms, which can be useful for the treatment of genetic diseases and the creation of accurate diagnostic methods

### STEM CELLS

Using stem cells that can differentiate into any type of body tissue opens up new opportunities for tissue and organ regeneration, as well as for research into the treatment of various diseases

### TISSUE ENGINEERING AND BIOPRINTING

Technologies that represent advanced methods of creating artificial tissues and organs by using advanced technologies to “print” living cells and biological materials into predefined shapes and structures

### CLINICAL PRE-TRIAL/TRIAL

The trend is focused on improving drug manufacturing processes, in particular through the use of biotechnology methods that allow creating more effective and safer medicines

### SYNTHETIC BIOLOGY (SynBio)

A BioTech branch that involves the creation and editing of living systems to create new or improve existing biological systems

# THE GLOBAL BIOTECH MARKET IS HOME TO A SIGNIFICANT NUMBER OF PLAYERS DEVELOPING INDUSTRIES AND OFFERING INNOVATIVE SOLUTIONS IN MEDICINE AND SCIENCE

## KEY PLAYERS ON THE GLOBAL BIOTECH MARKET

### HEALTHCARE

#### ELI LILLY

A pharmaceutical company known for developing innovative medicines for the treatment of diabetes, cancer and neurological diseases

#### PFIZER

A global pharmaceutical leader, developer of vaccines (including anti-COVID-19) and medicines for many diseases

#### ASTRAZENECA

The company is known for its medicines for cardiovascular, oncology and respiratory therapy

#### J&J

A pharmaceutical giant that produces medicines, medical equipment and consumer goods

#### ABBVIE

A pharmaceutical company specializing in biotechnology products, especially in immunology and oncology

#### ROCHE

Leader in cancer diagnosis and treatment. Develops innovative solutions in personalized medicine

### BIOINFORMATICS

#### IDBS

Offers solutions that promote the development of bioinformatics in the fields of healthcare, gene technology and medicine

#### ILLUMINA

Specialized in the development and production of genetic variation and function analysis systems

### TYPE OF TECHNOLOGY

- Tissue engineering and bioprinting
- Fermentation and biosynthesis
- DNA Sequencing
- PCR technology
- Cell Research
- Chromatography
- Nanobiotechnology
- Spectroscopy

# THE GLOBAL BIOTECH MARKET IS HOME TO A SIGNIFICANT NUMBER OF PLAYERS DEVELOPING INDUSTRIES AND OFFERING INNOVATIVE SOLUTIONS IN MEDICINE AND SCIENCE

## KEY PLAYERS ON THE GLOBAL BIOTECH MARKET

### AGRICULTURE

#### MONSANTO

One of the leading developers of genetically modified plants, seeds and plant protection products, focusing on increasing yields

#### SYNGENTA

Developing innovative seeds and plant protection products aimed at improving crop resistance to pests and diseases

#### PIONEER

A leader in the production of genetically modified seeds and the development of biological products for efficient agricultural production

#### CORTEVA

An innovative company specializing in solutions for plant protection and sustainable crops

### BIOINDUSTRY

#### NOVONESIS

A leader in the production of enzymes and microorganisms for the chemical and textile industries, biofuels, and water treatment

#### ROYAL DSM

Developing biotechnology solutions for the production of biopolymers, animal feed and construction materials

#### LANZATECH

Commercializing biosimilars and focusing on the development of one of the most diverse portfolios in the neuroscience industry

#### GEVO

Developing second-generation biofuels produced from renewable resources such as corn.

### TYPE OF TECHNOLOGY

- Tissue engineering and bioprinting
- Fermentation and biosynthesis
- DNA Sequencing
- PCR technology
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- Chromatography
- Nanobiotechnology
- Spectroscopy

# COUNTRIES AROUND THE GLOBE ARE IMPLEMENTING STRATEGIES TO DEVELOP BIOTECHNOLOGY THROUGH TAX INCENTIVES, RESEARCH SUPPORT AND INVESTMENT.

## SOME EXAMPLES OF THE IMPLEMENTATION OF BIOTECHNOLOGY IN THE WORLD

### 🇬🇧 GREAT BRITAIN

- In 2021, a strategy for Life Sciences Vision was adopted to develop the BioTech sector
- The government invests heavily in R&D, with such expenditures amounting to 2.9% of GDP in 2021. From 2011 to 2021, R&D expenditures as a share of GDP grew by 0.65 percentage points
- The government uses fiscal measures to stimulate the development of biotechnology. For instance, SME engaged in research and development can enjoy tax incentives of up to 230% of R&D expenditures

### 🇩🇪 GERMANY

- In 1996, the government initiated the BioRegio program, which was aimed at developing BioTech clusters. As of 2022, there were 24 BioTech clusters in Germany
- As of March 2024, a strategy for the development of the biotechnology industry, the Agenda von der Biologie zur Innovation “BIO-IT”, as well as a number of initiatives aimed at strengthening the country's innovation potential in BioTech are in the process of development
- Businesses engaged in biotechnology research and development may receive tax incentives in the amount of 25% of R&D expenses

### 🇮🇳 INDIA

- To develop the BioTech sector, the BIRAC agency was established in 2012, and in 2021 the National Biotechnology Development Strategy was developed by the Department of Biotechnology.
- The country is attractive for US and European companies to set up production facilities due to low R&D costs, skilled labor, and diversity of biological resources
- Tax incentives for research and development range from 100% to 200% of R&D expenses

# 1.2 BIOTECH SECTOR DEVELOPMENT IN UKRAINE

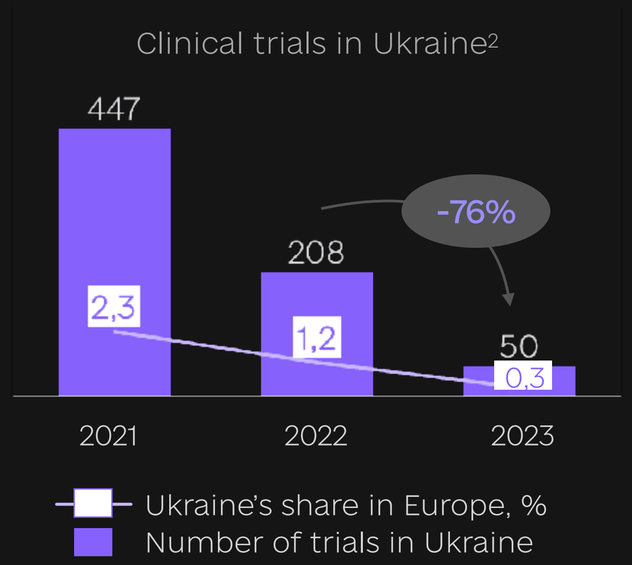
# THE DEVELOPMENT OF BIOTECH IN UKRAINE LAGS FAR BEHIND THE LEVEL OF THE LEADING COUNTRIES, BUT SHOWS POTENTIAL IN A RANGE OF TECHNOLOGIES

The need to develop biotechnology in Ukraine is driven by a number of challenges of a full-scale war, which create the need for bioengineering technologies, as well as environmental challenges such as climate change, soil degradation, water pollution, energy crisis, etc. However, according to the BioTech Innovation Index[1], Ukraine is ranked 53rd out of 54 countries surveyed with 12,5 points out of 100.

In 2022, only 16,2% of Ukraine's publications in the life sciences were related to biotechnology. Furthermore, the total number of clinical trials in Ukraine has been gradually decreasing, which indicates a low focus on the development of innovations, including those related to biotechnology in the healthcare sector. In contrast, the bioenergy industry in Ukraine has intensified, although it remains at a lower development level compared to European countries.

## HEALTHCARE

Clinical trials in Ukraine[2]




## INDUSTRIAL PROCESSING

Ukrainian bioenergy sector in 2022

**0,3 GW** Installed capacity, +18,6% CAGR 2018-2022

🇬🇧 7,3 GW 🇵🇱 1,8 GW 🇪🇺 11,7 GW

**9,0%** Share of bioenergy in total generation output[3]

🇬🇧 10,3% 🇵🇱 20,7% 🇪🇺 17,7%

## AGRICULTURE

Based on BTU-Biotech data for 2023

**24%** of Ukrainian agricultural holdings apply biotechnology in production

**+39,9%** Increase in the number of agricultural sector enterprises in Ukraine that used biological products compared to 2022

[1]Research by thinkBiotech LLC, USA; [2]WHO data; [3]Latest data of International Energy Agency

# THE SIGNIFICANT ECONOMIC AND SOCIAL ROLE OF BIOTECH IN UKRAINE REQUIRES INCREASED ATTENTION TO THE MOST IMPORTANT AND PROMISING BIOTECHNOLOGIES

Among the analysed biotechnology technologies in Ukraine, the most promising for further development are the following areas:

## TISSUE ENGINEERING AND REGENERATION

Significantly impacts the healthcare sector as it is used in the development of innovative treatments and contributes to the agricultural industry for the development of new crops

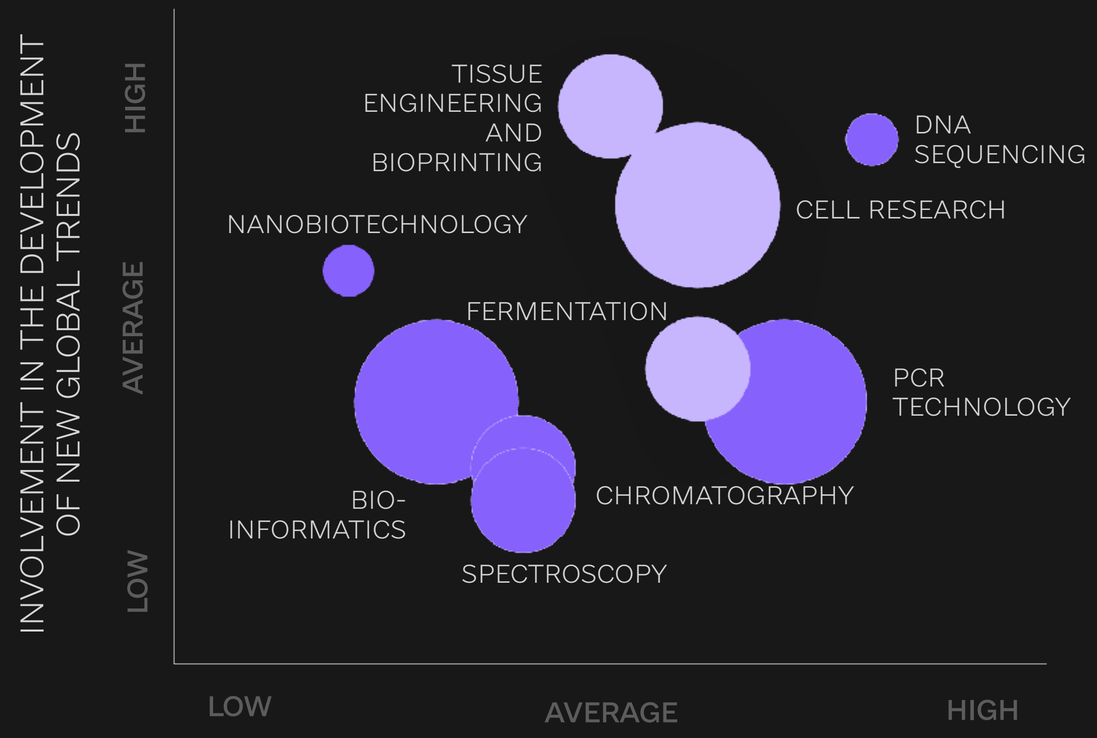
## CELL RESEARCH

A technology opens up new opportunities for personalised medicine by creating individual models of patients' diseases. In addition, it contributes to the development of biopharmaceuticals by enabling the efficient production of drugs and their testing in cellular models

## FERMENTATION

The technologies are widely used in agriculture, bioprocessing, biofuel production, and other industrial sectors in Ukraine

## DEVELOPEMNT OF KEY BIOTECHNOLOGIES IN UKRAINE



# BIOTECHNOLOGY IS THE FOCUS OF RESEARCH BY A NUMBER OF COMPANIES AND STATE INSTITUTIONS IN UKRAINE IN THE HEALTHCARE AND AGRICULTURAL SECTORS.

## CERTAIN PLAYERS ON THE UKRAINIAN BIOTECH MARKET

### HEALTHCARE

**FARMAK**

A pharmaceutical company with a separate biotechnology development unit

**BIODROOK**

A manufacturer of implants based on biopolymer materials and 3D printing that can be replaced by bone tissue

**SMARTCELLS**

A BioTech company with a focus on regenerative cell medicine

**YURIA-PHARM**

A pharmaceutical company with a strong focus on development of recombinant protein-based therapeutics

### AGRICULTURE

**BTU BIOTECH**

A BioTec company that produces microbial products for the agricultural sector

**BIOSENS**

A company specializing in food safety testing

**NATIONAL ACADEMY OF SCIENCES OF UKRAINE[1]**

Certain institutes are engaged in R&D in biotechnology for agricultural plants and feed

**CHEMLABORREACTIV**

A company providing food quality control

### TYPE OF TECHNOLOGY

- Tissue engineering and bioprinting
- Fermentation and biosynthesis
- DNA Sequencing
- PCR technology
- Cell Research
- Chromatography
- Nanobiotechnology
- Spectroscopy

[1]Institute of Food Biotechnology and Genomics, as well as Institute of Plant Physiology and Genetics
[2]The types of technology for individual companies are categorized according to open source data

# THE USE OF BIOTECHNOLOGY IN INDUSTRY IS AT AN EARLIER DEVELOPMENT STAGE COMPARED TO OTHER SECTORS

## CERTAIN PLAYERS ON THE UKRAINIAN BIOTECH MARKET

### BIOINFORMATICS

**RECEPTOR.AI** SW

Developer of an AI-powered platform that identifies biological products with the potential to become new medicines

**DEEPTRAIT** SW

A startup developing AI-based genome analysis tools

**EXPLOGEN**

Biologically active compounds discovery from bacterial sources

**SYSBIO**

Focuses on research in synthetic biology and genetic studies.

### INDUSTRIAL PROCESSING

**ENZYM GROUP**

Production of fermentation-based food additives and flavors

**ПРО-ЕНЕРДЖІ**

Renewable energy and water treatment solutions

**UTC**

Introducing biotechnology at companies to produce biofuels, biofeed, biofertilizers, etc

**S.LAB**

Developer of eco-friendly packaging from mushrooms and hemp

TYPE OF TECHNOLOGY

- Tissue engineering and bioprinting
- Fermentation and biosynthesis
- DNA Sequencing
- PCR technology
- Cell Research
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- Spectroscopy

[1]The types of technology for individual companies are categorized according to open source data

# 1.3 BIOTECH STRENGTHS AND WEAKNESSES IN UKRAINE

# UKRAINE HAS A HIGH SCIENTIFIC POTENTIAL IN THE FIELD OF BIOTECHNOLOGY, WHICH CREATES A STRONG BASIS FOR ENHANCING THE DEVELOPMENT OF THE SECTOR

## UKRAINE'S STRENGTHS FOR THE DEVELOPMENT OF THE TECHNOLOGY SECTOR

- Developed scientific potential in BioTech, supported by a number of specialized institutions and private educational initiatives, e.g. "BioSchool" from BioPharma and BioTech courses from Enzym Group
- Large agricultural potential and experience in the use of fermentation technologies create conditions for the active development of bioenergy production and biotechnology in agriculture
- Free access to natural resources and biodiversity in Ukraine contributes to the efficient use of available resources for scientific research and development of biotechnology products
- Lower cost of research in the biotechnology industry compared to the EU and North America, which can create a competitive advantage in terms of cost of innovation on international markets
- Highly developed pharmaceutical industry serves as a basis for innovation, as it creates a solid knowledge base for further development and implementation of innovative solutions in the biopharmaceutical sector
- The developed IT industry, as well as a network of incubators and accelerators for IT and BioTech startups, such as the Ukrainian Startup Fund, Yep!, CfE accelerator and others, expand the opportunities for the development of bioinformatics in Ukraine

# DESPITE THE EXISTING SCIENTIFIC POTENTIAL IN THE BIOTECH, THE LACK OF FINANCIAL AND REGULATORY SUPPORT HINDERS THE DEVELOPMENT OF THE SECTOR

## UKRAINE'S WEAKNESSES FOR THE DEVELOPMENT OF THE TECHNOLOGY SECTOR

- Lack of financial, scientific and technical support from the state, resulting in limited number of research projects in the field of biotechnology implemented by scientific institutes and HEIs
- Lack of in-depth experience in commercializing BioTech solutions and weak IP protection, which hinders the launch of innovative products on the market and their active use in economic sectors
- An outdated legislative framework for major research trends, such as genome editing, clinical trials, etc., that is not in line with the rapid pace of scientific development and international standards
- Limited domestic market due to low solvency of the population and conservatism of key industries that are end users of biotechnology
- Complex and lengthy registration and licensing procedures for innovative biotechnology products, especially in the pharmaceutical sector, restraining the innovations in the market
- Unstable government policies and unpredictable changes in legislation that complicate the process of planning research and implementation of new biotechnology

# 1.4

# BARRIERS & OPPORTUNITIES TO BOOST BIOTECH DEVELOPMENT IN UKRAINE

# INSUFFICIENT DEVELOPMENT OF INFRASTRUCTURE AND REGULATORY CAPABILITIES IN UKRAINE HINDERS INTERNATIONAL COOPERATION AND LIMITS THE INVOLVEMENT OF SCIENTISTS IN THE FIELD OF BIOTECHNOLOGY

## BARRIERS TO THE DEVELOPMENT OF THE TECHNOLOGY SECTOR IN UKRAINE

### OUTFLOW OF SCIENTIFIC PERSONNEL

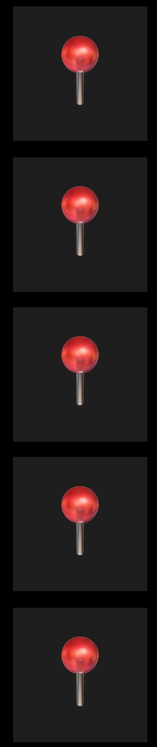
A significant number of scientists and researchers find more favorable conditions for conducting research in the field of BioTech abroad

### LACK OF COOPERATION AMONG ECOSYSTEM PLAYERS

Lack of cooperation between science, business and the state hinders the commercialization of research and the introduction of new biotechnologies

### WEAK PROTECTION OF THE IP

The low level of IP rights protection in Ukraine does not provide a secure environment for biotechnology developers, negatively affecting their interest in developing the industry



### LACK OF MODERN EQUIPMENT

Outdated scientific and laboratory equipment and necessity of its audit reduces the innovativeness of biotechnology developments, that affects Ukraine's competitiveness in international markets

### LIMITED ACCESS TO SCIENTIFIC INFRASTRUCTURE

The lack of innovation infrastructure open to business (science parks, innovation zones, etc.) reduces opportunities for research and implementation of developments in the real sector of the economy

# IMPROVING THE REGULATORY FRAMEWORK AND ACTIVE COOPERATION IN THE BIOTECH SECTOR WILL PROMOTE R&D AND COMPETITIVENESS OF INNOVATIONS

## KEY OPPORTUNITIES TO PROMOTE THE DEVELOPMENT OF THE SECTOR

01

### FAVORABLE REGULATORY ENVIRONMENT

- Reducing the time for registration of biotechnology products and introducing transparent procedures for conducting clinical trials
- Harmonisation of Ukrainian legislation with EU norms to ensure compliance of biotechnology products with international standards and expand export opportunities in the EU market
- Developing a legal framework for public-private partnerships in the field of biotechnology

### FINANCIAL INCENTIVES

### DEVELOPMENT OF INFRASTRUCTURE

02

### PARTNERSHIP DEVELOPMENT

- Integrating Ukrainian BioTech companies into EU cooperation and R&D support programs, in particular Horizon Europe
- Signing memorandums with domestic and international universities and research institutions for cooperation in the BioTech area
- Implementng joint R&D projects of Ukrainian BioTech companies and scientists with international experts

# FINANCIAL INCENTIVES AND INFRASTRUCTURE DEVELOPMENT WILL CREATE OPPORTUNITIES FOR BIOTECH PLAYERS TO DEVELOP THEIR INNOVATIVE IDEAS IN UKRAINE

## KEY OPPORTUNITIES TO PROMOTE THE DEVELOPMENT OF THE SECTOR

### FAVORABLE REGULATORY ENVIRONMENT

- Introducing grant programs for BioTech startups and tax incentives for companies conducting research in the field of biotechnology
- Introducing a mechanism of state guarantees for foreign investments in the Ukrainian BioTech industry

### PARTNERSHIP DEVELOPMENT

- Establishment of centers for collective use of equipment for the scientific community and business in the field of BioTech and Life Sciences
- Conservation and modernization of laboratory equipment in higher education institutions and research institutions conducting research in the field of BioTech

### FINANCIAL INCENTIVES

- Introduce a single electronic platform for procurement coordination and transparent placement of public orders. Ensuring the implementation of government orders for BioTech solutions

03

### INFRASTRUCTURE DEVELOPMENT

- Facilitating the launch of pilot production to scale up new biotechnology developments in Ukraine

04

2

# KEY PROJECTS: BIOTECH

# THE BIOTECH INDUSTRY STRATEGY ENVISAGES 6 PRIORITY AREAS AND IDENTIFIES 3 TOP PROJECTS FOR PRIORITY IMPLEMENTATION IN UKRAINE

**PRIORITY AREAS**

- R&D hub for biotechnology
- Biobank of materials
- Bioprinting
- DNA Sequencing and bioinformatics
- Biotechnology for agriculture
- Fermented products and biosynthesis

**TOP PROJECTS**

BIO-PHARMACEUTICAL MANUFACTURING

TISSUE ENGINEERING TECHNOLOGIES

BIOCLUSTER

# 2.1 TECHNOLOGY DEVELOPMENT PRIORITIES: BIOTECH

# DEVELOPMENT OF INNOVATION INFRASTRUCTURE IN UKRAINE WILL ACCELERATE AND MODERNIZE RESEARCH IN THE BIOTECHNOLOGY AREA

## TECHNOLOGY DEVELOPMENT PRIORITIES

### 01 R&D HUB FOR BIOTECHNOLOGY

BUILDING A RANGE OF R&D SPACES FOR DIFFERENT BIOTECH AREAS TO PROVIDE RESEARCH IN COOPERATION WITH LEADING UNIVERSITIES, RESEARCH INSTITUTIONS AND BUSINESSES

#### ADVANTAGES

- Providing access to advanced equipment for leading scientists, startups and companies
- Quick prototyping and testing of new technologies, which reduces the time to find innovations
- Enhancement of innovative developments through the implementation of joint business and science projects

#### KEY MEASURES

- Establishing cooperation with key stakeholders of the future R&D hub
- Audit of the existing infrastructure base that will become the basis for the hub and modernization of laboratory equipment
- Introducing financial support mechanisms, including partial reimbursement of expenses for joint R&D projects

### 02 BIOBANK OF MATERIALS

SPECIALIZED STORAGE FOR PRESERVING BIOLOGICAL SAMPLES (TISSUES, CELLS, DNA, ORGANS, FLUIDS, ETC.) FOR FURTHER RESEARCH

#### ADVANTAGES

- Improving the accuracy of disease diagnosis by analyzing samples in biobanks
- Promoting scientific discoveries through the ability to conduct research in biopharmaceuticals and genetics based on biological materials
- Possibility of long-term storage of biological samples

#### KEY MEASURES

- Developing clear regulatory standards to ensure the confidentiality of biobank and material donor data
- Implementing unified rules for the storage and transportation of biological samples in accordance with international standards
- Attracting investment for the development of biobanks and bioinformatic solutions

# THE DEVELOPMENT OF BIOPRINTING AND GENOME SEQUENCING TECHNOLOGIES WILL CONTRIBUTE TO THE PERSONALIZATION OF MEDICINE

## TECHNOLOGY DEVELOPMENT PRIORITIES

### 03 BIOPRINTING

CREATION OF TISSUES AND ORGANS THROUGH 3D PRINTING BASED ON BIOLOGICAL MATERIALS SUCH AS CELLS, BIOPOLYMERS, AND OTHERS

#### ADVANTAGES

- The ability to quickly create prototypes of tissues and organs for use in regenerative medicine
- Creating the ability to conduct clinical pre-trials on artificial organs, reducing the need for animal testing
- Optimizing the cost of producing complex structures and reducing resource use

#### KEY MEASURES

- Investing in research on new biopolymers and cellular structures for bioprinting
- Partnering with medical institutions to test and implement technologies
- Developing training and re-skilling programs for specialists in the area of bioprinting

### 04 DNA SEQUENCING AND BIOINFORMATICS

TECHNOLOGY BASED ON GENOMIC ANALYSIS TO CREATE INDIVIDUALIZED TREATMENT AND PREVENTION PLANS

#### ADVANTAGES

- Reducing side effects and increasing the effectiveness of therapy due to precise drug selection
- Possibility to predict the risk of developing diseases and increase life expectancy in Ukraine
- Early diagnosis of rare and complex diseases that cannot be diagnosed by traditional methods

#### KEY MEASURES

- Opening a genetic laboratory specializing in DNA sequencing
- Integrating genetic information into medical records and electronic systems
- Organizing information campaigns to popularize the benefits of genome analysis

# WIDESPREAD USE OF BIOTECHNOLOGY IN THE AGRICULTURAL SECTOR AND INDUSTRIAL PROCESSING WILL CONTRIBUTE TO THE INNOVATIVE GROWTH OF INDUSTRIES

## TECHNOLOGY DEVELOPMENT PRIORITIES

### 05 BIOTECHNOLOGY FOR AGRICULTURE

BIOTECHNOLOGIES AIMED AT INCREASING YIELDS, PROTECTING PLANTS AND REDUCING NEGATIVE ENVIRONMENTAL IMPACT

#### ADVANTAGES

- Developing climate-resistant plant varieties helps ensure stable yields even in adverse conditions
- Reducing the use of chemicals that have a negative impact on soil and water resources
- Opportunity to improve product quality by increasing the content of nutrients in agricultural crops

#### KEY MEASURES

- Modernizing regulatory standards for the use of biotechnology in agriculture
- Providing grant programs to agro-industrial companies engaged in R&D in BioTech
- Introducing tax incentives for farmers switching to biotechnology

### 06 FERMENTED PRODUCTS AND BIOSYNTHESIS

APPLICATION OF FERMENTATION TECHNOLOGIES TO ENHANCE THE PRODUCTION OF BIODEGRADABLE POLYMERS, BIOENERGY, ANTIBIOTICS AND OTHER FERMENTED PRODUCTS

#### ADVANTAGES

- Environmental benefits - fermentation and biosynthesis is more environmentally friendly processes than chemical synthesis
- Reduced costs –fermentation and biosynthesis processes have lower costs than traditional chemical methods, making them more cost-effective
- High efficiency – microorganisms can quickly process large volumes of raw materials, which increases production efficiency

#### KEY MEASURES

- Opening a genetic laboratory specializing in DNA sequencing, storage and analysis of genetic information
- Integration of genetic information into medical records and electronic systems
- Organization of information campaigns to popularize the benefits of genome analysis

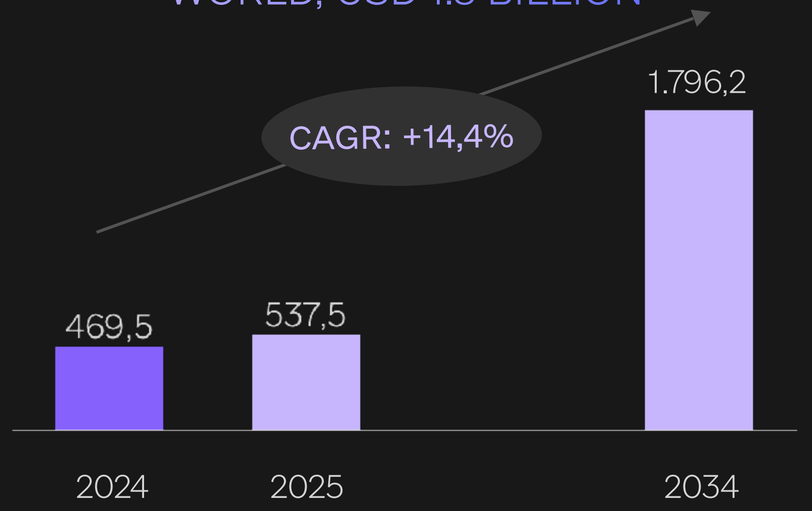
# 2.2

# TOP PROJECTS: BIOTECH

# TOP PROJECT 1 - BIOPHARMACEUTICAL PRODUCTION

## DEVELOPMENT OF THE BIOPHARMACEUTICAL SEGMENT IN THE WORLD

### DEVELOPMENT OF THE BIO-PHARMACEUTICALS SEGMENT IN THE WORLD, USD 1.8 BILLION




The biopharmaceutical industry develops medicines that are produced by living cells or organisms and created through biological processes. The industry includes a wide range of biological products, such as vaccines, gene therapy, biotissues, blood components, and others,. One of the most common biological products are monoclonal bodies, which are used to threat chronic diseases. Their advantage is high precision, as they affect only targeted cells without harming healthy ones

### GOVERNMENT INCENTIVES FOR BIOPHARMACEUTICAL DEVELOPMENT

- 25% tax credits for clinical trials
- State funding for the development of biotechnology vaccines and the creation of BioTech centers
- Public funding through grants and loans, as well as public-private partnerships

The largest region in 2024

46%

North America

The largest segment in 2024

38%

Monoclonal antibodies

### EXAMPLES OF BIOPHARMACEUTICAL COMPANIES

**SANOFI**

developments in the field of immunotherapy

FRANCE

**ROCHE**

focus on monoclonal bodies and immunotherapy

SWITZERLAND

**BIOGEN, INC.**

biological products in the field of neurology.

USA

**BAYER**

recombinant proteins, antibodies and vaccines

GERMANY

# TOP PROJECT 1 - BIOPHARMACEUTICAL PRODUCTION

## GROWTH DRIVERS OF BIOPHARMACEUTICAL PRODUCTION IN THE WORLD

### DEVELOPMENT OF BIOENGINEERING TECHNOLOGIES

Technologies, such as CRISPR-Cas9[1], are transforming approaches to the treatment of genetic diseases and creating new markets for biopharmaceutical products

### CONSEQUENCES OF THE COVID-19 EPIDEMIC

The emergence of new infectious diseases, such as COVID-19, has necessitated the rapid development of vaccines and antiviral drugs, and has stimulated public and private investment in modernizing biopharmaceutical infrastructure and expanding production capacity

**GLOBAL GROWTH DRIVERS**

### RISING DEMAND FOR MONOCLONAL ANTIBODY (MAB) TREATMENT

MAb's are used to treat cancer, autoimmune diseases and viral infections. The production of mAbs requires high-tech equipment and bioreactors, specialized laboratories for large-scale production of antibodies, and optimization of biotechnological processes to reduce production costs

### FIGHTING ANTIMICROBIAL RESISTANCE (AMR)

WHO programmes and private sector initiatives are aimed at funding research into new antibiotics and antimicrobials, developing alternative therapies, including phagotherapy and immunomodulators, and introducing government support mechanisms for pharmaceutical companies working to combat AMR

[1]A biological system for making precise changes to DNA

# TOP PROJECT 1 - BIOPHARMACEUTICAL PRODUCTION

## DRIVERS AND CONSTRAINTS TO DEVELOPMENT IN UKRAINE

### DRIVERS OF DEVELOPMENT IN UKRAINE

- Developed agricultural base provides sources for the creation of bioactive components
- The pharmaceutical sector is recognized as strategically important for the provision of medicines to the population in times of war
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### CONSTRAINTS TO DEVELOPMENT IN UKRAINE

#### 👉 UNDERDEVELOPED MEDICAL INFRASTRUCTURE

Insufficient number of modern laboratories and GMP-compliant manufacturing facilities reduces the ability to produce high-quality biological products

#### 👉 HIGH COST OF DEVELOPMENT

The development and patenting of new biological products requires a long-term injection of significant financial resources, which is a challenge for the Ukrainian market

#### 👉 LACK OF PERSONNEL

The outflow of talented professionals abroad due to low wages, limited career opportunities and insufficient funding for research

#### 👉 LOW LEVEL OF TRUST IN BIOLOGICAL PRODUCTS

Lack of awareness of the public and healthcare professionals about the benefits of biotechnology causes distrust in their use

# TOP PROJECT 1 - BIOPHARMACEUTICAL PRODUCTION

## ASSESSMENT OF THE FEASIBILITY OF IMPLEMENTING THE TOP PROJECT IN UKRAINE

### REQUIRED MEASURES

**IMPROVING THE LEGAL AND REGULATORY FRAMEWORK**

- Improving the legislation regulating pharmaceutical activity and the patenting
- Harmonization of Ukrainian legislation with EU standards

**DEVELOPING SECTORAL COOPERATION**

- Developing cooperation between pharmaceutical manufacturers and research institutions for joint R&D
- Establishing cooperation with universities in the training of BioTech specialists

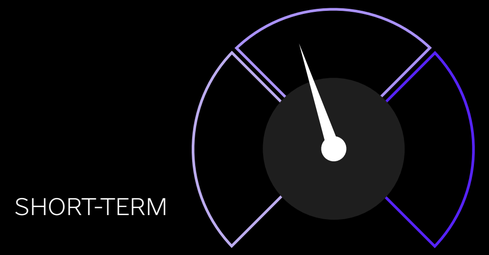
**STRENGTHENING GOVERNMENT SUPPORT**

- Providing state loan programs for the development of biopharmaceutical production
- Launching grant programs to finance R&D in BioTech

### EXPECTED DURATION OF THE TOP PROJECT

Medium-term

3-5 YEARS



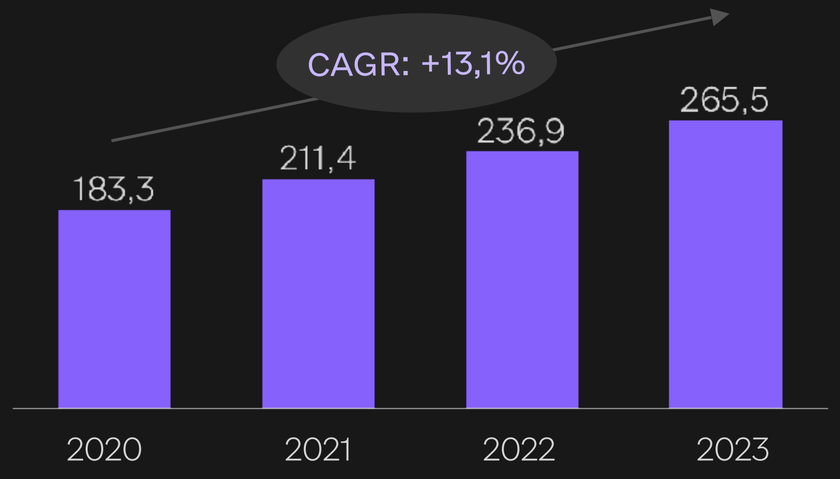

### EXPECTED EFFECT

- ✓ Increasing the level of scientific research to create new, more effective and innovative medicines
- ✓ Providing the domestic market with biopharmaceuticals to reduce dependence on imports
- ✓ Increasing the volume of domestic biopharmaceutical production and expanding Ukraine’s presence in the global pharmaceutical market, strengthening the country’s innovation potential through the development of advanced biotechnologies and international integration of the Ukrainian BioTech sector

# TOP PROJECT 2 - TISSUE ENGINEERING TECHNOLOGIES

## DEVELOPMENT OF THE TISSUE ENGINEERING SEGMENT IN THE WORLD

### SIZE OF THE TISSUE ENGINEERING MARKET, IN THE WORLD, BILLION USD




Tissue engineering is the technology for creation and modification of biological tissues by using stem cells, growth factors, differentiated cells, etc. The technology has the widest application in the healthcare sector, namely in orthopedics and dentistry for bone and cartilage regeneration, as well as in reconstructive medicine for restoration of damaged skin. In addition, it is being actively used in the agricultural industry in the areas of meat cultivation, genetic modification and plant propagation

### THE LATEST INNOVATIVE DEVELOPMENTS

**“Smart” biomaterials** are tissues that can respond to external stimuli such as temperature, pH, and electric fields, imitating the natural behavior of tissues

**Organ-on-a-chip** – creation of miniature tissue models on chips that imitate the natural behavior of tissues for research in controlled laboratory conditions

The largest region in 2023

38%

North America

The largest segment in 2023

31%

Orthopedic product

### COMPANIES OPERATING IN THE FIELD OF TISSUE ENGINEERING

**REGENERATIVE MEDICINE GROUP**
creation of human organs for transplantation

**MOSA MEAT**
cultured beef based on tissue engineering

**PLANTFORM CORPORATION**
Changes in the genetic characteristics of agricultural plants

# TOP PROJECT 2 - TISSUE ENGINEERING TECHNOLOGIES

## GROWTH DRIVERS OF TISSUE MEDICINE TECHNOLOGIES IN THE WORLD

### TECHNOLOGICAL INNOVATIONS

The introduction of the latest technologies, such as 3D printing and bioengineering, is helping to create more effective solutions in regenerative medicine

### LACK OF DONOR MATERIAL FOR TRANSPLANTATION

According to the WHO, only 10% of the global need for organ transplants is met worldwide, creating an urgent need to develop alternative methods, such as bioprinting

**GLOBAL GROWTH DRIVERS**

### INCREASE IN THE NUMBER OF CHRONIC DISEASES AND INJURIES

The increase in the number of patients with chronic diseases and injuries raises the need for effective treatment methods, including stem cells and biomaterials

### DEMOGRAPHIC CHANGES

The increase in life expectancy and, as a result, the aging of the population, increases the need for methods of tissue and organ restoration

# TOP PROJECT 2 - TISSUE ENGINEERING TECHNOLOGIES

## DRIVERS AND CONSTRAINTS TO DEVELOPMENT IN UKRAINE

### DRIVERS OF DEVELOPMENT IN UKRAINE

- The cost of research, development and implementation of innovations in Ukraine is lower than in European countries or the United States
- The need to restore the health of veterans and people affected by military operations
- The developed IT industry allows to create technological solutions that integrate with tissue medicine

### DEVELOPMENT CONSTRAINTS IN UKRAINE

👉 **DIFFICULTY IN ACCESSING THE LATEST TECHNOLOGIES**

The high cost of equipment and materials required for tissue engineering makes it difficult to integrate innovative solutions in Ukraine

👉 **REGULATORY BARRIERS**

Complex and lengthy approval procedures for new medical technologies can slow down their implementation

👉 **LACK OF MODERN INFRASTRUCTURE**

Insufficient number of specialized laboratories and centers slows down the development of the industry

👉 **LOW LEVEL OF COOPERATION BETWEEN SCIENCE AND BUSINESS**

Limited opportunities for integrating scientific discoveries into business processes and medical institutions, including military hospitals, hinder the development of the industry

# TOP PROJECT 2 - TISSUE ENGINEERING TECHNOLOGIES

## ASSESSMENT OF THE FEASIBILITY OF IMPLEMENTING THE TOP PROJECT IN UKRAINE

### REQUIRED MEASURES

**ENHANCING THE REGULATORY ENVIRONMENT**

- Introducing accelerated approval procedures for innovative biotechnologies
- Harmonizing the legislation with international standards for medical devices and supporting in FDA accreditation

**DEVELOPING RESEARCH INFRASTRUCTURE**

- Providing universities and research institutions with modern research equipment
- Launching shared laboratories in cooperation with the private sector and international partners

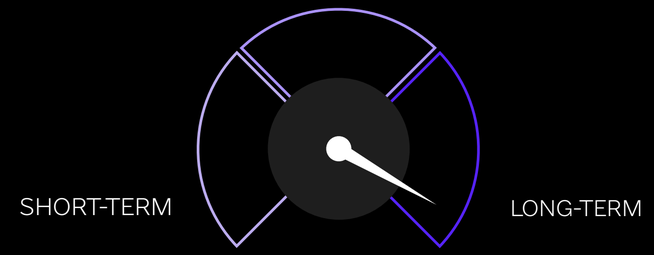
**EDUCATIONAL PROGRAMS AND TRAININGS**

- Developing master's programs in tissue medicine
- Organizing internships for Ukrainian scientists and medical specialists in international research centers

### EXPECTED DURATION OF THE TOP PROJECT

Long-term

7-10 YEARS



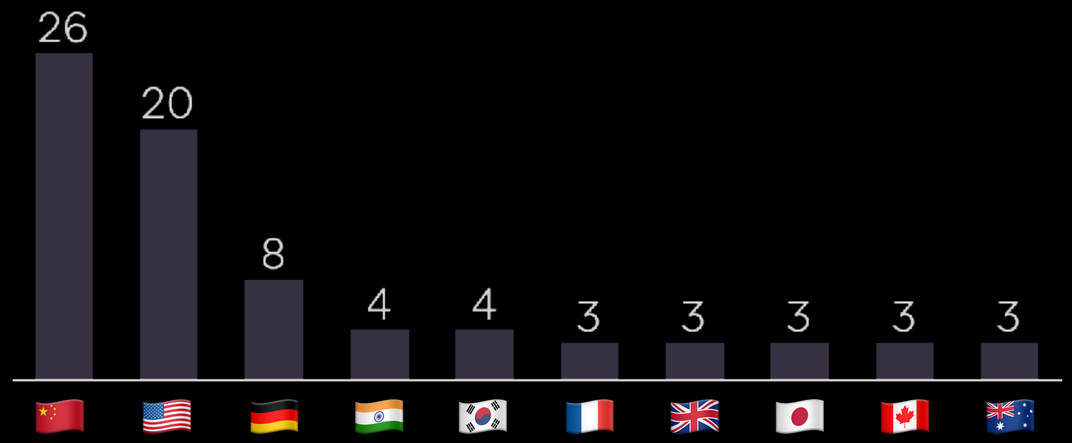

### EXPECTED EFFECT

- ✓ Reduction of rehabilitation time, reduction of complications and mortality of patients with chronic and traumatic conditions
- ✓ Reduction of patients' expenses for long-term treatment and rehabilitation
- ✓ The development of high-tech medicine and the creation of modern research centers will help reduce labor migration among healthcare workers

# TOP PROJECT 3 – BIOCLUSTER

## DEVELOPMENT OF THE BIOCLUSTER SEGMENT IN THE WORLD

### TOP-10 COUNTRIES BY LOCATION OF TOP-100 TECHNOLOGY CLUSTERS OF THE WORLD IN 2024




| Asia | North America | Europe |
|---|---|---|
| 40 | 23 | 17 |

### KEY PLAYERS IN THE CLUSTERS

- Research and development institutions
- Financial institutions (state, private investment funds)
- Technology developers
- End users of technologies

Clusters are a common tool for bringing together government, science, and business to scale up technologies, establish international relations, and promote a particular industry. Most of the world's leading clusters focus on several industries, including BioTech.

### SOME BIOCLUSTERS IN THE WORLD AND THE SHARE OF REGISTERED PATENTS IN THE BIOTECH INDUSTRY IN 2024

| Boston-Cambridge | Washington | Cambridge |
|---|---|---|
| 17% | 11% | 11% |

| Amsterdam–Rotterdam | London | Chengdu |
|---|---|---|
| 8% | 6% | 5% |

# TOP PROJECT 3 – BIOCLUSTER

## DRIVERS OF BIOCLUSTER GROWTH IN THE WORLD

### PROGRESS IN BIOTECHNOLOGY

The development of synthetic biology and the ability to program microorganisms to produce proteins, medicines, and bioplastics is increasing demand for biocluster infrastructure

### DIGITALIZATION AND USE OF BIG DATA

The growing amount of biological data requires the creation of bioclusters that provide access to computing capacities and artificial intelligence for data analysis

**GLOBAL GROWTH DRIVERS**

### FOCUS ON ENVIRONMENTAL SUSTAINABILITY

The growing use of biological materials in production, such as bioplastics and biofuels, is driving the formation of clusters aimed at creating sustainable solutions

### ED FOR LOCALIZED PRODUCTION

Crises in global supply chains due to geopolitical events have emphasized the importance of local production of medicines and vaccines

# TOP PROJECT 3 – BIOCLUSTER

## DRIVERS AND CONSTRAINTS TO DEVELOPMENT IN UKRAINE

### DRIVERS OF DEVELOPMENT IN UKRAINE

- Access to international grants from the EU to support biotechnology research
- Existing pharmaceutical companies in Ukraine that can become key participants in the biocluster
- Biodiversity Ukraine creates opportunities for the development of BioTech solutions within the biocluster

### CONSTRAINTS TO DEVELOPMENT IN UKRAINE

#### 👉 LOW LEVEL OF COOPERATION

Insufficient coordination and interaction between the government, scientific institutions, startups and businesses may hinder the creation of an effective biocluster ecosystem and further commercialization of biotechnology developments

#### 👉 INCOMPLETE REGULATORY AND LEGAL BASIS

Complicated certification and licensing procedures and an imperfect IP protection system slow down the development and introduction of new biotechnologies to the market, while the lack of full harmonization of the regulatory framework with EU requirements limits exports

#### 👉 INSUFFICIENT LEVEL OF INNOVATION CULTURE

Low level of interest in innovative products and insufficient awareness of the benefits of biotechnology in the business environment and society may hinder the effective operation and development of the biocluster and limit the domestic market for BioTech solutions

#### 👉 INSUFFICIENT NUMBER OF VENTURE CAPITAL FUNDS

Most BioTech startups do not have access to the necessary resources to fund research, clinical trials or scale up production. In the absence of venture capital funding, companies rely on their own funds or grant funding, which is not always stable or sufficient

# TOP PROJECT 3 – BIOCLUSTER

## ASSESSMENT OF THE FEASIBILITY OF IMPLEMENTING THE TOP PROJECT IN UKRAINE

### REQUIRED MEASURES

**CREATING A VIRTUAL PLATFORM FOR COLLABORATION**

- Developing an interactive portal
- Ensuring communication and cross-segment cooperation between representatives of business, startups, science and the state

**CONDUCTING CONFERENCES, SEMINARS, WORKSHOPS AND OTHER EVENTS**

- Providing legal advice and marketing services to promote effectively innovations in the market
- Conducting events to find investors and attract funding for technology startups based on the biocluster

**ENGAGING LEADING EXPERTS IN THE BIOCLUSTER ECOSYSTEM**

- Providing expert advice on product improvement and compliance with global requirements
- Assisting in finding international partners and financing opportunities for Ukrainian technology companies

### EXPECTED DURATION OF THE TOP PROJECT

Medium-term

3-5 YEARS


### EXPECTED EFFECT

- ✓ A stimulating environment has been created for the exchange of ideas, resources and expertise, as well as attracting investments for the development of BioTech solutions
- ✓ Strengthening cooperation between business, science and government to increase the number of innovative solutions and their commercialization
- ✓ Enhancing presence of Ukrainian companies and products on the global market, which will help strengthen Ukraine's innovation potential