

# Biologics for all

A world where people get the medicines they need, when they need them.

## Biologics

#### What are biologics?

In contrast to most drugs that are chemically synthesized, biologics are medical products derived from biological sources.

Examples include:

- vaccines
- · treatments for immune diseases like cancer
- · common therapies such as hormones
- · treatments for diabetes.

#### Why are biologics important?

Biologics are at the cutting-edge of medical research. They are often the most effective - and sometimes only - means to treat or prevent a variety of medical illnesses and conditions.

#### Why are biologics challenging to manufacture?

Biologics are highly sensitive to changes in the environment. To maintain safety and effectiveness, the process to create them has multiple steps which must be rigorously followed.



## Who we are



As we mark 10 years of Univercells, we celebrate the evolution of our group and the progress towards our goal of Biologics for All. The work we have done and our achievements in 2022 have brought us closer to our vision. The partnerships we have built are finding their place in the world and are poised to achieve the impact that Univercells was created to have!

José Castillo, Univercells Co-Founder and Quantoom CEO

Hugues Bultot, Univercells Co-Founder and Group CEO

#### **Our Group**

Number of staff: 420

Nationalities: 41

Gender split:

• Female 43%

• Male 57%

Number of affiliates: 4

Number of sites: 7

#### **Projects and** product use in 29 countries

#### 17 projects running at our facilities

#### **52** investigative medicinal products supported

Numbers correct as of: 31.12.2022

## Our purpose



#### The challenge

Globally there is a need for innovation in manufacturing technology for biologics.

#### We...

improve biomanufacturing technology and processes to make biologics easier and cheaper to produce.

#### The challenge

With supply concentrated in a few countries, biomanufacturing infrastructure needs to expand worldwide.

#### We...

provide innovators with access to production capacity and support emerging players in setting up their own facility.

#### The challenge

**Increased expertise** in biologics and biomanufacturing is urgently required.

#### We...

provide access to expertise in bioproduction, both services and advisory.

## How do we make biologics for all?

#### **Developing technology** and product innovation

Our engineering approach enables us to develop and design technology that makes biologics easier and cheaper to produce. This gives developers and manufacturers around the world the means to produce more affordable drugs and vaccines.

#### **Building access to** production capacity

Not only do our partners have access to our cutting-edge manufacturing facilities in Belgium, but we can also help them establish their own bioproduction facilities. Our aim is to support the creation of a globally distributed manufacturing network.

#### Providing access to and expanding expertise

Our team of experts works with academic institutions, government agencies, partners and clients around the world to support efforts around workforce development and training, as well as regulatory-affairs; helping build biomanufacturing expertise and supporting production autonomy.





#### Challenge

Existing biomanufacturing technology is expensive and inflexible. The production of a single vaccine requires millions of dollars of investment and the setting up of complex infrastructure. This is often financially out of reach for smaller countries and

organizations, hindering their ability to respond to local health concerns or disease outbreaks. mRNAbased vaccines provide a potential solution to this problem.

#### Action

mRNA-based vaccines represent a promising new approach to vaccine development, with big benefits in terms of speed, efficacy, and flexibility. This allows for the rapid development of diverse medicinal products with lower resource and investment requirements.

Ntensify is a line of low-footprint automated production technologies developed by Quantoom Biosciences, a Univercells company. It is designed to be flexible and customizable, providing partners with the capability to meet both pandemic and routine needs.

In June 2022, Quantoom Biosciences was chosen by Afrigen as the technology partner for the mRNA Technology Transfer Program from the World Health Organization (WHO) located at Afrigen Biologics in Cape Town, South Africa. The Hub aims to increase the global production of mRNA vaccines.

Quantoom Bioscience's technology will help Afrigen scale-up the production process that they developed. It will enable commercial production through a system - the Ntensify™ Midi - that requires limited human and capital resource investment and use.

By transferring technology and knowledge to countries with limited resources and infrastructure, the Hub aims to support the decentralization of production and support access to vaccines for all.

#### **Impact**

Ntensify™ Midi is designed to be 'free-to-operate' and allows flexibility in the type and quantity of vaccine product to be produced. Using this technology, the Hub could also pave the way for the development and production of other mRNA-based vaccines which have shown promise in clinical trials for a range of diseases. These include influenza, Zika, and rabies.

Ntensify™ Midi also allows for operation in more resource-constrained settings, with the additional benefits of:

- reduced costs thanks to the minimal requirement for RNA expertise and labor
- a small footprint system that integrates all process
- · no scale-up required because of unique intensified and chain production processes.

Univercells global health impact 2022

### **CASE STUDY 2**

Expanding capacity and supporting the global ecosystem

Jumet Campus (R&D and cGMP)





Louvain-la-Neuve (Regulatory Affairs)

Nivelles, Belgium (R&D equipment)





Paris, France - Biotech Hub (Molecular Biology Research)

#### Challenge

Following the COVID-19 pandemic, there have been several significant global initiatives focused on the decentralisation of biomanufacturing, expanding capacity, and pandemic preparedness.

The consensus is growing around the need for systems equipped to function in both pandemic and 'peace-time'.

#### Action

We are building an ecosystem that will help us achieve our goal of Biologics for All. Our group of companies is expanding the support they can provide by offering access to:

- · cutting-edge technology
- · production infrastructure
- strategic advisory support

In 2022, we expanded our facilities in France and Belgium, installed our shipping-container facility at Quantoom, and renovated the Univercells Techologies site. Our CDMO Exothera has extended its capacities to be the world's first nucleic acid CRDMO to use a continuous manufacturing system. In April, RLM consulting joined the group providing regulatory affairs support at all stages of medicinal product development.

We have built a network of partners to support the delivery of innovative solutions to global health challenges. In Senegal, our partnership with Batavia Biosciences will use their Hip Vax intensified production process on Univercells Technologies Nevoline Upstream platform to develop a Measles and Rubella vaccine. In South Africa, Quantoom's partnership with Etherna for LNP technology, will facilitate the scale-up of Afrigen Biologics' first African-owned COVID-19 vaccine.

By engaging with key stakeholders from across the global health landscape, we're providing the institutional support required to achieve our desired impact. Since our inception we have received strong support from the Belgian government and are embedded in the European institutional ecosystem. We are also members of various global platforms, including the World Economic Forum, and have strong relationships with key global health stakeholders including the Bill & Melinda Gates Foundation, Takeda and the World Health Organization.

#### Impact

In expanding our own and our partners' capacity, we are:

- cultivating a vibrant ecosystem of biotechnology innovation focused on addressing global health challenges
- creating more jobs in Belgium, Europe and in partner countries
- supporting our mission to serve as a hub for biomanufacturing in Belgium and Europe

In addition to improving accessibility, this expansion of capacity increases the speed and efficiency of biologic production. Building infrastructure that is closer to the end user reduces the time and costs associated with transportation and logistics.

Simultaneously, we're channeling learnings from our diverse partnerships around the world. This is helping ensure that best practices and key insights are shared with the stakeholders which helps set the agenda at the global and regional levels.

Univercells global health impact 2022 **CASE STUDY 3** Advisory support for access Institut Pasteur de Dakar Vaccine manufacturing facility (Senegal)

#### Challenge

The African continent currently imports nearly 99% of the vaccines it needs. As a result, countries in this region face significant challenges in developing and deploying the drugs and vaccines that they require. In April 2021, the African Union Commission and the African Centers for Disease Control asked that efforts be made to produce 60% of these vaccines locally by 2040.

The production of biologics is complex, resourceintensive and requires extensive technical expertise. Given the concentration of biomanufacturing in so few countries, the skills and technology required for the establishment of a robust production ecosystem are often difficult to access and therefore implement.

#### Action

The Institut Pasteur de Dakar (IPD) launched an innovative partnership to revolutionize production and access to vaccines in Africa. Working in collaboration with the government and international funders, a first-of-its-kind vaccine manufacturing facility has been established in Senegal to support the regional targets for self-sufficiency.

Vaccines will be manufactured at the IPD facilities as part of the MADIBA project (Manufacturing in Africa for Disease Immunization and Building Autonomy). Unizima plays a facilitating role in this partnership by providing support for workforce development, project management and implementation.

The project leverages cutting-edge equipment including Univercells Technologies' NevoLine™ Upstream platform and MedInStill's Pouch Filling

In March 2022, Unizima also launched the 'University Partnership' project, designed to support biomanufacturing upskilling in Senegal. Members of the Université Amadou Mahtar Mbow de Dakar arrived in Brussels to work with Université Libre de Bruxelles in a practical six-month internship at Quantoom Biosciences. This project includes the development of an updated curriculum in Bioinformatics which the two universities designed in partnership.

#### **Impact**

With advisory, strategic, and technology support from Unizima and Univercells Technologies, the MADIBA project aims to expand overall capacity and deliver on its mandate to achieve Senegalese national bioproduction targets and hit the regional target set by the African Union and African CDC.

When completed, the facility will have capacity to manufacture at least 300 million doses of vaccines per year and will include multi-suite drug substance and fill-finish capabilities.

In October 2022, supported by a grant from the Bill & Melinda Gates Foundation, IPD announced a program for the in-house development and

manufacturing of a Measles and Rubella vaccine. This used Batavia Biosciences' Hip-Vax intensified production process and Univercells Technologies' NevoLine™ and scale-X ™ platforms.

Through our University Partnership project, students and teachers from Senegal are engaging with colleagues from Belgium and Europe. This will give them hands-on experience working on our next-generation technology. The Bioinformatics curriculum will support the development of highly trained professionals who will be able to advance the national and regional biomanufacturing ecosystem in the years ahead.

Univercells global health impact



## and beyond

- Continue to focus on the development of innovative new products, informed by needs identified in the global ecosystem
- Expand our global footprint into the Americas, Asia and Africa
- Strengthen our efforts around
  Environmental, Social and Governance
  compliance to ensure environmental
  sustainability and impact
- Focus on managing our portfolio and growing our business



## Overview



### Three interconnected business models to make biologics available to all

#### Technology

Cutting-edge, scalable
technology portfolio to enable
partners to achieve low-cost,
low-footprint, high-quality and
high-performance production.
Applications in RNA, DNA from
R&D to commercial.



#### **CDMO**

Designing and operating bespoke bioproduction hubs with state-of-the-art technology which includes proprietary biomanufacturing technologies. Offer preclinical to commercial GMP capabilities and expertise for innovators in advanced therapies and vaccines.



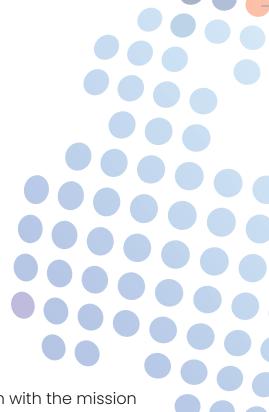
#### **Advisory**

Turnkey services to support emerging players wherever biologics can make a difference, making local bioproduction a reality.

Offering spans from design to operations of bioproduction sites which includes technology transfer, training, and regulatory affairs.







Univercells is a global life sciences group based in Belgium with the mission of making biologics available to all. Using our combined expertise in scaling, production, and bioprocessing, we find new and sustainable ways to widen access to life-changing drugs. Our affiliate companies deploy innovations in infrastructure, drug substance manufacturing, equipment manufacturing, equipment design, training, and on-the-ground health services. These drive down costs, shrink manufacturing footprints and meet the needs of the entire health value chain. We are supported by regional and national investors alongside international investors active in vaccines and healthcare. These include the Bill & Melinda Gates Foundation, the European Investment Bank and the Global Health Investment Fund.

## **About us**

