**Univercells** 

# Innovating for impact

We transform how biotech drugs are made so everyone, everywhere can get them.

## We're global biotech innovators driven by one purpose: to transform how biotech drugs are made so everyone, everywhere, can get them.

Through cutting-edge bioprocessing and technology, we create transformative platforms across drug discovery, development, and delivery. Our focus? Driving accessibility, affordability, and sustainability, to eliminate barriers for drug developers.

Collaborating with biotech and pharmaceutical industries, we pave the way for new vaccines and therapies targeting cancer, infectious diseases, and animal health. With world-leading and mission-aligned stakeholders like the Bill & Melinda Gates Foundation, the European Investment Bank, and the Global Health Investment Corporation, we're poised to make a difference on a global scale.

#### ✤ What are biotech drugs?

They include vaccines, therapies, and treatments, derived from living organisms and may involve DNA, nucleic acids, and other biological components. Unlike traditional drugs, biotech drugs are produced using complex biotechnology processes and techniques. The concept of biotechnology encompasses a wide range of procedures for modifying living organisms for human purposes. Biotech drugs offer targeted solutions for diseases such as cancer, autoimmune disorders, and infectious diseases.





"Amidst the intensity of 2023, we had three notable successes: the sale of one of our paradigm-shifting technologies, strategic expansion with a **new US site**, and global impact through participation in the **Bill and Melinda Gates Foundation's Global Grand Challenges.** 

These demonstrate our strategic vision and continued commitment to our purpose."

## Hugues Bultot CEO of Univercells

## Scientists and entrepreneurs united by **one purpose**

We work across 6 sites:

4 in Belgium

1 in France

in USA





Across **45** nationalities

46% women

With **37%** women in senior management

## Projects and products in **38** countries

**27** game-changing projects in our infrastructure

**115+** advisory projects

**260M** dose capacity for viral vector vaccines

**9** RNA manufacturing technologies to produce RNA vaccine installed across 3 continents





## Towards sustainable **innovation**

At Univercells, sustainability isn't an afterthought; it's woven into our operations. Sustainability is a balance between maximizing societal impact, ensuring financial sustainability, and aligning with our Environmental, Social, and Governance commitments.



# ESG //MPACT

#### Planet

**Our ambition:** Minimize as much as possible the negative impact of our operations on the planet.

**Our impact today:** Technologies that transform how biotech drugs are made and reduce environmental footprint. Smaller, faster and resource-efficient.

## R People

**Our ambition:** Build the best engaged team and stakeholder network.

**Our impact today:** Work to ensure that biotech drugs are produced in places historically lacking access to such technology. Diversity and equity are central to our mission, fueling our innovative approach. Our global workforce reflects the diverse markets we serve.



**Our ambition:** Set up exemplary governance management for the sector.

**Our impact today:** Impact investors and like-minded collaborators, governed in a dedicated Sustainability Committee.

#### OUR CONTRIBUTION TO THE UNITED NATION'S SUSTAINABLE DEVELOPMENT GOALS



## **Driving change**

Our answers to challenges in biotech drugs for lasting impact Conventional manufacturing methods to produce vaccines and therapies are expensive, long, and complex, leaving them vulnerable to environmental shifts. To ensure safety, effectiveness, and readiness for potential pandemics, we need innovative approaches that make these treatments accessible to everyone.



#### The challenge

A global demand for more affordable vaccines and therapies.

#### Our answer...

We innovate **biomanufacturing technologies and processes** to make vaccines and therapies easier, faster, and cheaper to produce.

#### The challenge

Rising demand for accessible vaccines and evolving environmental conditions require cheaper, faster, and simpler production processes.

#### Our answer...

We provide our partners access to our cuttingedge manufacturing facilities in Belgium while also supporting emerging innovators to develop their own **production capacity.** 

#### The challenge

The biotech industry urgently requires increased expertise in biologics and biomanufacturing.

#### Our answer...

We provide access to expertise in bioproduction and regulatory affairs, thanks to our **advisory services.** 

## Our progress in 2023

Advancing accessibility and affordability to biotech drugs through innovation and partnership

#### Technologies and processes

Our engineering approach enables us to develop and design transformative technologies and processes that make biologics easier, faster, and cheaper to produce.

#### Some use cases 2023...

9 Ntensify<sup>™</sup> platforms have been implemented.
exoREADY platform first results released.

OUR IMPACT ON: AFFORDABILITY, INNOVATION, PARTNERSHIP

#### **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.

#### Some use cases 2023...

- Univercells launched an RNA CDMO in Belgium.
- Expansion of Univercells activities in the USA.
- R&D Lab in MADIBA in Dakar ready for first test run on Measles and Rubella vaccines.

OUR IMPACT ON: AFFORDABILITY, ACCESSIBILITY

#### **Advisory services**

Our team of experts collaborate globally with academic institutions, government agencies, partners, and clients to provide strategic guidance, technical expertise, workforce training, and regulatory support. Together, we help strengthen biomanufacturing capabilities and support production autonomy.

#### Some use cases 2023...

- Advisory support to international development agencies.
- Workforce development:
- 3 training programs.
- Regulatory affairs support:10 approved clinical trials.

#### OUR IMPACT ON: ACCESSIBILITY, PARTNERSHIP

#### **OUR INNOVATION • R&D FOR IMPACT**

#### **Technologies and processes**

During our RNA manufacturing technology validation, we unearthed further barriers as opportunities to innovate for impact.

#### Some use cases 2023...

- Drug design: mRNA Rabies vaccines development.
- DNA: Good result with Nplify Rolling Circle Amplification (RCA) process.
- Delivery (formulation): New delivery systems with Freedom to Operate (FTO).

#### **OUR IMPACT ON: INNOVATION**

AFFORDABILITY, INNOVATION, PARTNERSHIP

## Our transformative technologies and processes



## Global demand for more affordable biotech drugs

#### Our achievements in 2023

In 2022, we reached a significant milestone with the development of the Ntensify<sup>™</sup> platform; a breakthrough in mRNA-based vaccine and therapy production. 2023 marked the technological validation and widespread adoption among customers. Initial runs demonstrated its ability to dramatically enhance productivity and cost-effectiveness.

Our RNA platform is now implemented in 9 locations across 6 countries, with a \$20 million commitment from the Bill & Melinda Gates Foundation to accelerate deployment in Africa. 2023 was also the year of the first promising results of our Adeno-Associated Virus (AAV) platform, exoREADY, which reduces the production cost of gene therapy.

## Our impact

## 2 to 3 times

cost reduction of reagents, representing **80% of cost of goods** thanks to our Ntensify™ process.

### 15 million

dose capacity for each of the 5 RNA manufacturing platforms implemented in 2023.

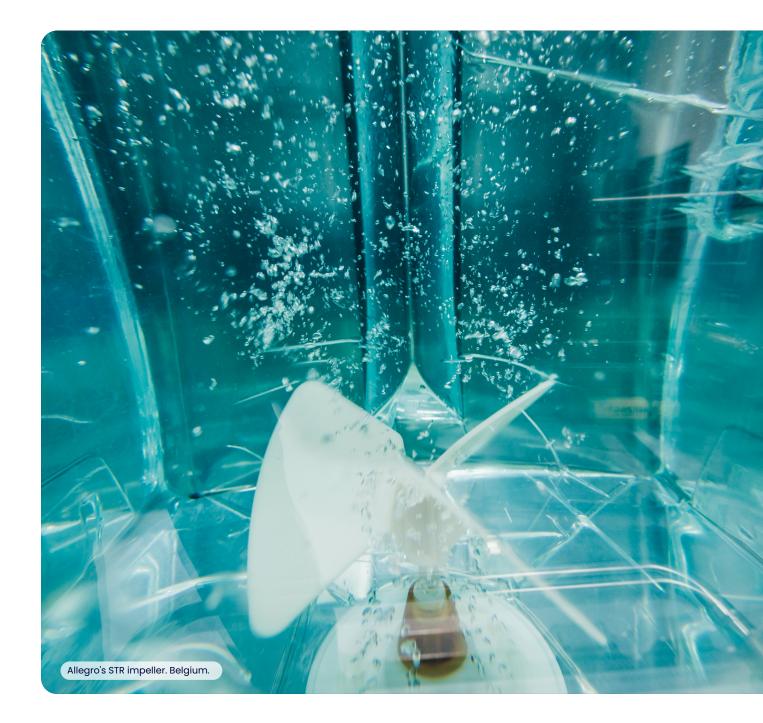
## 3 to 8 times

better yield to produce AAV thanks to the development of our exoREADY platform.



AFFORDABILITY, ACCESSIBILITY

## Reimagining production capacity possibilities



Rising demand for accessible vaccines and evolving environmental conditions requires cheaper, faster, and simpler production processes

#### Our achievements in 2023

The mRNA vaccine technology transfer hub, a World Health Organization initiative, has selected the Ntensify™ platform as its technology supplier for driving mRNA vaccine manufacturing. Our first installation was in South Africa.

Univercells has launched the world's first Contract Development and Manufacturing Organization (CDMO) offering an off-the-shelf process for semi-continuous production of RNA. This groundbreaking service is dedicated to expediting the development and manufacturing of RNA vaccines and therapies.

Our expansion in the United States is a strategic move, with 800m<sup>2</sup> of lab and office space in Andover, close to Boston's biomanufacturing hub. This expansion bolsters our technological capabilities and proximity to customers, reaffirming our dedication to customized solutions for American clients and global presence.



## Our impact

## 9 locations

across 6 countries have now implemented our RNA R&D and manufacturing platforms.

## 6 projects

conducted in our RNA CDMO with one first project in commercial phase.



## Advisory services to **accelerate accessibility** to biotech drugs

## The biotech industry urgently requires increased expertise in biologics and biomanufacturing

#### Our achievements in 2023

Our achievements demonstrate our commitment to nurturing emerging innovators to produce vaccines and therapies sustainably. In 2023, our technology transfer, coordination, and workforce development efforts facilitated the establishment of a vaccine production hub in Senegal. As a result, a R&D laboratory was developed, and the first test run on Measles Rubella vaccines was launched in Dakar.

We've contributed to advancing global health towards local medicine production by providing advisory support for Fill & Finish Contract Manufacturing, aligning with Africa's vision of regional autonomy. Our business case simulation tool has been shared with over 44 African manufacturers, fostering sustainable healthcare solutions for the continent.

Our commitment to workforce development has been translated in the setup of training programs mixing theoretical and practical knowledge transfer. We collaborate with manufacturers and universities to cultivate a pipeline of talent and provide a skilled workforce for the biomanufacturing industry.

Additionally, our regulatory affairs consultants have propelled over 40 customers along the regulatory pathway with a presence in the USA for Food & Drug Administration (FDA) regulatory support.

## Our impact

### 1st test run

on Measles Rubella vaccines, in Dakar, Senegal, for which we have supported the set up of the R&D laboratory.

### ±40 students

and lab operators from Senegal and Tunisia trained in our program: training in Measles and Rubella bioprocess, mRNA manufacturing, and an immersive internship in bioinformatics and process development.

## 7 orphan drugs

received specialized assistance in validating the clinical trial processes.

## 10 clinical trials

approved as a result of our regulatory affairs support.



AFFORDABILITY, INNOVATION, PARTNERSHIP

# Innovating for **impact**



While validating our RNA manufacturing technology, we identified additional barriers that must be addressed to fully realize the potential of our technologies

#### Our achievements in 2023

Continuous innovation and prototyping are crucial. That's why in 2023, we expanded our activities to include drug design, DNA technologies, and formulation.

#### Impact

• Drug design: RNA drugs can be de-risked by designing effective constructs in silico. We have built our own molecular design platform, which we used to produce a highly-promising mRNA Rabies vaccine with compelling in vivo results, which will move into Phase 1 clinical trials by 2025.

• DNA technologies: to make RNA and viral vectors, you need DNA. We have successfully prototyped and delivered promising early results for a novel process for DNA amplification. When optimized, this will enable seamless scalability for optimal linear DNA production for RNA manufacturing.

• **Delivery technologies:** to administer RNA drugs, they must be delivered to the right cell. RNA formulation is highly restricted by monopolistic IP. To overcome this, we have developed our own composition and proprietary lipids, which offer free-to-operate or unencumbered options to customers under conditions that support access.

# 2024 & beyond

• We will expand our impact to new applications and new markets, such as cancer, autoimmune, livestock and others.

• We will advance our commitment to a global footprint and establish our presence on one new continent.

• We will build on our R&D capabilities to tackle key challenges essential for our purpose:

to transform how biotech drugs are made so everyone, everywhere, can get them.

# **Univercells**

## Contact us

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