Univercells
Biologics for all

Biologics for all

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

2021

Univercells global health impact

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 and many common therapies like hormones and treatments for diabetes.

Why are biologics important

Biologics represent the cutting-edge of medical research and often are 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 very sensitive to changes in the environment and complicated to manufacture. The process to create them has many steps that need to be duly respected to maintain safety and effectiveness.

Univercells' team is committed to revolutionizing the availability of biologics around the world, making essential medicines affordable to all, in both quality and price.
We believe that it's not enough for a drug to simply exist.
To change the world, it must be accessible to everyone.

Who we are

442 people

41 nationalities

40% women

4 affiliates

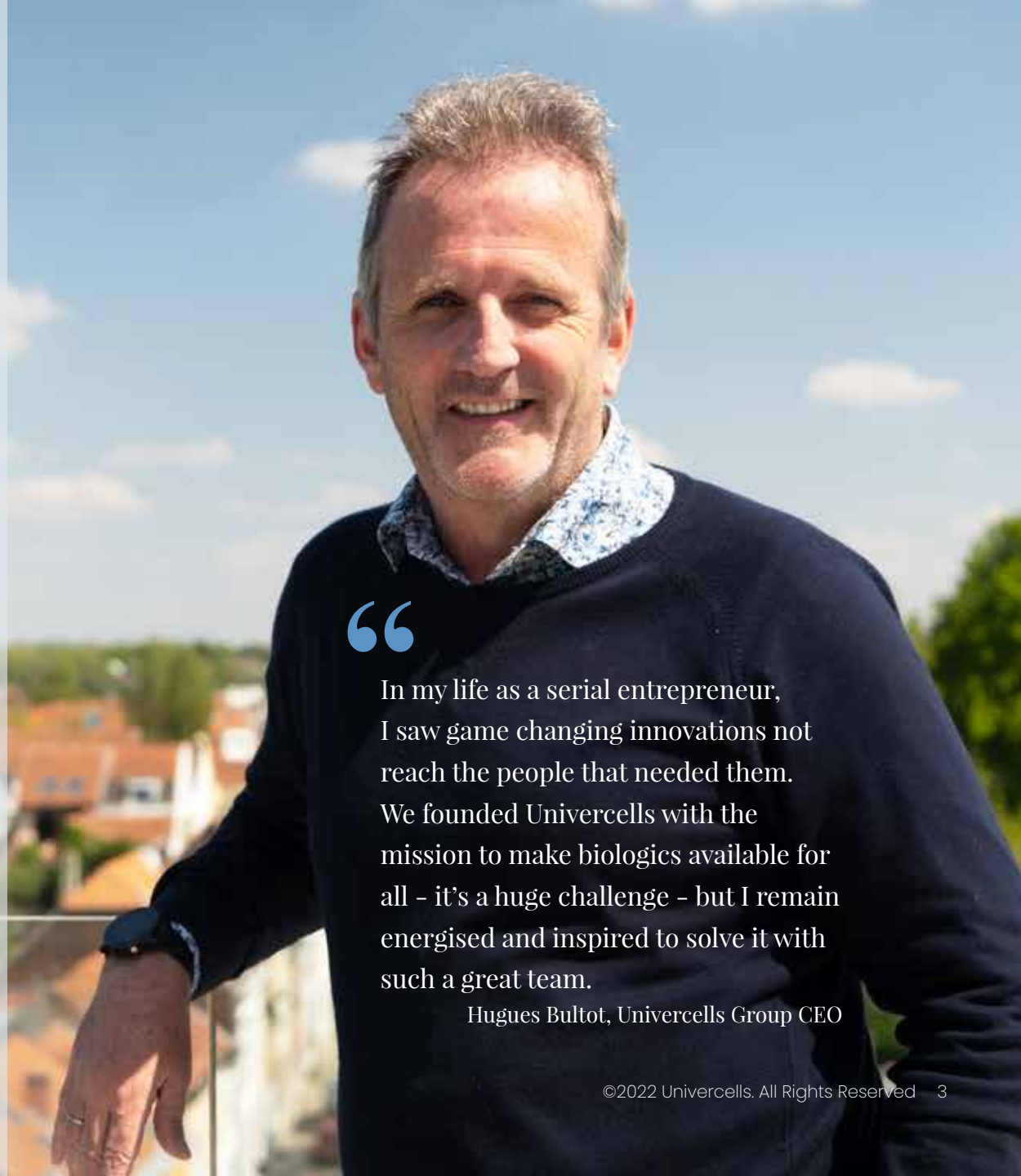
5 sites

26 countries using our technology

21 products made more accessible thanks to our expertise in Belgium

4 new technology platforms under development

Numbers as of 31/12/2021



"In my life as a serial entrepreneur, I saw game changing innovations not reach the people that needed them. We founded Univercells with the mission to make biologics available for all - it's a huge challenge - but I remain energised and inspired to solve it with such a great team.

Hugues Bultot, Univercells Group CEO

Why do we exist
Our challenge.

Many people and countries cannot afford the medicines they need

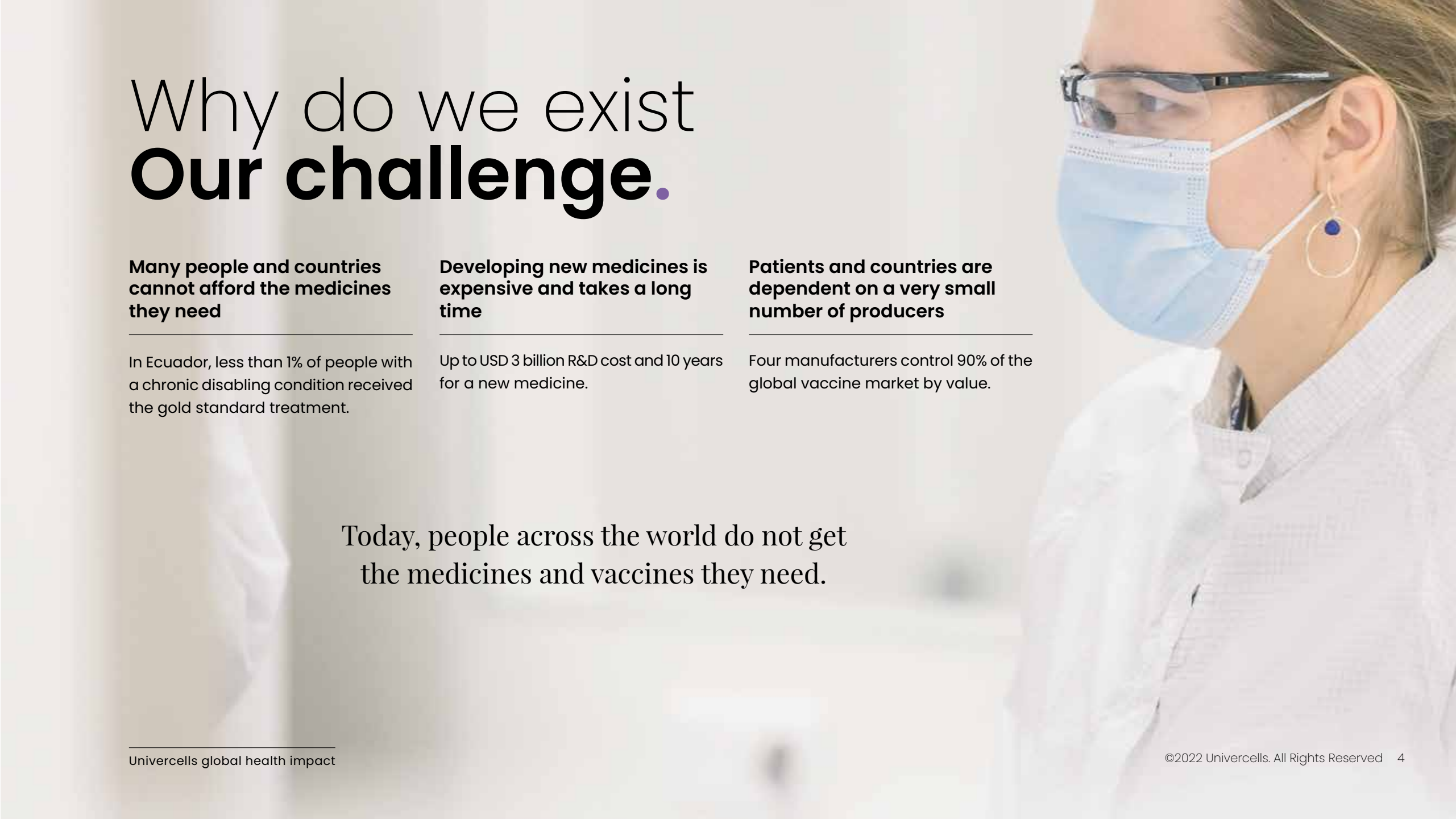
In Ecuador, less than 1% of people with a chronic disabling condition received the gold standard treatment.

Developing new medicines is expensive and takes a long time

Up to USD 3 billion R&D cost and 10 years for a new medicine.

Patients and countries are dependent on a very small number of producers

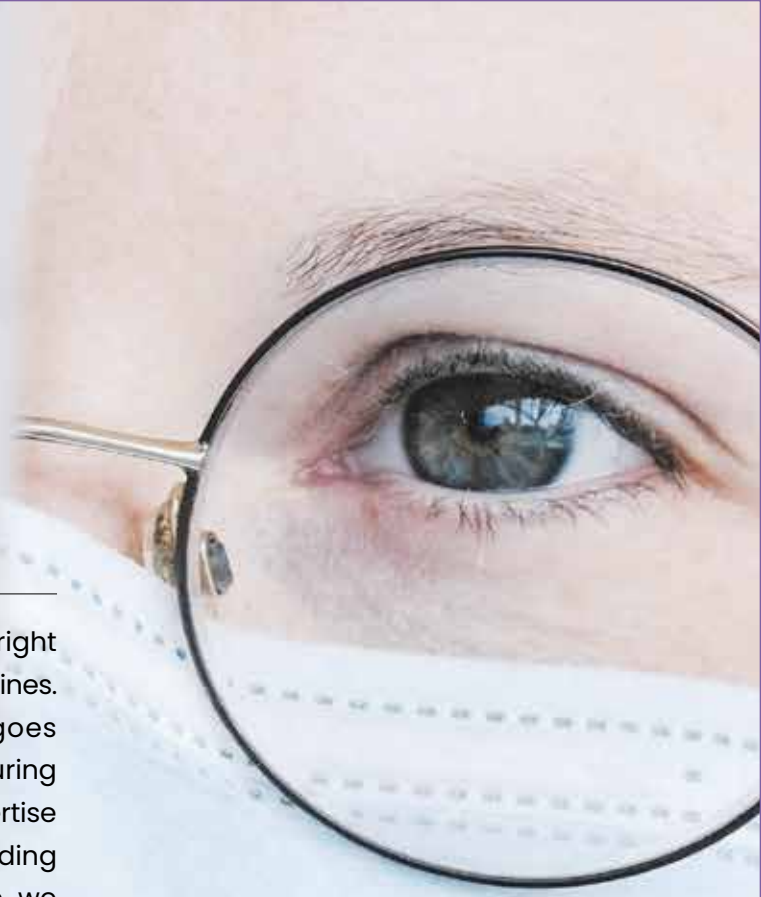
Four manufacturers control 90% of the global vaccine market by value.



Today, people across the world do not get the medicines and vaccines they need.

Why do we exist
Our role.

We are using 3 principles to make biologics accessible and affordable to all



Technology Driven Affordability

We believe that the only long-term way to drive down costs is through technology, not by paying people less. Our technologies are designed to provide a way to make biologics and medicines in a low-cost, low-footprint way, but still able to produce large volumes.

Innovation

We use an engineering approach to create new technologies that drive unprecedented access. But we believe innovation goes beyond technology. We innovate across our business – new business models, new service offerings and new ways of working.

Autonomy

We believe our partners have the right to control their own supply of medicines. We recognise that autonomy goes beyond the creation of manufacturing infrastructure. It requires both expertise and capacity. In addition to providing partners with access to expertise, we also offer access to manufacturing capacity for production at scale.

CASE STUDY 1

Technology driven affordability • Innovation • Autonomy

Innovative biomanufacturing technologies supporting global health vaccine development

Root cause

Promising vaccine candidates targeting global health and epidemic preparedness vaccines are made in ways that do not support access, affordability or rapid scale-up.

Lassa fever is an acute viral illness endemic to many parts of West Africa, causing significant annual outbreaks. There are an estimated 300,000 to 500,000 cases and 5,000 related deaths each year. Despite this disease burden, which is believed to be significantly underestimated, no vaccine for Lassa fever is currently available.

Action

A partnership focused on global equitable access to vaccines has come together to solve this. Batavia Biosciences and the International AIDS Vaccine Initiative are developing a Lassa Fever Vaccine, funded by the Coalition for Epidemic Preparedness Innovations, with trials supported by the European Developing Countries Clinical Trial Partnership.

Batavia Biosciences successfully produced vaccine material for clinical trials, ensuring vaccines are made in a low-cost and rapidly scalable way by using Univercells' innovative manufacturing technologies*.

* The scale-X ™ & NevoLine ™ from Univercells Technologies' product portfolio

Impact

The use of our technology enables the production of high volumes of vaccine doses in a small footprint facility, dramatically reducing capital and operational costs. The technology is particularly well suited to produce global health and epidemic preparedness vaccines such as Lassa fever.

In line with CEPI's goals, the partnership secured funding for a Phase IIb clinical trial that will provide crucial proof-of-concept efficacy data from populations located in regions prone to outbreaks of the potentially deadly disease.

This partnership also allowed vaccines manufactured with Univercells' innovative technology to be part of a Phase 1 clinical trial study performed under a stringent regulatory authority.

Batavia Biosciences uses our manufacturing technology to produce global health vaccines

Impact target 2021:

✓ **25% of our technology products are installed in low- and middle-income countries**

CASE STUDY 2

Technology driven affordability • Innovation • Autonomy

Rapid expansion of modular biomanufacturing capacity for pandemic resilience

Root cause

Despite huge progress in vaccine development in 2020 and the first approvals of new COVID-19 vaccines, global supply shortages persisted across the world in 2021 due to lack of biomanufacturing capacity.

Action

In response to the pandemic, Univercells took the decision to establish a new large-scale biomanufacturing facility, acquiring a site in 2020 with the support of the European Investment Bank.

Using our box-in-a-box approach to rapidly build, equip, and validate the viral vector facility, the team worked tirelessly throughout 2021 towards certification by the health authorities. With already 21 projects in R&D made more accessible thanks to our expertise, the facility received a positive opinion from Belgian health authorities for commercial production, making the incredible achievement of going from warehouse to GMP capabilities in 18 months.

Impact

The facility in Jumet provides additional large scale GMP manufacturing capacity ready to welcome customers needing manufacturing capacity of viral vector vaccines.

Most importantly, it created 140 jobs in Belgium and contributed to entrench Belgium as at the heart of biotechnology in Europe.

Finally, given that the facility design is suitable for both stick build and container-based solutions, it created a precedent for partners in low-and middle-income countries to replicate.

Thanks to our low-footprint approach, we were able to reduce CO2 emissions by 55% compared to a traditional approach.

“When the Jumet site was nothing more than an empty warehouse, we were already working hard to secure clients while also being 100% focused on getting the required quality approvals in a record time of 18 months. The effort was tremendous but paid off. We now have a running commercial facility with unique expertise to offer.

Emilie Gateau,
Platform Development Manager

Impact target 2021:

✓ **Accreditation granted by the Belgian health authorities**

CASE STUDY 3

Technology driven affordability • Innovation • Autonomy

Unlock the power of RNA by making it easier and more affordable to produce

Root cause

The COVID-19 pandemic demonstrated the power of RNA vaccines. Yet, as a lab-based technology, manufacturing scale-up remains a struggle. The way RNA is synthesized has indeed not significantly advanced since its discovery. Until now, there has not been a simple, scalable and cost-efficient way to produce RNA-based drugs.

Action

Using our engineering skills applied to synthetic biology, instead of microbiology, we identified the challenge coming and rapidly conceptualized and prototyped a new RNA production system, officially launching a business dedicated to this endeavour in June 2021. This built on the classical Univercells approach – low cost, low footprint, unencumbered use – while also working on addressing additional challenges linked to the production of mRNA vaccines and therapeutics such as cost of reagents, formulation and RNA chemistry. That's why in parallel to our RNA production system we also offer end-to-end services to support our partners in their journey of mRNA production.

Impact

By 2022 we will have a working production system, with a vision to empowering customers all over the world to harness the power of RNA in ways that they see fit. Major benefits of this technology include reduced costs thanks to minimal labor & RNA expertise required, single small footprint system integrating all process steps instead of investing in a suite of equipment as well as no need for scale-up given technology allows to manufacture all stages of the product development.

“The Bill & Melinda Gates Foundation supported us in 2016 for our polio platform. In 2021 we incubated our RNA initiative, launching a company dedicated to using our engineering approach to solve the challenge of RNA access. By the end of the year we were 70 people, and so glad to welcome the Bill & Melinda Gates Foundation again as our partner.

Jose Castillo,
Univercells co-founder and
Quantoom Biosciences CEO

CASE STUDY 4

Technology driven affordability • Innovation • Autonomy

Make local biomanufacturing a reality by offering a suite of services to support in-country partners

Root cause

There is a lot more to building a facility than equipment and walls. Creating national and regional health capacity in low- and middle- income countries (LMICs) requires a range of stakeholders to work together.

Few international organizations have the know-how, human resources, and commitment to make this happen.

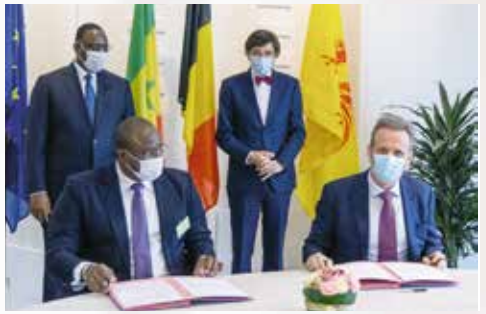
Action

Building on a groupwide project to support turnkey transfer and distributed manufacturing, Univercells invested into its capabilities and capacity to support the creation of new biomanufacturing sites, especially those in LMICs. This led to the launch of a dedicated business to work with partners to establish their own facilities.

Univercells is now working with governments and stakeholders across Africa and other LMICs to support their biomanufacturing autonomy objectives. We developed an end-to-end offering including strategic advice, facility design, set up, project and program management, tech transfer and workforce training. Our teams are committed to be on-the-ground, making it happen. We now have people in Senegal, Rwanda, Ecuador and Mexico.

Impact

By working on the ground to implement local biomanufacturing solutions, and linking them to robust, practical healthcare systems, we are dismantling an important barrier to better health and prosperity and enable self-sufficiency, increase local knowledge and create jobs.



Dr Amadou Sall from Institut Pasteur de Dakar signing Memorandum of Understanding with Univercells, a collaboration strengthening technological capacity for bioproduction and biomedical research in Senegal.

Front left, Dr Amadou Sall,
Back left, His Excellency, Macky Sall, President of Senegal
Front right, Hugues Bultot, Univercells Group CEO
Back right, Elio di Rupo, Minister-President of Wallonia

Impact target 2021:

✓ **3-5 potential leads for LMICs**

2022 and beyond

Create new technologies that address unmet health needs by continuously innovating.

Change the narrative on vaccine equity contributing to the global dialogue around biomanufacturing, vaccine autonomy, and global health.

Support geographic autonomy through decentralized manufacturing units installed on 4 continents.

Ensure European pandemic resilience as an industry leading production facility with agility at the core.

Transform access to RNA vaccines through a new model of manufacturing.

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About **UNIVERCELLS**

Univercells is a global life sciences company with the mission of making biologics accessible to all. Using our combined expertise in scaling, production, and bioprocessing, Univercells finds 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 to drive down costs, shrink manufacturing footprints and meet the needs of the entire health value chain. Headquartered in Jumet (Belgium), Univercells is supported by regional and national investors, as well as international investors active in vaccines and healthcare, such as the Bill and Melinda Gates Foundation, the European Investment Bank and Global Health Investment Fund, among others.

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Headquarter:
Allée Centrale 52
Zoning de Jumet
6040 Charleroi
Belgium

Contact:
info@univercells.com
+(32) 2 318 83 48

www.univercells.com