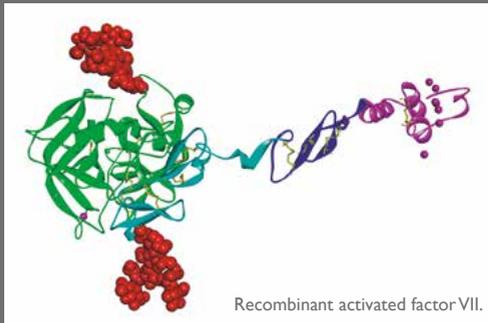


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A company
committed to
patients' lives

HIGHLIGHTS



Definition and implementation of the new strategy

The new strategy involves a renewed focus on core business, plasma-derived medicinal products and recombinant proteins. Priority is given to industrial activities, consolidation of our leadership in France and selective international development.

Construction of the Arras plant, a major industrial project

This new industrial site, slated to be operational by 2024, will have plasma fractionation capacity of 2.3 million litres. This plant will triple LFB's current fractionation capacity and merge together all of the production steps for immunoglobulins, albumin and fibrinogen.

Approval of SEVENFACT® in the United States

On 1 April 2020, the US Food and Drug Administration (FDA), the regulatory authority in the United States, granted approval for SEVENFACT®, a recombinant protein for the treatment of patients with certain forms of haemophilia.

MAJOR PROJECTS IN THE PIPELINE

Coagulation factors

Recombinant activated factor VII:

- > Application in progress for approval of label extensions in indications for pediatric patients and use in surgical settings in the United States.
- > Regulatory submission planned in Europe and Mexico.

Fibrinogen

- > Ongoing development and regulatory submission planned for congenital and acquired deficiency in the United States.
- > Regulatory submission planned for acquired deficiency in Europe.

Immunoglobulins

10% intravenous immunoglobulin

- > Ongoing development and regulatory submission planned for primary immunodeficiencies in the United States.

20% subcutaneous immunoglobulin

- > Ongoing development and regulatory submission planned for primary immunodeficiencies in Europe, including France, the United States and other regions.

LFB IS A BIOPHARMACEUTICAL GROUP THAT DEVELOPS, MANUFACTURES AND MARKETS **PLASMA-DERIVED MEDICINAL PRODUCTS AND RECOMBINANT PROTEINS** FOR THE TREATMENT OF PATIENTS WITH **SERIOUS AND OFTEN RARE DISEASES.**

CREATED IN FRANCE IN 1994, LFB IS TODAY ONE OF THE LEADING EUROPEAN COMPANIES PROVIDING PLASMA-DERIVED AND RECOMBINANT MEDICINAL PRODUCTS TO HEALTHCARE PROFESSIONALS. ITS MISSION IS TO OFFER PATIENTS NEW TREATMENT OPTIONS FOR UNMET NEEDS IN **THREE MAJOR THERAPEUTIC AREAS: IMMUNOLOGY, HAEMOSTASIS AND INTENSIVE CARE.**

LFB'S CURRENT MARKET PORTFOLIO INCLUDES **15 BIOMEDICINAL PRODUCTS** SOLD IN OVER 30 COUNTRIES.

4 

bioproduction sites worldwide, 3 of which are in France*



€ 350 million in sales*



2,200 employees worldwide, including 1,800 in France*

* 2019 data.



Laboratoire français du Fractionnement et des Biotechnologies. A public limited company with capital of 280,000,000 euros. Évry Register of Commerce no. 180 036 147. 3, avenue des Tropiques – ZA de Courtabœuf – 91940 Les Ulis – France. www.groupe-lfb.com. Photography credits: Patrick Allard, iStock images, Mikael Lafontan, Medical Productions, Photononstop/Uwe Umstätter-ImageBroker, LFB photo library, DR. Designed and created by: HAVAS PARIS. Printed in France in December 2020. December 2020 – D-20-0164.





INTERVIEW

Denis DELVAL,
Chairman and CEO

Denis Delval, Chairman and CEO of LFB, looks back on the actions implemented since his arrival in December 2017 and the ongoing strategic refocusing around a renewed vision of the company's future. In the current context marked by the global Covid-19 pandemic, he also stresses the strength of the company's commitments to patients' needs as a responsible player in healthcare.

You took over as head of LFB at the end of 2017. What is your assessment of your initial decisions?

The company was in trouble. My first initiative was therefore to launch a strategic review. This first overview of the situation served as the basis for the new strategy that we announced in mid-2018 with the approval of the Board of Directors. Our first priority: industrial activities, with significant investments at our sites in Les Ulis and Lille and the start of construction of a new factory in Arras. This new generation plant in Arras will ultimately triple our production capacity for plasma-derived medicinal products and support our ambitions for international growth. At the same time, we refocused on our core business, the production of plasma-derived medicinal products and recombinant proteins and this led to the sale in the spring of 2019 of CELLforCURE, our cell and gene therapy production site.

We have defined a dual approach for our markets. In France, we aim to regain our leadership position. Outside France, we opted for selective development in eight key countries: Germany, the United Kingdom, Italy, Spain, Belgium, the United States, Mexico and Turkey. Finally, we adapted our internal organisation, replacing most of our executive team. With the support of all of our employees, we have begun to turn the company around, based upon a foundation of strong values.

What are the next steps?

We will now consolidate our transformation and ensure that LFB regains its leading position. Internationally, the United States FDA granted approval in April 2020 for SEVENFACT®, a recombinant activated factor VII for the treatment of certain forms of haemophilia. The launch of SEVENFACT® on the US market is expected early 2021 by HEMA Biologics, a joint venture between LFB and US WorldMeds. We are also preparing marketing authorisation applications in Europe and Mexico. The FDA also approved our request to modify the registration for our recombinant antithrombin ATryn® in May 2020. In France, we are setting out to re-assert market shares for our marketed products. In Les Ulis and Lille, our investments in our industrial facilities between 2019 and 2021 will total almost 80 million euros. In 2019 and 2020 we recruited and trained nearly 200 employees at each of these sites. In Arras, we are investing around 550 million euros in a new factory, which will create 250 jobs by 2024.



Our ambition: to ensure that LFB regains its leading position.”

Commitment is part of LFB's DNA. How does this apply in the case of the global pandemic?

The Covid-19 crisis has of course given us the opportunity to highlight this part of our DNA. Among other things, LFB donated gowns and masks to nursing staff in hospitals. Additionally, an internal company sports challenge raised funds for the Paris Hospitals Foundation in France, the Puerta de Hierro Hospital in Madrid and a food aid organisation in the Boston region. We also supply our immunoglobulin free of charge to the Paris University Hospitals Group, as part of the ICAR clinical trial. The pandemic has also given rise to new collaborative efforts: in April 2020,

LFB joined the CoVlg-19 Plasma Alliance composed of the main global players in plasma-derived medicinal products who pledged to develop a hyperimmune immunoglobulin for patients with Covid-19. Finally, LFB has collaborated with the French biotech company XENOTHERA to manufacture XAV-19, a drug candidate containing a mixture of protective antibodies aimed at neutralising the virus and preventing respiratory failure requiring intensive care treatment. Our industrial bioproduction site in Alès is involved in this project. More broadly, LFB actively supports patient associations globally and thus contributes to a better understanding of rare and serious diseases and improved quality of life for patients. We also work very closely with, and provide support to, blood donor associations.

What are you currently most proud of?

Without any hesitation, I would say I'm most proud of the extraordinary work of all the LFB teams, who since the start of the Covid-19 pandemic have ensured the continuity of the production of our 15 medicinal products for the treatment of serious and often rare diseases. Their exemplary commitment is the best proof that LFB is focused first and foremost on the health of patients to improve their quality of life.

THE EXECUTIVE COMMITTEE

Members of the Executive Committee, from left to right:

José MORENO
CEO of LFB USA

Hanna LEPERS
Executive Vice President
France Operations

David LOISON
Executive Vice President
Financial Affairs

Anne-Laurence SABATINI
Executive Vice President
International Operations

Capucine ASSÉO
Executive Vice President
Legal and Compliance

Denis DELVAL
Chairman and CEO

Didier VÉRON
Executive Vice President
Corporate Affairs



Patrick DELAVault
Executive Vice President
Scientific and Medical Affairs

Virginie SCANU
Executive Vice President
Human Resources

Carole RESMAN
Executive Vice President
Production

Dominique SOULARD
Executive Vice President
Quality and Pharmaceutical Affairs

4 BIOPRODUCTION SITES

LFB is a major industrial healthcare player in France. Its plasma-derived medicinal products are produced in two complementary bioproduction sites, in Les Ulis and Lille. A new plant under construction in Arras will triple LFB's production capacity and thus accelerate its development globally. Two other sites specialise in the production of recombinant medicinal products, in Alès, France and in Massachusetts, United States.



The Les Ulis plant (Essonne) specialises in the upstream processing of plasma-derived medicinal products, from plasma reception to intermediate product. The Les Ulis site is also the head office of LFB.



510 employees in production and quality out of a workforce of **970** employees in Les Ulis



The Lille plant (Nord) specialises in the downstream processing of plasma-derived medicinal products, from intermediates to aseptic filling. Packaging for LFB's liquid products is carried out at Carvin (Pas-de-Calais).



710 employees in production and quality out of a workforce of **810** employees in Lille and Carvin



The future new generation plant in Arras (Pas-de-Calais) will house all of the production steps for immunoglobulins, fibrinogen and albumin.

Creation of **250** jobs by 2024

x3 Increase in the production capacity for LFB's medicinal products



LFB develops cell lines, industrial-scale processes and manufactures clinical and commercial batches of recombinant proteins, including monoclonal antibodies, via its EMABling® technological platform. This plant's status as a CDMO (Contract Development & Manufacturing Organisation) means that it can offer its production services to third parties.



70 employees in Alès



Located in Massachusetts, United States, the Charlton plant specialises in the production of recombinant proteins using LFB's rPRO™ technological platform. This technology consists of expressing the desired protein of interest in mammalian milk by genetic recombination. The research laboratories are located in Framingham.

50 employees in Charlton, **90** in the United States

OUR KNOW-HOW

Medicinal products derived from living organisms

As a biopharmaceutical company, LFB was a pioneer in industrial innovation with its implementation of nanofiltration in 1995. Since then, it has continued to demonstrate its capacity for innovation. How? By developing new medicinal products and new indications and by optimising the industrial processes for them. This has allowed hospital practitioners to save the lives of patients with serious or rare conditions for which there are few available treatment options. Majority of these cases are chronic and require lifelong care.

15
biomedical products

A KEY PLAYER IN PLASMA-DERIVED MEDICINAL PRODUCTS

Since 1994, LFB has been a recognised player in the field of plasma-derived medicinal products. Its treatments rely on specialised knowledge of fractionation: isolating and purifying the proteins found in human plasma, which contains over 300 proteins. The 15 medicines produced by LFB at its French plasma fractionation sites in Les Ulis and Lille, require mastery of advanced bioproduction techniques.

PRODUCT SAFETY, A TOP PRIORITY

Plasma-derived medicinal products and recombinant proteins are manufactured within a strict pharmaceutical framework defined by regulatory authorities. The production process includes various purification, virus removal/inactivation and filtration steps that ensure the safety of the medicinal products.

SECURE PLASMA SUPPLIES

In France, EFS (Établissement Français du Sang) supplies LFB with plasma for the manufacture of its plasma-derived medicinal products, which are made available principally to French patients. The Europlasma subsidiary of LFB has plasma collection centres in Austria and the Czech Republic. These centres, along with others located in Europe and North America, are used for the production of medicinal products destined for countries outside France.



AN INNOVATIVE PLAYER IN RECOMBINANT MEDICINAL PRODUCTS

Always at the forefront of industrial innovation, LFB owns two technological platforms dedicated to the production of recombinant medicinal products. The EMABling® platform, located in Alès, is used to develop and produce recombinant monoclonal antibodies by cell culture. On the other side of the Atlantic, in the heart of Massachusetts, the rPRO™ technology serves to develop and produce medicinal products by genetic recombination.

“Patients with haemophilia may develop anti-drug antibodies termed inhibitors which results in the need for the use of therapies that can bypass the need for FVIII or FIX in the coagulation system.”



For the past decades, such patients only had 2 options for bleed management, and the licensure of another agent will offer prescribers and patients with inhibitors a third option.”

Dr. Guy YOUNG, MD,
Children's Hospital Los Angeles, United States

“Patients with polyneuropathies, such as Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) and Multifocal Motor Neuropathy (MMN), require careful diagnostics to develop an adequate treatment strategy.”



Many questions regarding the understanding of these diseases and the individual therapeutic response are still open. Therefore, I highly appreciate LFB's study activities to gain new insights on how to improve the treatment for our patients.”

Prof. Dr. med. Claudia SOMMER,
Department of Neurology, University Hospital Würzburg, Germany

OUR THERAPEUTIC AREAS

Essential live-saving treatments

LFB fulfils a public health mission: to provide healthcare professionals and patients with live-saving and often unique medicinal products. To meet demand for these products, LFB has committed to increase its production by building a new plant. LFB's biomedical products are mainly prescribed to patients with serious and often rare diseases. A range of 15 biomedical products developed in three major therapeutic areas: immunology, haemostasis and intensive care. LFB also helps train hospital doctors in the management of emergency situations.



RESTORING A BALANCED IMMUNE SYSTEM

In the field of immunology, LFB offers therapeutic solutions for treating patients with primary and secondary immunodeficiencies and certain autoimmune diseases. LFB offers specific immunoglobulins for the prevention of certain infections.

2/3

of LFB's biomedical products are intended for the treatment of patients with rare diseases

TREATING RARE COAGULATION DISORDERS



In the field of haemostasis, LFB provides therapeutic solutions for blood coagulation disorders caused by congenital coagulation factor deficiencies.

Some patients are born with a quantitative or qualitative coagulation factor deficiency. These are rare diseases that require life-long treatment. The most common diseases in this area are haemophilia A (factor VIII deficiency), haemophilia B (factor IX deficiency), and Von Willebrand disease (Von Willebrand factor deficiency).

RESPONDING TO CRITICAL SITUATIONS WITH EMERGENCY MEDICINES



In the field of intensive care, LFB supplies medicinal products to treat patients, often in critical situations, with serious deficiencies of essential proteins. These situations are mainly hypovolaemia, severe bleeding or thrombosis. In these emergency circumstances, healthcare professionals can use LFB's medicinal products to provide patients with the protein or proteins they need.

“For the past ten years, LFB has helped us to refresh and maintain the knowledge of our teams.”



More than a classic partnership, it is a true cooperation. LFB has developed interactive training software to train us in the management of certain emergency situations. These virtual simulation tools are offered to hospitals in anaesthesia and intensive care departments. These tools are presented and managed by healthcare professional “ambassadors” to their colleagues. LFB's HemoSims® Trauma serious game is a cutting-edge educational tool for healthcare professionals. In two hours, this interactive software provides training in good practices for the care of a severe trauma patient. The simulation takes place in two stages: a prehospital stage, during which we take on the role of doctor, nurse, stretcher bearer... followed by an in-hospital stage, in the crash room. After the simulation, we review together the positive points and the difficulties encountered. A multiple-choice test then covers the major topics in the management of severe trauma patients. HemoSims® Trauma allowed us to open up a real dialogue among the teams of our trauma network in the Rhône-Alpes region in France. It is also a practical tool, requiring less logistics than a classic simulation on a mannequin: only a computer is required to quickly train a large number of people. HemoSims® also exists for the management of post-partum haemorrhage and in cardiac surgery. I think that virtual simulation tools are very important in the both the initial and continuing training of caregivers. We can see that they are increasingly used in the field of health!”

 **Dr. Guillaume MARCOTTE,**
Intensive care anaesthetist, Hospices civils de Lyon, France



OUR COMMITMENTS

Reciprocal trust

LFB maintains a relationship of trust with its employees, healthcare professionals, patient and blood donor associations, and in particular with FFDSB (Fédération Française pour le Don de Sang Bénévole). This trust is based on transparency. Transparency with regard to our values first and foremost, since LFB's top priority is the health of patients. Transparency also about LFB's mission, as the company and its employees are fully committed to providing treatments, while meeting today's social and environmental challenges. Lastly, transparency about biological safety, since LFB remains at the forefront in terms of product safety.

TAKING CARE OF OUR EMPLOYEES



LFB has an active recruitment policy (approximately 250 hires on permanent contracts estimated in 2020 in France, including 75% in production and quality). The company invests heavily in training its employees and in partnership with various schools and universities. Employee well-being and success are essential. 11 company agreements have been signed in France on quality of work life, professional equality between women and men, management of jobs, professional paths and careers, integration of young people and diversity within professions and at work. 95% of employees have permanent contracts, with near gender equality (47.3% women / 52.7% men).

A SUSTAINABLE DEVELOPMENT CHALLENGE



Control of water and energy consumption, reduction of greenhouse gas emissions, waste management... LFB continually strives to reduce its environmental impact and, since 2011, its carbon footprint has fallen sharply. Between 2018 and 2019, LFB's recycling of non-hazardous waste more than doubled from 25% to 59.9%. The company has also worked towards reducing travel: shuttle service for employees at major sites, carpooling, remote technologies (videoconferencing, collaborative spaces) and remote working, etc. The industrial sites of Les Ulis and Lille currently consume 100% renewable electrical energy of French origin.

SUPPORT FOR BLOOD DONOR ASSOCIATIONS



LFB provides support to blood donor organisations in France. These associations promote voluntary blood donation in partnership with institutional organisations.

LFB's 5 common values

- Integrity
- Exemplary practice
- Team spirit
- Culture of excellence
- Initiative

A COMMITMENT TO SERVE PATIENTS



LFB actively supports patient associations, which are essential players in healthcare. For more than 10 years, this commitment has translated in France into specific initiatives carried out, in particular, with ADAAT (association for alpha-1 antitrypsin deficient patients), AF3M (French association of multiple myeloma patients), AFH (French association for haemophiliacs), AFNP (French association for peripheral neuropathies), IRIS (association for patients with primary immunodeficiencies). LFB supports Le Rire Médecin, which organises the intervention of clowns in French paediatric hospitals. The company also supports global patient associations, such as WFH (World Federation of Haemophilia) or IPOPI (International Patient Organisation for Primary Immunodeficiencies).

“Patients are part of a community of players, including doctors and nursing staff, researchers, manufacturers, health authorities, etc.”



In this environment, everyone has a role to play. We are interdependent and cooperation is key. Manufacturers, such as LFB, manufacture our medicinal products today and work to develop those of tomorrow, and conduct clinical trials. As an international patient association, our vision is to ensure access to early diagnosis and appropriate treatment for every patient, in every country. Our expertise as patients is unique! For manufacturers, this is essential insight they can rely on to develop solutions adapted to our needs. In the field of rare diseases, the national scale is not sufficient. No company today can alone meet the needs of all patients in one country. Countries need a variety of medicinal products as an assurance of continuity that only a plurality of players can provide. This is especially true since supply disruptions can lead to tragedies. From the point of view of patient needs, LFB's internationalisation therefore makes perfect sense. Likewise, through its membership in the CoVlg-19 Plasma Alliance, LFB is exemplary. It is great news that companies are coming together to find a potential treatment through combined research efforts. And speaking of the Covid-19 pandemic that has been so unexpected, and so anxiety-provoking, I would like to warmly thank the LFB employees who, despite the uncertainties, ensured the continuity of our treatments, and the blood donors who supported their efforts: to all of you, well done and thank you!”



Martine PERGENT,
President of the IPOPI association
IPOPI is a grouping of 68 national member associations representing 416 rare immune system diseases.

