

## **NFL Biosciences: 2021 half-year financial and business report**

Admission on Euronext Growth Paris: €5m raised from institutional, historical, and individual investors (July 2021)

CESTO II Phase II/III clinical trial approved in Australia (May 2021) and France (September 2021)

Clinical team strengthened

NFL Bioscience's patent issued in the US (September 2021)

"Innovative company" qualification by BPIfrance recognized

**NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company that is developing botanical drugs for the treatment of addictions, is releasing its 2021 half-year financial report and an update on its business following its admission to Euronext Growth Paris at the beginning of July 2021.**

### **Admission to Euronext Growth Paris: €5m raised**

NFL Biosciences shares have been listed on Euronext Growth Paris since July 5, 2021, following a €5m capital increase (gross), with the price per share set at €3.80. The transaction was subscribed for by longstanding shareholders, institutional investors and individual investors, all aware of the potential global public health impact of the development of innovative treatments in the dependence and addiction field. These resources will enable NFL Biosciences to accelerate its development by:

- carrying out the Phase II/III clinical trial for its smoking cessation aid drug candidate NFL-101;
- recruiting experienced experts to further strengthen its organization;
- launching the NFL-201 and NFL-301 programs, for the treatment of cannabis addiction and the reduction of alcohol consumption.

During the last few months, NFL Biosciences has moved forward with its operations in line with its business plan and objectives.

### **Phase II/III clinical trial for NFL-101 approved by the regulatory authorities in Australia in May and France in September**

In line with its business plan presented at the time of its capital increase, the Phase II/III clinical trial approved at the end of May 2021 in Australia<sup>1</sup>, a country well known for the quality of its clinical trials and the availability of competitive research tax credits, has also been approved by the French National Agency for the Safety of Medicines and Health Products (ANSM) and also received a favorable opinion from the French Ethical Review Board (CPP) in September 2021.

The Phase II/III clinical trial - CESTO II - will include 318 smokers, aged 18 and over. The trial will be international, multicentric, randomized, double blind and placebo controlled. It will include three arms (two dose arms and one placebo arm) and patients will be monitored during 12 months. CESTO II's primary objectives are to select the best dose and assess the efficacy of NFL-101 versus placebo, for both immediate and gradual smoking

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<sup>1</sup> Approved by the Bellberry Human Research Ethics Committee (HREC) and the University of Tasmania (UTAS)

cessation. The main criteria for assessment are the person's continued abstinence for four weeks (US Food & Drug Administration (FDA) criterion) and six months (European Medicines Agency (EMA) criterion). The biomarkers used to confirm abstinence are exhaled carbon monoxide and urinary cotinine. A range of secondary criteria will also be assessed, including the number of cigarettes smoked, withdrawal symptoms and level of craving.

The clinical centers where the first patients will be recruited over the coming weeks, are the University of Tasmania (UTAS) clinical centers in Hobart and Launceston in Australia, to be followed by the Clinical Investigation Centers (CIC) at the Poitiers, Bordeaux and Rennes hospitals in France.

### Two dedicated additions to lead the CESTO II clinical trial

As envisaged after the capital increase, NFL Biosciences has recruited a Medical Operations Director, who will head up the CESTO II clinical trial and future clinical trials. Dr. Violaine Desort-Henin has more than 12 years' experience in clinical project implementation for biotechnology companies and pharmaceutical groups. Her expertise has been further strengthened with the recruitment of a Senior Clinical Project Leader, enabling NFL Biosciences to achieve operational capacity to monitor progress with CESTO II. Marie-Laure Fraisse has 15 years' experience managing international and multicentric clinical projects at various stages of maturity.

### NFL Biosciences patent registered in the United States

On September 21, 2021, the United States Patent and Trademark Office (USPTO) issued, with number US 11,123,395, the product patent for NFL-101, a nicotine-free botanical drug candidate comprising natural proteins extracted from tobacco leaves, focused primarily on smoking cessation. The addition of cannabis proteins to the extract is covered by one of the claims with a view to a potential future use for cannabis cessation. This patent protects the innovation that NFL-101 is based on through to 2036 in the United States. This patent is also issued in France through to 2036. National registration applications are in the review phase in the following regions and countries: China, Japan, Canada, South Korea, Australia, Brazil, India, Indonesia, Israel, Mexico, Philippines, Eurasia, Saudi Arabia, United Arab Emirates, Nigeria.

### 2021 first-half year financials (January 1 - June 30, 2021)

The accounts for the first half of 2021, prepared in accordance with French GAAP, were approved by the Board of Directors during its meeting on September 30, 2021. The accounts have been subject to a limited review by the statutory auditors. The accounts for the period do not include the results of the capital increase, which had a settlement-delivery date of July 2, 2021.

Corporate accounts (€)	June 30, 2021 (6 months)	December 31, 2020 (12 months)
Net revenues	-	-
Total operating income	-	-
EBIT	(221,051)	(318,028)
Financial income (expense)	(354)	-
Non-recurring income (expense)	-	4,984
<b>Net income</b>	<b>(221,405)</b>	<b>(261,500)</b>
Shareholders' equity	(71,380)	150,025
Intangible assets (patents)	120,566	108,946
Liabilities	1,247,447	174,613
Cash and cash equivalents	175,972	310,201
<b>Balance sheet total</b>	<b>1,428,067</b>	<b>576,638</b>

## **NFL Biosciences qualified as an "Innovative Company" by BPIfrance**

The "Innovative Company" qualification allows a *Fonds Commun de Placement dans l'Innovation* (FCPI) to count its possible participation in NFL Biosciences in the mandatory part of its investment in innovative companies, as defined in I of article L. 214-41 of the Monetary and Financial Code.

## **Outlook**

Dr Ignacio Faus, NFL Biosciences CEO, said: *"The need for smoking cessation has increased as a result of the Covid-19 pandemic, while the pharmacological treatments available are unchanged, are relatively ineffective over the long term, are quite difficult to monitor and are sometimes subject to limiting side-effects. NFL Biosciences has set up a clinical team that will work with our CROs, Eurofins Optimed and InClin and with the five clinical centers in France and Australia, where the patients, smokers who would like to make a new attempt to stop, will be recruited and treated over the coming quarters. We are also working to assess other countries so that we can be in a position to complete our recruitment as quickly as possible"*.

Over the coming months, NFL Biosciences will continue to further strengthen its governance operations.

The assessment of the projects for the treatment of cannabis dependence (NFL-201) and alcohol dependence (NFL-301) will continue to move forward.

## *About NFL Biosciences*

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NFL Biosciences is a biopharmaceutical company based nearby Montpellier, France, whose most advanced botanical drug candidate is an aid to stop smoking. Known as NFL-101, this natural nicotine-free product, extracted from standard tobacco leaves, is protected by two patent families. NFL Biosciences aims to offer smokers who would like to stop a safe, natural solution that is effective over the long-term, with short-term personalized administration.

Alongside NFL-101, NFL Biosciences has various development projects focused on botanical drugs for the treatment of cannabis use disorder and alcoholism.

The shares of NFL Biosciences are listed on Euronext Growth Paris (FR0014003XT0 – ALNFL). Find out more at [www.nflbiosciences.com](http://www.nflbiosciences.com)

## *Contact*

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