

NFL Biosciences: 2021 full-year business and earnings update

Phase II/III clinical trial rolled out for the drug candidate NFL-101 for smoking cessation: first patients recruited and recruitment capacity ramped up

Organization further strengthened and active ingredient manufacturing partnership set up

Intellectual property extended with an NFL Biosciences patent registered in the United States

Co-development agreement signed for the drug candidate NFL-301 to reduce alcohol consumption

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company that is developing botanical drugs for the treatment of addictions, is reporting its 2021 full-year earnings, approved by the Board of Directors on March 24, 2022, while looking back on its progress following its admission to Euronext Growth Paris at the start of July 2021.

Phase II/III clinical trial rolled out for NFL-101, a drug candidate for smoking cessation: first patients recruited in France

Approved by the French National Agency for the Safety of Medicines and Health Products (ANSM)¹, the CESTO II Phase II/III clinical trial received a favorable opinion from the French Ethical Review Board (CPP) in September 2021. The recruitment of patients was launched in January 2022 at the Clinical Investigation Centers (CIC) at the CHU teaching hospital centers in Poitiers, Bordeaux and Rennes, overseen by Eurofins-Optimed as the Clinical Research Organization (CRO). Various initiatives are underway to add other Clinical Investigation Centers.

To optimize the allocation of its resources, and in view of the positive developments within the health context in France and more generally across Europe, NFL Biosciences has decided to not start recruiting patients in Australia and to focus on opening additional centers in France. This decision will enable it to reduce the overall cost of the clinical trial, simplify its management and accelerate patient recruitment.

The clinical trial is targeting male or female smokers who are aged 18 to 70, smoke more than 11 cigarettes per day and are genuinely committed to stopping. The trial includes three arms (two dose arms and one placebo arm) and will monitor patients over 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 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.

Organization further strengthened

In the third quarter of 2021, and aligned with the additional resources from the the capital increase, NFL Biosciences further strengthened its teams with a Medical Operations Director and a Senior Clinical Project Leader, giving it the operational capacity needed to continue moving forward with CESTO II. At the start of 2022, NFL Biosciences also welcomed on board an Investor Relations Director on a part-time basis, while a Financial Director is scheduled to arrive at the end of March.

¹ Agence nationale de sécurité du médicament et des produits de santé

Active ingredient manufacturing partnership set up

In November 2021, NFL Biosciences selected the company Diverchim to manufacture the active ingredient for NFL-101 for its use in additional clinical trials beyond the CESTO II study (Phase II/III). The development plan mapped out will also cover the preclinical development of the active ingredient of NFL-201, NFL Biosciences' drug candidate for treating cannabis addiction.

Thanks to this partnership, NFL Biosciences has secured control over the production of its botanical extracts with a view to anticipating future development requirements all the way through to its potential market release.

Intellectual property extended with an NFL Biosciences patent registered in the United States

On September 21, 2021, the United States Patent and Trademark Office (USPTO) issued, with number 11,123,395, the product patent for NFL-101. The addition of cannabis proteins to the extract is covered by one of the claims with a view to a potential future application for cannabis cessation. This patent protects the innovation that NFL-101 is based on through to 2040 in the United States. This patent is also approved in France through to 2040. 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.

Co-development agreement for NFL-301, a drug candidate to reduce alcohol consumption

In February 2022, NFL Biosciences set up a co-development agreement with ATHENA Pharmaceutiques, a market leader for the development and manufacturing of oral delivery drugs, to develop and produce NFL-301, a natural drug candidate from NFL Biosciences aimed at reducing alcohol consumption.

2021 full-year earnings (January 1 - December 31, 2021)

The full-year financial statements for 2021, prepared in accordance with French GAAP, were approved by the Board of Directors during its meeting on March 24, 2022. The audit procedures on the annual accounts have been finalized. The auditors' reports will be issued after finalization of the Management Report, prior to the publication of the Annual Financial Report.

The initial public offering on Euronext Growth Paris in July 2022 led to an issue premium of €4,960,724.34, with €3,287,481 of shareholders' equity. The gross amount received came to €5m.

EBIT totaled €(978K), reflecting the costs incurred to set up the CESTO II clinical trial, including the strengthening of the team from the third quarter of 2022, the manufacturing of active ingredient batches, and the payments to the CROs.

To optimize these resources, NFL Biosciences is deploying various financing arrangements, which are reflected in the €270.7K of debt and the research tax credit for €141.8K. Various applications for additional public funding are underway in France and in other countries.

Corporate accounts (€)	December 31, 2021 (12 months)	December 31, 2020 (12 months)
Net revenues	-	-
Total operating income	39	3
EBIT	(901,867)	(318,028)
Financial income (expense)	(217,643)	-
Non-recurring income (expense)	-	4,984
Net income	(978,243)	(261,500)

Shareholders' equity	3,287,481	150,025
Intangible assets (patents)	124,034	108,946
Liabilities	270,749	174,613
Cash and cash equivalents	3,039,570	310,201
Balance sheet total	3,685,207	576,638

Outlook for 2022

Dr Ignacio Faus, NFL Biosciences CEO, commented: “NFL Biosciences is continuing to roll out the Phase II/III clinical trial for NFL-101 (smoking cessation), as well as the development of NFL-201 (cannabis addiction) and NFL-301 (aimed at reducing alcohol consumption).

In line with our international development strategy, the company will be ramping up its initiatives enabling the development of NFL-101 and NFL-301 in the United States. Within this framework, various meetings are planned with the US FDA, focused primarily on ensuring that the development plan for the drug candidates and the future clinical trials are acceptable for the FDA.

During the Covid-19 pandemic, consumption of tobacco and alcohol has increased dramatically in most countries. More than ever, there is a need for safe, effective and natural medicinal products that will have a long-lasting impact on the lives of the millions of people who would like to stop smoking and reduce their alcohol consumption”.

About NFL Biosciences

NFL Biosciences is a biopharmaceutical company based in the Montpellier area which develops botanical drug candidates for the treatment of addictions. NFL Biosciences' ambition is to bring new, natural, safer and more effective therapeutic solutions to the entire world population, including low- and middle-income countries. Its most advanced product, called NFL-101, is a standardized, nicotine-free tobacco leaf extract protected by two patent families. NFL Biosciences intends to offer smokers who want to quit a natural, safe, easy-to-administer and personalized alternative. NFL Biosciences is also developing NFL-301, a natural drug candidate for the reduction of alcohol consumption and has a drug development project for the treatment of cannabis use disorders.

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

Contact

Bruno Lafont – info@nflbiosciences.com - +33 4 11 93 76 67

Agence Calyptus – nflbiosciences@calyptus.net - +33 1 53 65 68 68