

NFL Biosciences: 2022 first-half business and earnings

Phase II/III clinical trial for the drug candidate NFL-101 for smoking cessation continues to move forward, with the participation of eight clinical centers in France

Intellectual property extended. NFL Biosciences patent registered in China and South Korea

Partnership with Themis Medicare to develop NFL-101 in India

Partnership with Athena Pharmaceutiques for the global development of NFL-301

Recruitment of a Finance Director

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company that is developing botanical drugs for the treatment of addictions, is reporting its results for the first half of 2022, approved by the Board of Directors on October 24, 2022. The half-year financial statements at June 30, 2022 were subject to a limited review by the Company’s Statutory Auditors. NFL Biosciences, listed on the stock market since July 2021, continues to make progress in the development of NFL-101, its drug candidate for smoking cessation.

NFL-101 phase II/III clinical trial continues to move forward, with the participation of eight clinical centers in France

In recent months, the CESTO II phase II/III clinical trial assessing the efficacy and dosing of its drug candidate NFL-101 has been rolled out at eight clinical centers in France: the CHU teaching hospital centers in Bordeaux, Clermont-Ferrand, Dijon, Marseille, Montpellier, Poitiers and Rennes, and the Eurofins-Optimed research institute in Grenoble, which is also the contract research organization (CRO) of the study.

The clinical trial is targeting men or women aged 18 to 70 who smoke more than 11 cigarettes per day and are genuinely committed to stopping smoking. 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. The main criterion for assessment is the subject’s continued abstinence for four weeks (US Food & Drug Administration (FDA) criterion). The main secondary criterion for assessment is the subjects’s continued abstinence for six months (European Medicines Agency (EMA) criterion). Many other secondary criteria will also be assessed, including the number of cigarettes smoked, withdrawal symptoms and level of craving. The biomarkers used to confirm abstinence are exhaled carbon monoxide and urinary cotinine.

Considering the rate of recruitment of the eight clinical centers, in the absence of events that are beyond the Company’s control or linked to economic and geopolitical developments, subject recruitment is expected to be completed during the first half of 2023.

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 in the development and manufacturing of oral delivery drugs, in order to jointly develop and manufacture NFL-301, a natural drug candidate originated at NFL Biosciences. NFL-301 is indicated for the reduction of alcohol consumption.

The development of the formulation, launched during the first quarter of 2022, is still underway. The Company will then establish dialogue with the European and American regulatory agencies (EMA and FDA) for the product’s clinical development.

Intellectual property extended with an NFL Biosciences patent registered in China and South Korea

NFL Biosciences is continuing to move forward with its knowledge management and protection strategy. This has resulted in the filing of two patent families granting it exclusive rights to its drug candidate NFL-101. This product patent, initially registered and approved in France, concerns an “aqueous extract of tobacco leaves and its use for the treatment of dependence”. The innovation that NFL-101 is based on is therefore protected through to 2036 in France, the United States, and now also in China (300 million smokers) since April 2022 and in South Korea (9 million smokers) since May 2022.

National registration applications are still in the review phase in the following regions and countries: Japan, Canada, Australia, Europe, Brazil, India, Indonesia, Philippines, Saudi Arabia, United Arab Emirates and Nigeria.

Partnership with Themis Medicare to develop NFL-101 in India

In October 2022, NFL Biosciences set up a partnership with Themis Medicare Ltd to develop NFL-101 for the Indian market. Themis Medicare, a pharmaceutical company headquartered in Mumbai with a legacy of over 50 years of making new treatment options available to patients, submitted an investigational new drug (IND) application for a phase II / III clinical trial to the Central Drugs Standard Control Organization (CDSCO), India’s national regulatory authority (NRA).

India has approximately 267 million smokers, and their options for smoking cessation are very limited. Once the study is approved, the clinical trial will be conducted in India, targeting 334 smokers. The cost of the process, from submission to completion of the study, will be paid for by Themis Medicare. Themis will purchase the NFL-101 active pharmaceutical ingredient (API) from NFL Biosciences. NFL Biosciences will also receive double-digit royalties on sales.

Recruitment of a Finance Director

During the first half of 2022, the Company further strengthened its team by recruiting a Finance Director. Guillaume Audema has spent six years with an audit firm, where he became a manager. He joined NFL Biosciences after an initial experience as finance director in another company.

2022 first-half earnings (January 1 – June 30, 2022)

The accounts for the first half of 2022, prepared in accordance with French GAAP, were approved by the Board of Directors during its meeting on October 24, 2022. The limited review of the half-year financial statements has been completed and the financial report for the first half of 2022 will be made available on October 26, 2022; it can be consulted on www.nflbiosciences.com, under “Investors” and “Documents”

The initial public offering on Euronext Growth Paris in July 2022 led to a €4,960,724.34 issue premium, with a gross total of €5m received (€4.2m net). Since then, NFL Biosciences has rolled out its business plan in line with the strategy presented at the time of its IPO, while further strengthening its organization to accompany these new steps forward in the development of its botanical drug candidates for the treatment of addictions, and particularly NFL-101.

First-half EBIT totaled €(1,301)K, compared with €(978)K in 2022, reflecting the costs incurred for the CESTO II clinical trial, the strengthening of the teams from the third quarter of 2021, the manufacturing of batches of active ingredients, the intellectual property costs, and the payments to different CROs. Following the decision taken to recruit patients in France, the subsidiary in Australia will be dissolved during the second half of this year. This decision to recruit all of the patients in France was taken thanks to: (i) the good pace of recruitment in the various French CHU centers, and (ii) the significantly lower cost of clinical trials in France compared with Australia.

The ramping up of the clinical trial is reflected in the increase in accounts payables to €534K for the first half of this year, compared with €120K at December 31, 2021, primarily including accrued invoices. The Company still has an €85K government-backed loan, with repayments based on one quarter per year to start up in 2023. A previous financing line dependent on the success of the NFL-101 phase I trial, recorded in quasi-equity, is currently being repaid based on €18K per quarter and will be paid back in full by December 2023.

Cash and cash equivalents at June 30, 2022 totaled €2,044,267 and do not include the research tax credit, worth €100,670 for the first half of this year and €159,447 for 2021, which had not yet been received by the Company as of June 30, 2022.

NFL Biosciences operates with a very low level of fixed costs and overheads, outsourcing activities to various industrial firms. This strategic choice enables more flexibility with the deployment of its financial resources with a view to advancing its development programs. The majority of free cash is allocated to its clinical programs.

Requests for funding submitted to BPI France are currently at an advanced review stage, with repayments subject to the success of the projects: (i) a €1.8m request concerning the CESTO2 study, for an initial total of €1.3m, revised upwards following the decision to recruit patients exclusively in France, thus increasing the level of eligible expenses; (ii) a €245K request concerning the formulation and clinical trial approval for NFL-301, a drug candidate for reducing alcohol consumption. The applications are currently being reviewed by BPI France, with a response expected over the coming weeks.

The Company is continuously looking into the various financing options available in France and other countries, with a preference for non-dilutive financing.

Corporate accounts (€)	Jun 30, 2022 (6 months)	Dec 31, 2021 (12 months)	Jun 30, 2021 (6 months)
Net revenues	-	-	-
Total operating income	5	39	0
EBIT	(1,300,816)	(901,867)	(221,051)
Financial income (expense)	107,829	(217,643)	(354)
Non-recurring income (expense)	-	-	-
Corporate income tax	-121,632	-141,266	-
Net income	(1,071,354)	(978,243)	(221,405)
Shareholders' equity	2,216,127	3,287,481	(71,380)
Intangible assets (patents)	139,577	124,034	120,566
Liabilities	736,661	270,749	1,247,447
Cash and cash equivalents	2,044,267	3,039,570	175,972
Balance sheet total	3,043,765	3,685,207	1,428,067

Outlook for 2022

Dr Ignacio Faus, NFL Biosciences CEO: *“NFL Biosciences is continuing to roll out the phase II/III clinical trial for NFL-101 (smoking cessation), in addition to developing NFL-201 (cannabis addiction) and NFL-301 (reducing alcohol consumption). As control over manufacturing know-how is a key element in the NFL-101 value chain, the production of GMP batches of the product is underway and a clinically ready batch is expected in 2023. We are also continuing to look for partners for NFL-101 outside of Europe and the United States, in low or mid-income countries. A first partnership has already been set up in India”.*

Progress with the NFL-301 product, the second pillar of the Company's global strategy, is moving forward in partnership with the French firm Athena Pharmaceutiques. NFL Biosciences hopes to obtain a first usable formulation in early 2023.

In line with its international development strategy, NFL Biosciences will be ramping up its initiatives enabling the development of NFL-101 and NFL-301 in the United States and other countries. Within this framework, various meetings are being scheduled 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 in the United States.

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

Contacts

