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GENFIT: ANNUAL RESULTS FOR 2013

- **GROWTH INVESTMENTS MAINTAINED AT A VERY HIGH LEVEL**
- **INCOME STABILIZED AND TREASURY SIGNIFICANTLY STRENGTHENED**
- **MAJOR SCIENTIFIC AND REGULATORY PROGRESS IN THE PRINCIPAL PROPRIETARY RESEARCH PROGRAMS DESTINED FOR OUT-LICENSING**

Lille (France), Boston (Massachusetts, United States), March 12, 2014 – GENFIT (Alternext: ALGFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of drug discovery and development, focusing on the early diagnosis and preventive treatment of cardiometabolic and associated disorders, today announces its consolidated financial statement for the year ending December 31st, 2013.

Jean-François Mouney, Chairman and CEO of GENFIT, declared: *"2013 marked a turning point in GENFIT's history, as illustrated by the progress made by GFT505 in NASH and the first safety data obtained in the Phase IIb clinical study, and also by the active support of regulatory agencies. We are also particularly satisfied that GFT505 has shown an enlarged therapeutic potential in other indications, in particular covering all the stages of NASH up to cirrhosis. In parallel, our other research programs have progressed according to plan and continue to represent out-licensing opportunities. From a financial point of view, the strong increase in net loss corresponds to our efforts devoted to maximizing the transaction value of GFT505. A coherent and controlled strategy since, at the same time, GENFIT has strengthened its treasury while creating value for all its shareholders."*

Consolidated financial statement (IFRS standards) *(million EUR)*	**31/12/2013**	**31/12/2012**
Total income	5.97	6.01
Current operating result	(10.42)	(7.71)
Financial result	0.18	(0.01)
Net result	(12.65)	(5.41)
End-of-year cash situation (gross)	20.92	6.3

CONSOLIDATED FINANCIAL RESULTS FOR 2013

The financial year ending December 31st, 2013 was marked by the following elements:

- Total income is virtually stable at €5.97 million, compared to €6.01 million in 2012. Of this total, industrial revenues accounted for €1.9 million (compared to €1.67 million in 2012) and public research funding made up of operational grants and Research Tax Credit accounted for €3.91 million (compared to €4.31 million in 2012).
- Given the major increase in investments for clinical and pre-clinical studies of the drug candidate GFT505, the operating charges for 2013 were €16.38 million versus €13.73 million in 2012.
- Personnel costs increased by 16.9% to €6.48 million in 2013. This increase, due in particular to the annual bonus awarded to employees, compensates the wage moderation measures that were previously applied and the implication of the personnel that contributed to the positive scientific results obtained during the period and to the associated capital-raising operations. The average number of employees over the 2013 financial year was 75, compared to 82 during 2012.
- Consequently, the current operating result shows a loss of €10.42 million for the 2013 financial year versus a loss of €7.71 million for 2012.

- The activation of deferred tax liabilities following the re-evaluation operation of the Company's real estate complex situated in the Eurasanté business park in 2012, was completely recovered in the 2013 result with the sale of the complex to a specialized real-estate investor. Given this recovery of €2.32 million, generating an exceptional tax burden of the same sum, the financial exercise shows a net loss of €12.65 million compared to a net loss of €5.41 million in 2012.
- On December 31st, 2013, GENFIT's cash and cash equivalents showed a strong increase at €20.92 million, compared to €6.3 million on December 31st, 2012.

MAJOR ACHIEVEMENTS FOR 2013

During the 2013 financial year, GENFIT continued and concentrated its efforts on its core business of proprietary research programs in the field of metabolic diseases.

- **GFT505: strengthening in NASH and broadening of therapeutic potential**

  - **Broadening of therapeutic potential:** In January 2013, new pre-clinical data in human hepatic cells showed that the therapeutic potential of GFT505 covers all the stages of NASH up to cirrhosis; the underlying anti-fibrotic mechanism of action identified during this work opens the door to the evaluation of GFT505, beyond NASH, in hepatic/cirrhotic fibrosis linked to chronic viral- or alcohol-induced hepatitis.

  - **Strengthening in NASH and first safety data:**

    - Following the conclusive results of pre-clinical, clinical, and toxicology studies obtained in 2012, the Company obtained positive opinions on the design of a Phase IIb study in NASH from the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA).
    - The international multi-center Phase IIb study, initiated at the end of Q3, 2012 in Europe and the United States with the aim of recruiting 270 patients went according to plan. The last patients to be included in the study were recruited during the period.
    - In October 2013, the Data Safety and Monitoring Board (DSMB), an independent committee of international experts set up to ensure patient safety during this study, analyzed the complete safety data for patients that had been treated for more than 6 months with GFT505 at the first dose tested, 80 mg/day. Based on this data, the members of the DSMB unanimously concluded that GFT505 showed no safety issue that compromised the continuation of the study, and a second recruitment phase was launched and completed within a few days. The dose of 120 mg/day of GFT505 is currently administered to this second patient cohort.
    - In total, over the first and second recruitment phases, 275 patients have been randomized.

- **Progress on the research programs TGFTX3 and TGFTX1**

  - **TGFTX3 Program**: Following the discovery by GENFIT in 2012 of novel synthetic ligands of the Rev-Erbα receptor, and the pharmacological demonstration that they regulate glucose metabolism, studies performed in 2013 enabled their therapeutic potential to be confirmed in several animal models of Type 2 diabetes. The ongoing medicinal chemistry program has resulted in the identification of more potent Rev-Erbα agonists that comply with established drug-likeness criteria.

- **TGFTX1 Program:** During the period, GENFIT has identified and validated a new family of ligands of the RORγt nuclear receptor. These novel compounds inhibit the secretion of the cytokine IL-17 by Th17 lymphocytes, through their antagonist activity on RORγt. These results represent major progress in the development of new drug candidates for the treatment of diseases involving the Th17 pathway, such as psoriasis, multiple sclerosis, rheumatoid arthritis, and chronic inflammatory intestinal diseases.

- **Biomarker Programs**

In conjunction with its therapeutic research programs, GENFIT focused in 2013 on the identification of specific and measurable biological parameters associated with the development of Type II diabetes (BMGFT02) and NASH (BMGFT03), as early markers of risk for these diseases.

In NASH in particular, GENFIT has worked on the development of new diagnostic solutions to allow the identification and stratification of diseased or at-risk populations, with the aim of determining which patient subsets are most likely to respond to treatment. This work has two major themes: the discovery of new biomarkers capable of replacing the liver biopsy that is currently the only approved diagnostic tool for the disease, and the development of algorithms that combine several existing but insufficient biomarkers.

To this end, GENFIT has access, via the cohorts recruited for the Phase IIb study of GFT505, to patients with varying degrees of NASH severity, thus enabling the development of companion tests and, with a suitable partner, of true diagnostic tools.

- **Partnership with Sanofi**

- The industrial partnership with Sanofi, that dates back to GENFIT's creation in 1999, has been renewed many times over the years. The collaboration in progress was initiated in 2011 for a period of 3 years, and aims through two distinct programs to identify molecules capable of addressing the mitochondrial dysfunction that is associated with certain pathologies including metabolic diseases.
- Within this 3-year contract, GENFIT receives upfront annual payments to support its research, as well as additional milestone payments according to the progress of the preclinical and clinical development, registration, and commercialization of the resulting drug candidates. The total of these upfront and milestone payments could reach up to €39.6 million, in addition to royalties from future sales of the drug candidates.
- Two major scientific milestones have been successfully achieved since the beginning of this latest collaboration, and have each resulted in a milestone payment by Sanofi, in early 2012 and early 2013.

- **Strengthening of funds**

Several capital increases took place during the financial year ending December 31st, 2013:

- €6.85 million was raised with the continued implementation of the convertible loan agreement signed at the end of December 2012 by the Company; this implementation took the form of several successive capital increases reserved to the Bondholder from January to August 2013;
- €14.3 million was raised in April 2013 following a private placement capital increase.

These different operations enabled GENFIT to strengthen its financial situation and to pursue its development strategy, by giving it the means to maintain the current level of investment in the different research programs in progress, particularly the GFT505 program.

POST-CLOSURE EVENTS AND PERSPECTIVES FOR 2014

Post-closure events

- **Extension of the therapeutic potential of GFT505 beyond NASH:** In January 2014, the effects of GFT505 on the proliferation of 21 human cancer cell lines were evaluated in vitro. GFT505 blocked proliferation in the majority of these cell types, suggesting that it may not only prevent the development of liver cirrhosis but also reduce the associated risk of liver cancer.

- **Granting of « Fast Track » designation for GFT505 in NASH:** In February 2014, the Food and Drug Administration (FDA) granted Fast Track designation to the GFT505 development program in NASH. The FDA's Fast Track program is designed to facilitate the development of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. The aim is to ensure that new therapies for serious conditions are available to patients as soon as possible. This designation permits close and regular contact between GENFIT and the FDA, thus enabling the joint definition of the most efficient development plan through frequent meetings and an accelerated review process.

- **Partnership with Sanofi:** The positive results obtained in 2013 have enabled the achievement of a third scientific milestone, resulting in a new milestone payment.

- **Strengthening of funds:** Following on from the operations that took place in 2013, the Company launched a capital increase with shareholders' preferential subscription rights maintained in February 2014, for a total, emission prime included, of €5 million. This operation was four times over-subscribed.

Perspectives for 2014 :

- **Transfer an early option on the GFT505 commercialization rights, or continue its development up to the end of the Phase IIb trial to maximize its value:** Following the solid scientific results obtained for its most advanced drug candidate and the discussions that are underway with several biopharmaceutical companies, the Company intends to valorize the clinical, pre-clinical, and toxicological data obtained in order to negotiate the compound commercialization rights in the best interests of the Company and its shareholders. These discussions will thus be pursued with the aim of maximizing the transaction. According to the economic conditions that are proposed and to GENFIT's financial resources, the Company could decide to transfer an early option, or to wait for the results of the ongoing Phase IIb clinical trial to transfer the GFT505 commercialization rights.

- **Extension of the partnership with Sanofi** With the success of the current collaboration with Sanofi resulting in the achievement of a scientific milestone each year, the Company will propose to Sanofi to extend the research collaboration on one of the two programs initiated in 2011.

- **Signature of an industrial co-development partnership for the program TGFTX1 or TGFTX3,** based on the progress made in 2013.

- **Strengthening of funds and progressive transformation into a specialized biopharmaceutical company:** The funds raised will enable the Company to assure its potential partners that it has the financial capacity to best negotiate GFT505 commercialization rights, and that it has the means to initiate its progressive transformation into a specialized biopharmaceutical company, by seizing the opportunity to acquire and then develop molecules at the clinical development phase in its areas of therapeutic excellence.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in therapeutic fields linked to cardiometabolic disorders (prediabetes/diabetes, atherosclerosis, dyslipidemia, inflammatory diseases…). GENFIT uses a multi-pronged approach based on early diagnosis, preventive solutions, and therapeutic treatments and advances therapeutic research programs, either independently or in partnership with leading pharmaceutical companies, including Sanofi, to address these major public health concerns and their unmet medical needs.
GENFIT's research programs have resulted in the creation of a rich and diversified pipeline of drug candidates at different stages of development, including GENFIT's lead proprietary compound, GFT505, that is currently in Phase IIb.
With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 80 employees. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111). www.genfit.com

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