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GENFIT: ANNUAL RESULTS FOR 2012

- **GROWTH INVESTMENTS MAINTAINED AT A HIGH LEVEL AND LOSSES SIGNIFICANTLY DECREASED**
- **SIGNIFICANT PROGRESS IN ALL THE PROPRIETARY RESEARCH PROGRAMS DESTINED FOR OUT-LICENSING**
- **POSITIVE OPINION OF REGULATORY AGENCIES FOR THE ONGOING CLINICAL DEVELOPMENT OF GFT505**

Lille (France), Boston (Massachusetts, United States), April 12, 2013 – 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, 2012.

Jean-François Mouney, Chairman and CEO of GENFIT, declared: *"2012 was a key financial year for GENFIT, during which GFT505, our leading proprietary drug candidate, not only achieved all its clinical objectives, but also received a positive opinion from the major international regulatory agencies in an indication, NASH*, for which no treatment currently exists. These extremely favorable perspectives, together with the progress made in our other research programs, open the way to a change in the scope of our company in the years to come, in favor of major industrial alliances. More than ever, GENFIT intends to defend its interests as well as those of its shareholders, by maximizing the valorization of all its candidate molecules."*

Consolidated financial statement (IFRS standards) *(million EUR)*	**31/12/2012**	**31/12/2011**
Total income	6.01	6.78
Current operating result	(7.71)	(7.67)
Financial result	(0.01)	(0.05)
Net result	(5.41)	(9.68)
End-of-year cash situation (gross)	6.3	12.80

CONSOLIDATED FINANCIAL RESULTS FOR 2012

The financial year ending December 31st, 2012 was marked by the following elements:

- Total revenues amounted to €6.01 million, compared to €6.78 million in 2011. Of this total, industrial revenues accounted for €1.67 million and public research funding made up of operational grants and Research Tax Credit accounted for €4.31 million.

- Despite maintaining investment in clinical trials and regulatory toxicology studies for the drug candidate GFT505 at a high level, operating charges for 2012 were €13.73 million versus €14.45 million in 2011.

- Personnel costs also decreased by almost 7% to €5.54 million versus €5.94 million in 2011. The average number of employees over the 2012 financial year was 82, compared to 92 during 2011.

- Consequently, the current operating result shows a loss of €7.71 million for the 2012 financial year versus a loss of €7.67 million for 2011.

- Taking into account the activation of deferred tax liabilities, the consolidated net result for 2012, according to international IFRS standards, shows a decreased net loss of €5.41 million, compared to a loss of €9.68 million in 2011.

- On December 31st, 2012, the cash and cash equivalents of the Company amounted to €6.3 million, compared to €12.8 million on December 31st, 2011.

- The treasury stands at €16 million as of today's date.

MAJOR ACHIEVEMENTS FOR 2012

Significant clinical and regulatory progress for GFT505

- **Pre-clinical results obtained in NAFLD/NASH:** a series of animal studies confirmed the efficacy of GFT505 in different pre-clinical models of Non-Alcoholic Fatty Liver Disease (NAFLD)/ Non-Alcoholic Steato-Hepatitis (NASH) and showed that the compound blocks hepatic fibrosis development. A second series of pre-clinical studies demonstrated the therapeutic efficacy of GFT505 on established hepatic disorders, and opened the possibility of evaluating GFT505 in other diseases associated with hepatic fibrosis, such as primary biliary cirrhosis, viral hepatitis, or drug-induced hepatitis. During Q2, 2012, other pre-clinical data showed that the oral administration of GFT505 not only blocked the development of fibrosis, but induced its regression.

- **Regulatory toxicology studies:** the complete regulatory toxicology package, including the final results of carcinogenicity studies and of long-term toxicity studies in monkeys, published in early February 2012, confirmed the safety of long-term treatment with GFT505. At the highest doses tested, GFT505 had no major adverse effect relevant to humans. In particular, none of the adverse effects previously observed in similar studies with the different classes of oral anti-diabetes drugs were observed.

- **Latest clinical data:** during Q2, 2012 the results of the GFT505-111-7 study demonstrated the safety and efficacy of increasing doses of GFT505 up to a dose three-fold higher than the current therapeutic dose of 80 mg/d. The primary aim of this study was to demonstrate the safety of GFT505 in obese or overweight subjects at doses significantly higher than the current therapeutic dose of 80 mg/d used in all Phase IIa proof-of-concept studies to date. GFT505 was thus administered for 14 days at 120 mg/d, 180 mg/d, and 240 mg/d, and the results compared to those obtained under placebo. No serious adverse event was reported in this study, and no undesirable effects were reported in subjects treated at 240 mg/d. Moreover, at all tested doses, there were strong beneficial effects on markers of hepatic dysfunction, plasma lipid parameters, glycemia, and inflammatory markers.

- **Potential therapeutic indications:** having completed the program of Phase IIa clinical trials and regulatory toxicology studies, the indications to be pursued as a priority for the Phase IIb development of GFT505 are the prevention and treatment of NAFLD/NASH in Type II diabetic patients, as well as the prevention of cardiovascular events in high-risk Type II diabetes patients.

- **Positive feedback from regulatory authorities for the launch of Phase IIb studies:** following the conclusive results of pre-clinical, clinical, and toxicology studies obtained in the first half of 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). This international multi-center study that will recruit 270 NASH patients was therefore launched at the end of Q3, 2012 in Europe and the United States. The treatment of the first patients with GFT505 began in mid-November 2012.

TGFTX1 and TGFTX3 programs: industrial alliances anticipated in the short-term

GENFIT uses its know-how in the biology and chemistry of nuclear receptors, as well as its in-depth knowledge of cardiometabolic and inflammatory diseases, to direct the **TGFTX1** and **TGFTX3** research programs that target two nuclear receptors: the Rev-Erb (Rev-Erbα/Rev-Erbβ) receptor for the TGFTX3 program, and the ROR (RORα/RORγt) receptor for the TGFTX1 program.

- **TGFTX3 program:** the therapeutic potential of new proprietary compounds has been demonstrated in *in vivo* diabetes models. Novel synthetic ligands of the Rev-Erbα receptor have been discovered, and GENFIT has shown by pharmacological studies that they regulate glucose metabolism. An international patent application has thus been submitted for the families of candidate molecules.

- **TGFTX1 program:** GENFIT now has *in vitro* proof of concept of a role in inflammation. The first molecules developed in this program that targets the RORγt nuclear receptor have shown beneficial effects in functional tests. The therapeutic applications are wide, although the majority of RORγt inhibitors currently under development target principally auto-immune diseases such as psoriasis or rheumatoid arthritis.

Biomarker Programs

In conjunction with its therapeutic research programs, GENFIT focalized in 2012 on the identification of specific and measurable biological parameters associated with the development of Type II diabetes (BMGFT02) and more recently NAFLD/NASH (BMGFT03), as early markers of risk for these diseases.

- The evaluation of the potential industrial valorization of the biomarker technologies developed as part of the MicroPath consortium did not prove conclusive. Their development was therefore suspended in the second half of 2012, enabling GENFIT to focus its resources on the BMGFT02 and BMGFT03 programs.

- In the context of the BMGFT02 program in particular, several candidate biomarkers of the transition from pre-diabetes to diabetes have been identified thanks to the Company's transcriptomics technologies, certain of which are part of the IT-Diab research consortium.

Partnership with Sanofi

Following on from the positive results obtained during the previous biannual contract, Sanofi and GENFIT decided in early 2011 to extend and reinforce their historical alliance (that dates back to GENFIT's creation) for three more years with two new research programs. This new collaboration aims to identify molecules capable of addressing the mitochondrial dysfunction that is associated with certain pathologies including metabolic diseases.

Within this new contract, GENFIT classically receives upfront annual payments to support its research during the three years of the collaboration, 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 products.

Halfway through the period of this collaboration, the progress as evaluated by the two companies is very positive. The two programs conducted in parallel advance according to the contractual plan of action, with notably the identification and characterization of the first "hits". A first major scientific milestone was

successfully achieved in early January 2012, resulting in the first milestone payment in March 2012. The solid scientific results obtained during the second half of 2012 have enabled the two programs to continue as planned in 2013.

Strengthening of funds

Several reserved capital increases in favor of the Company Yorkville for a total of €4.85 M have 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 2013

Post-closure events

- **GFT505 program**: new pre-clinical data obtained in January 2013 show that the therapeutic potential of GFT505 covers all the stages of NASH up to cirrhosis and its evolution towards liver cancer. The underlying anti-fibrotic mechanism of action of GFT505 revealed by these latest studies opens the door to its evaluation in hepatic/cirrhotic fibrosis linked to chronic viral- or alcohol-induced hepatitis. A new patent application has thus been filed covering the use of GFT505 for treating pro-fibrotic diseases and certain types of cancer.

- **Partnership with Sanofi:** the solid scientific results obtained during the second half of 2012 enabled a second milestone to be reached in January 2013, resulting in a further milestone payment.

- **Strengthening of funds:** following on from the operations that took place in 2012, further reserved capital increases in favor of the Company Yorkville have been performed for a total of €5.65 M.

- **Finalization of a real estate transaction:** the Company completed the sale of its laboratories and offices situated in the Eurasanté business park, to an investor specialized in healthcare real estate. This transaction, that is non-dilutive for shareholders, generated €9.6 M in cash before taxes at the time of the operation.

Perspectives for 2013

- **GFT505**: transfer an option on the compound commercialization rights, or bring the clinical development of the product up to the beginning of Phase III trials to maximize its value.
  Following the solid scientific results obtained for GFT505 and the discussions that are underway with several biopharmaceutical companies, GENFIT intends to valorize the clinical, pre-clinical, and toxicological data obtained over the past two years 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 continue alone, or to co-pilot the Phase IIb clinical trial in risk-sharing with a privileged industrial partner after the transfer of an option on the GFT505 commercialization rights.

- **Partnership with Sanofi:** achievement of a major new scientific milestone in the context of the collaborative program with Sanofi. This year, GENFIT expects to demonstrate the *in vivo* proof of therapeutic efficacy of the new chemical series identified during this contract, thus achieving another key step.

- **TGFTX1 and TGFTX3 programs:** signing of a new industrial co-development alliance for the identified compounds, following on from the progress achieved in 2011 and 2012.

- **Progressive and continuous strengthening of funds,** in the case that an agreement is not reached for an option on the GFT505 commercialization rights**.**

***About NAFLD/NASH:**
NAFLD (non-alcoholic fatty liver disease) and in particular NASH (non-alcoholic steatohepatitis) are serious liver diseases that can lead to cirrhosis and liver cancer. The development of NAFLD/NASH is associated with the pathophysiological process of insulin resistance in patients that are overweight and/or diabetic. NAFLD is believed to affect 70-80% of diabetic patients, and progresses to chronic liver disease (NASH) in 20-50% of cases. Mortality due to liver disease is thus 2-3-fold higher in the diabetic population than in the overall population. The NASH market was estimated at 615 $M in 2010 and should reach 2,008 $M in 2018.

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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