

2015
Press release



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GENFIT: ANNUAL RESULTS FOR 2014

Lille (France), Boston (Massachusetts, United States), April 3, 2015 – GENFIT (Euronext: GNFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of developing therapeutic and diagnostic solutions in metabolic and inflammatory diseases, that notably affect the liver or the gastrointestinal system, today announces its consolidated financial statement for the year ending December 31st, 2014.

Consolidated financial statement (IFRS standards) (million EUR)	31/12/2014	31/12/2013
Total income	6.77	5.97
Current operating result	(16.22)	(10.42)
Financial result	0.23	0.18
Net result	(17.02)	(12.65)
Cash, cash equivalents and current financial instruments	76.3	20.92

CONSOLIDATED FINANCIAL RESULTS FOR 2014

The financial year ending December 31st, 2014 was marked by the following elements:

- Total income has increased to €6.77 million, compared to €5.97 million in 2013. Of this total, industrial revenues accounted for €1.61 million (compared to €1.90 million in 2013) and public research funding made up of operational grants and Research Tax Credit accounted for €5.07 million (compared to €3.92 million in 2013);
- Given the major increase in investments for clinical and pre-clinical studies of the drug candidate GFT505, the operating charges for 2014 were €22.99 million versus €16.38 million in 2013;
- Amongst the operating charges, personnel costs increased to €8.31 million in 2014 (compared to €6.47 million in 2013). This increase was due particularly to the strengthening of the clinical development team and the impact of the bonuses awarded to employees in recognition of their role in the development of the Group and especially in the capital-raising operations undertaken during the financial year. The average number of employees over the 2014 financial year was 81, compared to 75 during 2013;

- Consequently, the current operating result shows a loss of €16.22 million versus a loss of €10.42 million in 2013;
- Given a financial result of €0.23 million, and the observation, according to IFRS standards, of a burden of €1.05 million in share-based payment transaction expenses corresponding to equity warrants attributed during 2013, the financial exercise shows a net loss of €17.02 million compared to a net loss of €12.65 million in 2013;
- GENFIT's cash and cash equivalents and current financial instruments showed a strong increase from €20.92 million at the end of 2013, to approximately €76.3 million on December 31st, 2014.

MAJOR ACHIEVEMENTS FOR 2014

GFT505: Major scientific and regulatory progress

In 2014, the Company announced several major breakthroughs concerning its compound GFT505:

- In January, the Company revealed new pre-clinical data on the inhibitory effect of GFT505 on the proliferation of 21 human cancer cell lines from different cancer types. GFT505 blocked proliferation in the majority of these cell lines, suggesting that it may have protective effects in several types of tumor;
- In February, 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 and accelerate the review of new drugs that are intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs;
- In March, the Company announced new data demonstrating the curative effects of GFT505 in an experimental model of NASH associated with metabolic disorders. In a study using a NASH model (*foz/foz* mice subjected to a high-fat diet) that accurately reproduces the natural evolution of the disease in Man, the results show that GFT505 eliminates NASH and improves fibrosis;
- In April, the Company announced new data illustrating the anti-fibrotic properties of GFT505 in a non-liver model of fibrotic disease. These studies revealed the efficacy of GFT505 in a model of chronic bowel inflammation widely used to identify new treatments for Crohn's disease. The results clearly showed that oral treatment with GFT505 protects the intestine from inflammatory injury and reduces associated fibrosis;
- In May, the Company announced the granting in Europe of a new patent for GFT505, that provides protection in 32 European countries plus Hong Kong, as well as the allowance of the American patent. With the granting of these new patents, GFT505 will be protected in these major markets up to the end of 2035, via the usual patent extension clauses;

- In June, the Company announced that the independent Data and Safety Monitoring Board (DSMB) of international experts charged with ensuring the safety of use of GFT505 in the Phase 2b study in NASH (GOLDEN-505 study), had analysed the safety data collected during the study after up to one year of treatment. The DSMB provided its unrestricted approval to continue the clinical trial as planned in the initial protocol;
- In October, the Company announced the allowance in China of a patent for GFT505. Moreover, the USPTO (United States Patent and Trademark Office) allowed the patent in hepatic fibrosis. With the granting of the new patents, GFT505 will be protected in NASH and other liver diseases in these major markets up to the end of 2035, via the usual patent extension clauses;
- In December, the Company announced that all the patients of the GOLDEN-505 study had completed the one-year treatment period, with no safety issues and a low drop-out rate.

Progress and renewal of the historical co-research partnership with Sanofi

The previous collaboration contract and licensing agreement signed on March 9, 2011, in the context of the historical co-research partnership of the Company with Sanofi, initially covered a period of three years of shared research between the scientific teams of the two parties.

Within this contract, Sanofi grants the Company 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.

Several scientific milestones have been successfully reached in the development of the molecules resulting from the two programs initiated as part of this collaboration contract, including the third and final milestone in March 2014. The Company has thus received three milestone payments amounting to a total of €1.6 million.

The Company has notably demonstrated the beneficial activity of several of the identified molecules in different in vivo models that are relevant to the targeted pathologies. An extension to the latest collaboration contract and licensing agreement was signed in September 2014, thus prolonging the current phase of shared research between the scientific teams until May 2015.

As part of the renewal of this agreement, the Company obtained an increase in the milestone payments linked to the achievement of the different clinical development phases of the drug candidates arising from the collaboration.

As of 31 December 2014, the Company thus remains eligible:

- for additional milestone payments that could represent a total of €8 million for clinical development up to marketing approval of a product;
- for additional milestone payments that could represent a total of €6 million upon marketing approval of a product and its market entry;
- and for royalties on the sales of a product, of a value of 3% of its net pre-tax revenue.

Financing and transfer of the Company's shares to compartment B of the Euronext Paris regulated market

Capital increases

Three capital increases have contributed to the strengthening of the treasury and the financial situation of the Company:

- In January-February, the Company successfully completed a capital increase with maintenance of preferential subscription rights. Together with the private placement operation of April 2013, this capital increase notably aimed to accelerate the research confirming the anti-fibrotic potential of the drug candidate GFT505 and to strengthen the funding of the biomarker program in NASH (BMGFT03). The gross proceeds of the capital increase amounted to approximately €5 million, after the application of the extension clause, the operation being more than 4-fold over-subscribed.
- In June, the Company successfully completed a capital increase by private placement, with the aim notably of financing the completion of the Phase IIb clinical trial of GFT505 in NASH and to prepare the clinical dossier for Phase III trials. The gross proceeds amounted to approximately €49.7 million.
- In December, the Company successfully completed a capital increase by private placement, with the aim notably of extending the clinical development of GFT505 in other indications than NASH within the new program TGFTX5, and to enable the purchase of one or two molecules at the clinical development stage in major therapeutic domains. The gross proceeds amounted to approximately €20.9 million.

Transfer of the Company's shares

Since 17 April 2014, the Company's shares have been transferred by direct listing to the Euronext Paris regulated market, compartment B. The Company's shares were listed on the Alternext market of Euronext Paris since 2006.

POST-CLOSURE EVENTS AND PERSPECTIVES FOR 2015

Major post-closure events

In January 2015, the Company announced the results of a clinical study of the cardiac safety of GFT505, in which two doses were tested: a therapeutic dose of 120mg/d and a supra-therapeutic dose of 300mg/d. The data showed that, in keeping with regulatory requirements, the repeated daily administration of GFT505 for 14 days at up to 2.5-fold higher than the therapeutic dose had no adverse effect on cardiac electrical activity.

In March 2015, the Company announced the topline results of the Phase IIb study of GFT505 in NASH (GOLDEN-505 study). These first results showed that GFT505 demonstrates dose-dependent efficacy on the primary endpoint of the study, after correction for baseline severity and site heterogeneity by a standardized statistical analysis. Treatment with GFT505 also had significant beneficial effects on cardio-metabolic parameters, and GFT505 was safe and well-tolerated throughout the one-year treatment period of the study.

Perspectives

The Company intends to pursue its strategy of value creation founded on the development of its proprietary therapeutic and diagnostic assets, and notably on the development of its most advanced product GFT505, which the Company expects to be its major catalyst for growth in the coming years.

With this in mind, discussions will be undertaken with the regulatory authorities (FDA and EMA) in order to launch a program of Phase III clinical trials of GFT505 in NASH in 2015.

The Company also intends to exploit the multitude of data collected during the GOLDEN-505 study to continue the progress of its biomarker program in NASH.

Given these objectives and the available treasury, the Company could call on the market to finance its growth; the possible signing of a total or partial transfer agreement of the commercialization rights of its proprietary compounds, in particular GFT505, could enable the financing of a part of the development of these key programs.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS & OTHER COMPREHENSIVE INCOME (IFRS STANDARDS)

The financial table corresponding to the Consolidated Statement of Profit or Loss & Other Comprehensive Income is available in the on-line press release via the Company's web-site (<http://www.genfit.com/press-releases/>).

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (IFRS STANDARDS)

The financial table corresponding to the Consolidated Statement of Financial Position is available in the on-line press release via the Company's web-site (<http://www.genfit.com/press-releases/>).

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in fields of high medical need due to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on contributing to bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH - Nonalcoholic steatohepatitis) or the bowel (such as the inflammatory bowel disease). GENFIT implements mutually beneficial approaches that combine novel treatments and biomarkers; its research programs have resulted in the creation of a rich and diversified pipeline of drug candidates, including GENFIT's lead proprietary compound, GFT505, that is completing a Phase 2b study in NASH.

With facilities in Lille, France, and Boston, MA (USA), the Company has approximately 80 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT; ISIN: FR0004163111). www.genfit.com

Disclaimer:

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf-france.org) or on GENFIT's website (www.genfit.com).

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in GENFIT in any country.

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