

www.genfit.com



# **Press Release** Communiqué de Presse 2010

### **GENFIT: RESULTS FOR FIRST HALF OF 2010**

- REINFORCEMENT OF INTERNAL RESEARCH AND PROGRESS IN THE GFT505 **CLINICAL RESULTS**
- **TIGHTLY CONTROLLED CASH EXPENDITURE**
- **FAVORABLE PERSPECTIVES IN VIEW OF A STRUCTURAL INDUSTRIAL DEAL**

Lille (France), Cambridge (Massachusetts, United States), September 30, 2010 - 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 financial results for the first half of 2010, ending on June 30, 2010.

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, declared: "During this period, GENFIT recorded several major achievements thanks to the important clinical results obtained for GFT505, that give our drug candidate a new competitive advantage in the treatment of pre-diabetic and diabetic populations, a therapeutic area where the need for innovative treatments has never been so strong. At the same time, our proprietary research efforts have continued for early-stage programs such as TGFTX1 and TGFTX3, two recently deorphanized nuclear receptors that play a key role in diabetes and the inflammatory state associated with cardiometabolic disorders. The three early biomarker BMGFT programs have also recorded significant progress. From a financial point of view, the first half of 2010 was influenced by our clinical research efforts with a view to signing a major industrial deal for our leading product under the best conditions. Such a deal will enable GENFIT to return to strong and profitable growth as was the case over the period 2000-2006".

#### Key financial figures for the first half of 2010 (IFRS standards):

(million EUR)	1 <sup>st</sup> half of 2010	1 <sup>st</sup> half of 2009	
Revenues from industrial alliances	2.06	3.23	
Public funding of R&D expenses	2.01	2.30	
Total revenues	4.08	5.62	
Operating result	(3.67)	(3.01)	
Financial result	(0.11)	(0.04)	
Pre-tax income	(3.78)	(3.05)	

- The total operating revenues for the first six-month period of 2010 amounted to € 4.08 million versus € 5.62 million for the first half of 2009.
- Industrial revenues amounted to € 2.06 million as of June 30, 2010, and were largely made up of the research fees from multi-annual collaborative research programs with the pharmaceutical companies Servier and Sanofi-Aventis. The remaining revenue is made up of milestones corresponding to the contractual payment of major achievements in the discovery and the clinical development of compounds generated during collaborative partnerships with Servier and Solvay.
- In the first half of 2010, public funding of R&D expenses, which includes operating subsidies and the Research Tax Credit ("Crédit Impôt Recherche"), amounted to a total of € 2.01 million versus € 2.30 million during the same period in 2009. During this period, the Research Tax Credit increased from € 1.25 million as of 30 June 2009 to € 1.38 million as of 30 June 2010, due to the evolution of internal research expenses.



### Press Release Communiqué de Presse

- Operating subsidies amount to € 0.63 million as of 30 June 2010 versus € 1.04 million as of 30 June 2009, due to the contractual completion of three subsidized research programs during the first quarter of 2010. The resulting drop in revenue from subsidies should be partially compensated by the initiation of two new subsidized programs during the second half of 2010.
- As of 30 June 2010, the operating charges totaled € 7.61 million versus € 8.35 million as of 30 June 2009. The personnel costs of the Group were modestly decreased compared to the same period in 2009. The average number of Company employees was 112 during the first half of 2010, compared to an average of 123 during the first half of 2009. The remaining reduction in the operating charges is largely due to a temporary decrease in the Company's annual patent fees, which vary during the year according to the deposition date of patent applications.
- The **operating loss** amounts to € 3.67 million in the first half of 2010 versus € 3.01 million in the first half of 2009, when the operating result was favorably affected by a transitory decrease in the Company's development costs for GFT505.
- The **financial result** amounts to € (0.11) million as of 30 June 2010 versus € (0.04) million as of 30 June 2009, due to a lower profitability of the Company's financial investments (lower medium-term served interest rates and postponement of financial income recognition on certain longer-term investments).

(million EUR)	1 <sup>st</sup> half of 2010	1 <sup>st</sup> half of 2009
Pre-tax income	(3.78)	(3.05)
Tax burden	(1.50)	(0.33)
Net result	(5.28)	(3.38)

- The tax burden includes a charge of € 1.16 million corresponding to the depreciation of the activated deferred tax calculated on fiscal losses stated in December 2007. At year end, the management could not determine when these deferred tax stocks would be cancelled out and has therefore decided to book this exceptional item. Taking into account the future expected fiscal results, the remaining activated deferred tax should be absorbed in a reasonable timeframe as requested by IFRS standards.
- Consequently, the **net result** amounts to € (5.28) million as of 30 June 2010 versus € (3.38) million as of 30 June 2009.

(million EUR)	As of 30/06/10	As of 31/12/09
Cash balance and treasury	18.01	17.43
equivalents		

• The Company's cash balance and treasury equivalents amounted to € 18.01 million as of June 30, 2010 versus € 17.43 million as of December 31, 2009.



#### Major achievements for H1, 2010:

#### **Proprietary compounds and research programs**

GFT505: In January 2010, GENFIT announced the results of two clinical trials of major importance for
the continuing development of GFT505, its most advanced drug candidate. The results of the GFT5052094 trial showed that GFT505 treatment led to a reduction of the global cardiovascular risk in prediabetic patients with fasting hyperglycemia, glucose intolerance, and abdominal obesity. In addition
to the effects of GFT505 on glycemia, this study confirmed and extended the beneficial effects on
plasma lipids previously observed in the GFT505-2083 trial.

The results of the **GFT505-1095 trial** showed that the co-administration of GFT505 with a statin is not associated with a risk of pharmacokinetic drug-drug interaction that can lead to undesirable side-effects in the case of certain fibrate/statin co-prescriptions.

These latest results provide GFT505 with a new competitive advantage in the treatment of prediabetic and diabetic populations.

It should also be noted that the « carcinogenicity » studies that are mandatory for this type of drug candidate have been in progress since July 2009, with two rodent species treated over a period of two years. Halfway through these studies, no evidence of carcinogenicity has been observed.

- The TGFTX1 and TGFTX3 programs address cardiometabolic diseases and certain neurodegenerative
  diseases in which they are implicated via the key pathways of inflammation and oxidative stress. Two
  specific screening campaigns carried out during H1, 2010 have resulted in the identification of several
  active ligands for these two nuclear receptors, thus leading to their deorphanization.
- The three BMGFT programs, based on an innovative technology for the detection of early markers, have also recorded significant progress. These programs aim to provide a rapid, targeted, and predictive response concerning the efficacy of new treatments for certain metabolic and neurodegenerative diseases.

**BMGFT01**, dedicated to the early detection of atherosclerosis, is the most advanced program. The first steps of validation of the approach in animal models having been completed during the first half of 2010, and clinical validation initiated, the Company is currently building a research consortium which it will pilot, with the aim of entering the phase of industrial valorization.

**BMGFT02**, dedicated to diabetes and the early detection of pancreatic dysfunction, is also progressing. Its development will benefit from the major clinical research cohorts that are currently being enrolled as part of the **IT-Diab consortium**. In the context of this collaborative program, the authorization of the French health agencies was obtained at the end of the first semester of 2010 for the initiation of two clinical studies. These studies will follow a total of 1000 patients longitudinally over a period of 5 years, with the aim of better understanding the factors involved in the conversion from the early diabetic state to diabetes, which is particularly linked to pancreatic beta cell dysfunction.

Finally, the studies performed as part of the **BMGFT03** program, that targets neurodegenerative diseases and in particular Alzheimer's disease, have led to the intellectual property protection of the results. The valorization of this data for the continuing development of a biomarker is currently envisaged via a partnership with an industrial specialized in this therapeutic area.

## Press Release Communiqué de Presse

2010

#### Strategic research alliances with pharma industry partners:

- **Sanofi-Aventis:** Given the significant scientific progress achieved in 2009, an extension of this program and its prolongation for three years to the end of 2013 is currently under discussion.
- Servier: Initiated in 2004, the industrial partnership with Servier was extended at the beginning of 2009 until the end of 2010. This partnership is mainly based on the research program « SERX1 », dedicated to the treatment of several risk factors of insulin resistance and type 2 diabetes. Significant progress in the development of this target has been recorded during H1, 2010, and the Company has received a milestone payment. A second such payment will be received during H2, 2010.
- **Abbott/Solvay:** Significant progress has been recorded in each of the collaborative programs, as illustrated by the entry of a drug candidate into Phase I clinical trials. GENFIT received a milestone payment following this clinical entry.

#### **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 (SANOFI-AVENTIS, SERVIER, ...), 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 II.

With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 100 employees. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111). <a href="https://www.genfit.com">www.genfit.com</a>

#### **Contacts:**

#### **GENFIT**

Jean-François Mouney – CEO & Chairman of the Management Board +33 (0)3 2016 4000

#### **MILESTONES – Press Relations**

Bruno Arabian

+33 (0)1 75 44 87 40 / +33 (0)6 87 88 47 26 - <u>barabian@milestones.fr</u>



#### **Consolidated Balance Sheet:**

(in 000's of euros)	30/06/2010	31/12/2009
Non current assets		
Goodwill	74,9	74,9
Other intangible assets	121,4	105,7
Other tangible assets	8 702,9	9 160,2
Other non current financial assets	57,0	38,7
Other non current assets	1 681,9	1 774,6
Deferred tax debit	1 921,4	3 420,0
Non current assets	12 559,6	14 574,2
Current assets		
Inventory	188,9	207,5
Tax payable	0,0	0,0
Receivables	152,2	60,5
Other current assets	3 925,1	6 152,0
Current financial assets	0,0	0,0
Cash and cash equivalents	18 011,1	17 433,7
Current assets	22 277,3	23 853,7
TOTAL ASSETS	34 836,8	38 428,0
Capital	2 915,5	2 817,7
Premiums	16 278,2	14 361,6
Consolidated reserves	-1 462,5	5 769,3
Translation differential	-22,7	-54,5
Net result	-5 278,6	-7 373,9
Shareholders equity group share	12 430,0	15 520,2
Minority interests		
Total shareholders'equity	12 430,0	15 520,2
Non current liabilities		
Non current provisions	227,4	212,9
Non current conditional loans	2 991,4	2 825,6
Non current financial liabilities	8 673,0	6 863,9
Deferred tax credit		
Other non current liabilities	2 935,5	3 450,1
Non current liabilities	14 827,3	13 352,5
<u>Current liabilities</u>		
Current provisions	2,6	3,1
Current conditional loans	167,8	155,7
Current financial liabilities	1 971,5	2 907,7
Trade payables	2 851,5	3 706,0
Other current liabilities	2 586,2	2 782,7
Current liabilities	7 579,6	9 555,3
TOTAL SHAREHOLDERS EQUITIES AND LIABILITIES	34 836,8	38 428,0



#### **Consolidated Income Statement:**

(In 000's of euros)	6 months Closed on 30/06/10	6 months Closed on 30/06/09
Revenues from industrial alliances	2 065,2	3 227,2
Public funding of R&D expenses	2 012,6	2 298,5
Other income	2,2	100,0
Total income	4 080,0	5 625,7
Purchases consumed	-804,7	-1 010,9
Operational subcontracting	-1 526,1	-1 530,0
Personnel expenses	-3 582,0	-3 643,7
Other operational expenses	-1 278,0	-1 668,9
Net expenses for depreciation, provisions and losses in value	-424,1	-500,0
Current operating profit	-3 535,0	-2 727,8
Stock option plan Expenses	-142,2	-277,9
Results on disposals of non current assets	6,3	-0,5
Operating profit	-3 670,9	-3 006,2
Net income generated by cash	101,6	228,4
Financial expenses and income	-210,9	-270,8
Financial result	-109,3	-42,4
Profit before income tax	-3 780,3	-3 048,6
Tax burden	-1 498,4	-327,0
Profit for the period	-5 <b>278,6</b>	-3 375,6