Net profit doubles reaching 67.5 million euros

Grifols’ turnover increased by 17.7\%^{1} to 666.7 million euros in the first quarter of 2012

- Over 90\% of revenue is generated in international markets. Spain reduces its weight to 9\% of total sales revenue
- The strengthening of commercial structures in North America helps boost sales by more than 23\%^{1} to exceed 400 million euros
- Improvement in operating margins reflects some of the synergies related to raw materials and manufacturing costs being achieved
- Adjusted^{2} EBITDA increases by 41.3\%^{1} reaching 213.1 million euros. EBITDA Margin increases over 500 bps reaching 32\% of sales
- Grifols improves the financial conditions initially negotiated to purchase Talecris and anticipates a reduction in financial expenses

Barcelona, April 24, 2012.- Grifols, (MCE:GRF, MCE:GRF.P and NASDAQ:GRFS), the third-largest company in the world in the production of plasma-based biological pharmaceuticals, as well as world leader by sales of immunoglobulins (IVIG) and A1PI used to treat pulmonary emphysema, had revenues increasing by 17.7\%^{1} in the first quarter of 2012, reaching 666.7 million euros, in comparison to the 566.5 million euros that would have been achieved taking into consideration the combined pro-forma income of Grifols and Talecris\(^1\) during the same period in 2011. On a reported\(^3\) basis, excluding, for comparison, Talecris sales from January to March 2011 as Talecris was acquired in June 2011, there was a 155.0\% increase.

An increase in sales volume has been seen across all divisions and continues to be the primary driver of growth although, in general terms, prices have stabilised. The negative impact of the exchange rate (especially the euro-dollar) seen in previous quarters, has been offset and has not affected reported growth in comparable terms.

In addition, results from January to March 2012 confirm the anticipated changes to the relative weight of each business area as a proportion of total group income. The Bioscience Division, which accounts for 88.1\% of Grifols sales revenue, totalled 587.2 million euros, an increase of 16.4\% in pro-forma\(^1\) results and 187.5\% in reported results\(^3\). Continued growth is seen in the sales volume of the main hemoderivatives and Grifols consolidates its leadership in intravenous immunoglobulin (IVIG) and alpha1-antitrypsin, used for treating pulmonary emphysema, with double digit growth.

Sales of the Diagnostic Division increased 16.1\% to 34.7 million euros, and sales in the Hospital Division hit 27.0 million euros, 12.4\% up on sales in the same period of the previous year.

\(^1\) Unaudited pro-forma results for Q1 2011 are provided for guidance purposes since the purchase of Talecris took place in June 2011.
\(^2\) Excluding costs associated to the acquisition of Talecris and non-recurring costs.
\(^3\) The results reported do not include Talecris sales from January to March 2011 since the purchase of Talecris took place in June 2011.
Changes in the geographic distribution of income have also been confirmed in the quarter. Furthermore, growth continues in all areas where the company operates through company subsidiaries located in 24 countries or through distribution agreements.

In fact, from January to March 2012 more than 90% of Grifols business took place outside of Spain, with North America accounting for 62.5% of the group’s total income, Europe 22.7%, and other geographic areas 13.6%. Latin America already generates 5% of group business. Globally, Grifols’ sales in international markets exceeded 600 million euros, representing 21% growth on a pro-forma basis and over 200% growth in reported terms.

Strong momentum in the United States and Canada where sales revenue was 416.8 million euros, with an increase of 23.1% in pro-forma results and 372.3% in reported results when compared to 2011. In this respect, the new combined commercial structure (including marketing and sales) put into place after the second quarter of 2011 has consolidated, allowing Grifols to offer a wider portfolio of hemoderivative products, integrated and completely adapted to the different needs of the healthcare professionals who operate in this market. Moreover, marketing for other products and services specifically related to the diagnostic field (Diagnostic Division) and hospital logistics (Hospital Division) has started, contributing to the market penetration in this geographic area. In fact, from January to March 2012 projects have continued to be developed in order to implement Misterium® Clean Rooms and the Gri-fill® system in the North American market. Alongside this, the gradual introduction and marketing of the complete line of Oncotools®/Oncopharm® and Phocus Rx™ products is being contemplated in the short term.

Sales in Europe reached 151.4 million euros. Excluding Spain, where healthcare changes are taking place as part of the measures adopted to control the public deficit, sales revenue reached levels similar to those in the first quarter of 2011. However, sales in Spain have decreased around 5% on a pro-forma basis to 61.9 million euros and its contribution has dropped, currently representing 9% of Grifols total income.

Furthermore, recurring income in other geographic areas continues to rise. As of March 2012, sales revenue totalled 90.8 million euros, representing a 26% increase in pro-forma results and 60.9% on a reported basis.

Margins and Profits

In the first quarter of 2012, Grifols’ adjusted EBITDA increased 41.3%, reaching 213.1 million euros and representing 32.0% of sales. On a reported basis, which for comparison purposes exclude the results from Talecris from January to March 2011, growth was 209.9%.

Taking into account the costs associated with the acquisition of Talecris and other non-recurring costs, gross operating results (EBITDA) totalled 202.6 million euros from January to March 2012 with an EBITDA margin of 30.4% to sales.

The EBITDA from the quarter benefited from continuing a cost control and reduction policy on operating expenses, and the notable improvement in gross margins, positively affected by a moderate impact of prices, and the optimization of raw materials and manufacturing costs. In this respect, inventory reduction in the face of greater global needs for plasma in order to produce hemoderivatives and obtaining and marketing more products per litre of plasma processed are two of the projected operating synergies directly linked to the streamlining of raw materials.

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3 The results reported do not include Talecris sales from January to March 2011 since the purchase of Talecris took place in June 2011.
The group continues to work on the optimization of processes to achieve the synergies related to production efficiency for both fractionation and purification of proteins and it has started to impact on results.

Finally, net adjusted profit\(^2\) amounted to 79.2 million euros as of March 2012, representing 11.9% of sales. This means a 117.3% growth in reported results\(^3\). Taking into consideration the integration costs associated with the acquisition of Talecris, net profit totalled 67.5 million euros, equivalent to 10.1% of sales.

Net profit for this quarter has not benefit from the improved financing conditions negotiated at the beginning of 2012. The impact of this will translate in a reduction in finance expenses from the second quarter of the year. Grifols estimates that it could see annual savings of approximately 55 million dollars since, among other things, this renegotiation has led to lower interest rates and a change to the tranches of the credit agreement signed with the different institutions involved in the financing for the acquisition of Talecris.

**Grifols Pro-forma Results\(^1\) First Quarter 2012**

<table>
<thead>
<tr>
<th>(Millions of euros)</th>
<th>3M2012</th>
<th>3M2011</th>
<th>% CHANGE</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL SALES</td>
<td>666.7</td>
<td>566.5</td>
<td>17.7%</td>
<td>16.0%</td>
</tr>
<tr>
<td>Bioscience Division</td>
<td>587.2</td>
<td>504.6</td>
<td>16.4%</td>
<td>14.5%</td>
</tr>
<tr>
<td>Diagnostic Division</td>
<td>34.7</td>
<td>29.9</td>
<td>16.1%</td>
<td>15.9%</td>
</tr>
<tr>
<td>Hospital Division</td>
<td>27.0</td>
<td>24.1</td>
<td>12.4%</td>
<td>12.4%</td>
</tr>
<tr>
<td>Raw Materials &amp; Others</td>
<td>17.7</td>
<td>7.8</td>
<td>125.2%</td>
<td>121.1%</td>
</tr>
<tr>
<td>ADJUSTED EBITDA(^2)</td>
<td>213.1</td>
<td>150.9</td>
<td>41.3%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>32.0%</td>
<td>26.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NET ADJUSTED PROFIT(^2)</td>
<td>79.2</td>
<td>81.9</td>
<td>-3.3%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>11.9%</td>
<td>14.5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Grifols Reported\(^3\) Results First Quarter 2012**

<table>
<thead>
<tr>
<th>(Millions of euros)</th>
<th>3M2012</th>
<th>3M2011</th>
<th>% CHANGE</th>
<th>% CHANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOTAL SALES</td>
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<td>261.4</td>
<td>155.0%</td>
<td>151.3%</td>
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<tr>
<td>Bioscience Division</td>
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<td>204.2</td>
<td>187.5%</td>
<td>182.9%</td>
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<tr>
<td>Diagnostic Division</td>
<td>34.7</td>
<td>29.9</td>
<td>16.1%</td>
<td>15.9%</td>
</tr>
<tr>
<td>Hospital Division</td>
<td>27.0</td>
<td>24.1</td>
<td>12.4%</td>
<td>12.4%</td>
</tr>
<tr>
<td>Raw Materials &amp; Others</td>
<td>17.7</td>
<td>3.1</td>
<td>453%</td>
<td>442.9%</td>
</tr>
<tr>
<td>EBITDA</td>
<td>202.6</td>
<td>64.8</td>
<td>212.9%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>30.4%</td>
<td>24.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADJUSTED EBITDA(^2)</td>
<td>213.1</td>
<td>68.8</td>
<td>209.9%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>32.0%</td>
<td>26.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NET PROFIT</td>
<td>67.5</td>
<td>33.6</td>
<td>100.7%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>10.1%</td>
<td>12.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NET ADJUSTED PROFIT(^2)</td>
<td>79.2</td>
<td>36.5</td>
<td>117.3%</td>
<td></td>
</tr>
<tr>
<td>% of sales</td>
<td>11.9%</td>
<td>13.9%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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\(^2\) Excluding costs associated to the acquisition of Talecris and non-recurring costs.

\(^3\) The results reported do not include Talecris sales from January to March 2011 since the purchase of Talecris took place in June 2011.
Balance Sheet as of March 2012

Reduction in inventory levels
Total assets as at March 2012 drop to 5,543.0 million euros, as opposed to the 5,807.7 million euros reported in December 2011. These differences are due to, amongst others, the effect of foreign exchange translation in the balance sheet.

The reduction in inventories continues as expected. This trend that started during the third quarter of 2011 has been confirmed in the first three months of 2012. Since December 2011, inventory levels have been reduced by over 34 million euros and stock turnover stands at approximately 290 days.

Cash flow improvements seen during the previous quarters have allowed Grifols to ensure the planned debt reduction of 240 million dollars, leading to a decline in the group’s net cash position in the first quarter of the year.

Capital Investment: CAPEX plan implementation progresses
During the first quarter of 2012 Grifols maintained its investment plan (CAPEX) to progressively expand its production facilities in Spain and the United States allocating in the region of 40 million euros to March 2012.

The investments related to the construction of the new facility for plasma fractionation in Parets del Vallés (Barcelona – Spain) and those aimed at increasing plasma fractionation capacity at the Clayton facilities (North Carolina, USA) continue at a good pace.

Furthermore, Grifols has finalized the construction of Phase IV of the production facilities located in Las Torres de Cotillas (Murcia – Spain). With this, the integration of the production at this new manufacturing facility is considered as complete, allowing for an increase in capacity and automation to produce intravenous saline solutions in flexible containers destined to supply the Spanish healthcare network. The Spanish Ministry of Health has recently inspected and approved the new plant.

Firm commitment to R&D during the quarter: Acquisition of 51% of Araclon Biotech and start of a new medical study
Grifols’ commitment to investigation remains firm in this quarters’ results with R&D expenditure growth over 4.3%\(^1\) compared to the same quarter in 2011, totalling 28.3 million euros, that represents approximately 4.2% of sales.

With regard to new projects, It is worth noting Grifols’ commitment to finding solutions to Alzheimer’s disease (AD), and in this context, the acquisition of 51% of the Aragonese company Araclon Biotech, dedicated to the research and development of therapies and diagnostic methods for neuro-degenerative diseases.

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Grifols' investment in Araclon Biotech is in line with the group interest in boosting its commitment to R&D, driving several complementary researches that may lead to treatments for Alzheimer's patients. In this respect, the work at Araclon Biotech has been positive to date, both with regard to the development of a useful and effective test that contributes to early diagnosis and to a vaccine for its treatment.

Grifols has started a new medical study for the treatment of Alzheimer's with plasma derivatives, with approximately 400 patients from Spain and the United States taking part. This trial, complementary to two previous studies by the group, involves the combined treatment of plasmapheresis with the administration of albumin and intravenous immunoglobulin (IVIG), two of the main plasma derivatives, in different regimens and doses.

Furthermore, the group is continuing its R&D projects for the use of plasmin in cases of acute peripheral arterial occlusion and the ongoing studies for the use of Fibrin Sealant biological glue in various types of surgery, amongst other projects.

**Grifols' new financial structure: Covenant improvements**

During the first quarter of 2012 Grifols has successfully concluded negotiations on the modification and improvement of the terms and conditions of the credit agreement signed to finance the acquisition of Talecris. These include:

- A reduction of interest rate and a retranching.
- Only two financial covenants in place, relating to leverage ratio and interest coverage, and elimination of covenants relating to limitations in fixed assets investment and the debt service coverage ratio.
- Amendment to the leverage ratio (Net Financial Debt/EBITDA) limiting the distribution of dividends, improving from the current 3.75x to 4.5x.
- Voluntary debt repayment through early amortisation of 240 million dollars.

All the improvements attained mean annual savings on financial expenses and were made possible thanks to Grifols' good results following the completion of the acquisition of Talecris. The improvements obtained in the main financial categories and ratios, excising initial estimates, stand out. To this effect, at the close of 2011, the group's leverage ratio (NFD/EBITDA) was 4.3x (3.9x at constant exchange rate), much lower than the expected 5x adjusted EBITDA². Meanwhile, estimated net financial debt rose to 2,738.2 million euro, with a cash position of 340.5 million euros.

This trend has continued during the first quarter of 2012. As at March 2012 net financial debt stood at 2,628 million euros and the net financial debt ratio over adjusted EBITDA² was 3.8 times. Furthermore, the forecast increase in cash flow remains unchanged, maintaining an upward trend thanks to Grifols' greater exposure to countries with shorter collection periods, a trend that has enabled the planned debt reduction of 240 million dollars.

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Summary of the Credit Structure as of March 31 2012

<table>
<thead>
<tr>
<th>Secured senior debt</th>
<th>Amount (millions)</th>
<th>Maturity</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tranche A</td>
<td>$886</td>
<td>5 years</td>
<td>3.25%</td>
</tr>
<tr>
<td>Tranche B</td>
<td>$1,960</td>
<td>6 years</td>
<td>3.50%</td>
</tr>
<tr>
<td>Revolving Credit Line</td>
<td>$200</td>
<td>5 years</td>
<td>3.25%</td>
</tr>
</tbody>
</table>

In February 2012, Standard & Poor’s confirmed Grifols’ Secured Senior Debt rating at BB and unsecured debt at B, with global corporate rating at BB – with a positive outlook. In general terms, the credit rating agency values positively the initiative undertaken by Grifols with regard to the improved finance conditions as this reflects the group's commitment to expedite the completion of the planned calendar for deleveraging.

Moody’s, which has not made any additional revision, maintains secured senior debt rating at Ba3, unsecured at B3, and Grifols’ global corporate long term credit rating as B1.

Equity
As of March 2012, Grifols’ share capital was 117.9 million euros represented by 213,064,899 ordinary shares (Class A) and 113,499,346 non-voting shares (Class B). This includes the two share capital increases that took place in 2011 to cover the non-cash payment portion of the acquisition of Talecris and as alternative dividend payment to group shareholders.

Analysis by division: Positive performance across all divisions
The operating results achieved by the group reflect the positive performance across all divisions and confirm Grifols’ position in the plasma products sector as the world’s third-largest company by sales volume.

Bioscience Division: 88.1% of income
Bioscience income totalled 587.2 million euros in the first quarter of 2012, a 16.4% increase over the same period in 2011 in pro-forma terms and 187.5% on a reported basis. After the integration process, this business area maintains an upward trend based on the increase in the sales volume of plasma derivatives as the division’s main engine of growth. By product, sales of intravenous immunoglobulin (IVIG) and alpha1-antitrypsin, a major plasma product for the group following the purchase of Talecris, are worth noting. Also, sales of factor VIII and albumin saw double digit growth in units sold, powered by the quarterly performance in Russia and China.
Throughout this quarter, in addition to the consolidation of the sales force and the commencement of new research projects to increase the therapy possibilities of plasma derivatives, Grifols has released the results obtained from the first clinical study it has performed on the impact of plasmapheresis on blood cholesterol levels in plasma donors.
This initiative is a result of Grifols’ commitment to plasma donors that make the treatment with plasma derivatives possible, benefiting patients. In this sense, the analysis of over 9,000 samples of plasma donations from the 663 individuals on the clinical study suggest that plasmapheresis reduces low-density lipoprotein levels (LDL) or “bad cholesterol”. Furthermore, this process increases the levels of high-density lipoproteins (HDL) or “good cholesterol” in individuals with low basal HDL cholesterol levels.

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This discovery, without having assessed its clinical impact, could benefit not only plasma donors, but millions of people with high blood cholesterol levels. Furthermore, it confirms plasmapheresis as a non-invasive technique free from side-effects. Plasmapheresis is currently the most widely used method to obtain plasma since it allows for the separation of the plasma from other blood components (such as red blood cells, platelets and other cells). These are immediately re-injected into the donor at the same time as the donation, leading to a quicker and better donor recovery.

**Diagnostic Division: 5.2% of the sales**
Diagnostic saw 16.1% revenue growth, hitting 34.7 million euros, with a general increase across the main lines of business. This division is characterised as much by its internationalization as by all its possible growth pathways.

It is worth noting the increase in the sale of reactive gel cards for blood typing in all of the markets where Grifols is present.

**Hospital Division: 4% of turnover**
The income of the Hospital Division increased by 12.4% to March 2012, reaching 27.0 million euros. International growth, mainly in hospital logistics, and the geographical diversification strategy through agreements have been the main engines of growth.

In this respect, it is relevant the start of the distribution in Spain of the Actial Farmaceutica probiotic, VSL#3®, a nutritional supplement that contributes in maintaining the balance of intestinal flora and strengthens the immune system, is important. The product is suitable for adults and children, and is included in Grifols’ Gastroenterology and Nutrition line (previously Clinical Nutrition). It will be distributed both in hospital centres and in pharmacies.

**Raw Materials Division & Others: 2.7% of turnover**
Revenue at the Raw Materials Division & Others totalled 17.7 million euros. The increase is explained by the income from the agreements with Kedrion and by the increase in the activity of Grifols Engineering.

**First quarter 2012 highlights**

**Grifols acquires 51% of Araclon**
During the first quarter of the year, and in relation to the promotion of the group’s R&D policies, it is worth noting the acquisition of 51% of the capital of Araclon Biotech that has ensured the viability of this company’s project.
Araclon Biotech was founded as a spin-off from the University of Zaragoza in 2004. Its main areas of research focus on the validation and marketing of a blood diagnosis kit for Alzheimer’s and the development of an effective immunotherapy (vaccine) for this disease.
The operation was carried out by Gri-Cel, S.A., Grifols’ investment vehicle, that centralises the group’s investments in companies and R&D projects in fields of medicine different to its main business, such as advanced therapies. After the acquisition, Grifols becomes the majority shareholder in Araclon Biotech with 51% of its share capital and the other founding partners maintain a 49% stake.

**Ongoing commitment to Human Resources**
In March 2012 Grifols’ average workforce comprised 11,055 employees, an 81% increase over the first quarter of 2011, as a result of the acquisition of Talecris. 74% of employees are located in North America, while 24% are based in Europe.

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**Grifols Engineering designs and builds Nanotherapix experimental facilities**
Grifols Engineering has built the new experimental facilities for Nanotherapix, a technology company where Grifols has a 51% holding via Gri-Cel, S.A. These experimental laboratories with a surface area of approximately 235m² will allow the company to continue research and development into a gene therapy platform, based on the autologous use of patients’ cells, genetically altered through an adenoviral vector.

**Grifols receives the Quality Management Certification for its medical devices in the United States**
The ISO certification 13485:2003+AC:2009 is an international standard of quality that establishes the benchmark for design, production and distribution of Grifols’ medical devices, as well as valuing the quality of management systems implemented by the company and the supervision of various related parameters including defined safety standards. Even though Grifols’ medical devices are manufactured in Spain, they are distributed in the United States, where the certification has been attained.

**Grifols obtains FDA approval for the production of antithrombin in Clayton**
The FDA has approved the new antithrombin production plant at Grifols' manufacturing facilities in Clayton and the first lots have already been obtained. This product was still being manufactured as part of a contract agreement with Bayer in Berkeley (California). This is the only antithrombin approved by the FDA in the United States.

**Grifols awarded prize by the Entrepreneur Circle and The Wharton Business School of the University of Pennsylvania for its international track record**
The Prince of Asturias, Felipe de Borbon, awarded the president and chief executive officer of Grifols, Victor Grifols, a prize in recognition of the company's international track record in recent years. The award was granted by the Entrepreneur Circle alongside the renowned international business school *The Wharton School* of the University of Pennsylvania.

**Grifols receives top marks in the Plan Profarma 2011 once more**
Grifols was awarded the highest mark “Excellent” under the Plan Profarma for scientific research, development and technological research, an inter-ministerial initiative created to highlight those companies with significant innovative business.

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**About Grifols**

Grifols, with presence in more than 100 countries, is a global pharmaceutical company specializing in the Hemotherapy sector, the medical discipline that treats disease using blood components. The company’s class A shares have been listed on the Spanish Stock Exchange (MCE:GRF) since 2006 and have been part of the Ibex-35 since 2008. In 2011, the company listed non-voting class B shares on the Mercado Continuo (MCE:GRF.P) and in NASDAQ-United States via ADRs (NASDAQ: GRFS). Grifols is the third company worldwide in plasma protein therapies, in terms of capacity after the recent purchase of Talecris, with a balanced and diversified range of products. In upcoming years, the company will strengthen its leadership in the industry as a vertically integrated company, as a result of on-going investment plans. Grifols is the world leader in plasma collection with 147 plasma donor centers in the United States to ensure a continued and reliable supply of human plasma for the production of plasma therapies. In terms of production capacity (fractionation), Grifols owns and operates several plants in Spain and the United States that allow it to respond to the growing market demand. Grifols’ sustained growth will be supported by a strong presence in the United States, Canada and Europe, where upcoming sales are expected to represent 53%, 7% and 26%, respectively.

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² Excluding costs associated to the acquisition of Talecris and non-recurring costs.
³ The results reported do not include Talecris sales from January to March 2011 since the purchase of Talecris took place in June 2011.
Unaudited pro-forma results for Q1 2011 are provided for guidance purposes since the purchase of Talecris took place in June 2011.

Excluding costs associated to the acquisition of Talecris and non-recurring costs.

The results reported do not include Talecris sales from January to March 2011 since the purchase of Talecris took place in June 2011.

DISCLAIMER
The facts and figures contained in this report which do not refer to historical data are “projections and forward-looking statements”. The words and expressions like “believe”, “hope”, “anticipate”, “predict”, “expect”, “intend”, “should”, “try to achieve”, “estimate”, “future” and similar expressions, insofar as they are related to Grifols Group, are used to identify projections and forward-looking statements. These expressions reflect the assumptions, hypothesis, expectations and anticipations of the management team at the date of preparation of this report, which are subject to a number of factors that could make the real results differ considerably. The future results of Grifols Group could be affected by events related to its own activity, such as shortages of raw materials for the manufacture of its products, the launch of competitive products or changes in the regulations of markets in which it operates, among others. At the date of preparation of this report Grifols Group has adopted the measures it considers necessary to offset the possible effects of these events. Grifols, S.A. does not assume any obligation to publicly inform, review or update any projections and forward-looking statements to adapt them to facts or circumstances following the preparation of this report, except as specifically required by law.

This document does not constitute an offer or invitation to purchase or subscribe shares, in accordance with the provisions of the Spanish Securities Market Law 24/1988, of July 28, the Royal Decree-Law 5/2005, of March 11, and/or Royal Decree 1310/2005, of November 4, and its implementing regulations.