

Almirall S.A. and Subsidiaries (ALMIRALL Group)

**Directors' Report** (Year ended 31 December 2013)





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# 1. Summary of 2013. Main achievements

The financial year 2013 was characterised by the deployment of commercial efforts related to the launch of Eklira® Genuair® and Bretaris® Genuair® (aclidinium) in the territories in which the Group is present. Almirall and Menarini (commercial partner for Europe) commenced sales of Eklira Genuair and Bretaris Genuair (respectively) in Germany, the UK and Scandinavia during the last quarter of the year. For its part, Forest (commercial partner for the USA) commenced sales of Tudorza Pressair in the United States in December 2012. During 2013, launches have been carried out in 14 countries and it has become the Group's best-selling product (€84.1 million, 12% of the total).

In this respect, in September the Group increased its international presence through the commencement of commercial activities in Canada, the world's seventh-largest pharmaceutical market. The new subsidiary is mainly centred on therapeutic solutions for respiratory and dermatological illnesses. Tudorza® Genuair® was launched in Canada during the last quarter of the year.

In June, it was announced that Constella®, which is the first and only medicine approved by the European Commission for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults, is now available in Germany, the United Kingdom and Scandinavia. It has also been recognised by the Scottish Medicines Consortium as having added value for the treatment of IBS-C in adults. The product has been launched in nine countries and additional launches are expected in 2014.

In the corporate development area, in December Almirall announced the acquisition of Aqua Pharmaceuticals, LLC ("Aqua"), a private dermatology prescription company and leader in the USA. Aqua has a portfolio of very well know prescription brands in acne, steroid-responsive dermatoses, seborrheic dermatitis, actinic keratosis and atopic dermatitis. The effective date of the acquisition was 31 December 2013, after approval was obtained from the US anti-trust authorities. For this reason, the Group has only included that company's balance sheet in the 2013 financial statements, without any impact on the 2013 income statement, expect for the purchase costs (which have been normalised). In 2013 Aqua posted sales of USD 129 million and a net profit of USD 29 million.

In the regulatory area, during the first half of the year Almirall and Forest Laboratories announced positive results in the Phase III studies for the combination of aclidinium and formoterol for the treatment of chronic obstructive pulmonary disease COPD (same indication as Eklira). In this respect, in November Almirall announced that an application for registration had been filed with the European Medication Agency (EMA) based on the efficiency and safety data obtained in two pivotal studies in Phase III (the ACLIFORM/COPD and AUGMENT/COPD studies) performed in 25 countries, which finalised this year. Other long-term safety studies (LAC-MD-32 and LAC-MD-36 studies) complete the set of clinical safety data obtained from the over 4,000 patients participating in the programme.

Finally, in December the Group announced the reorganisation of its European operations in order to optimise the potential of its portfolio of both new and existing products. The European pharmaceutical markets, particularly in Spain, have been negatively affected in recent years by decisions taken by the health authorities in line with economic criteria, which have slowed growth in these markets, as well as hampering the introduction and penetration of new products.



# 2. Performance of the main items in the functional income statement

#### **Functional income statement**

Total income  Net sales	825.5	900.2	
Net sales	000.0		(8.3%)
	692.9	682.9	1.5%
Other income	132.6	217.3	(39.0%)
Cost of sales	(233.1)	(262.2)	(11.1%)
Gross margin on sales	459.8	420.7	9.3%
% of sales	66.4%	61.6%	
R&D	(126.7)	(159.5)	(20.6%)
% of sales	(18.3%)	(23.4%)	
External and administrative expenses	(448.1)	(420.5)	6.6%
% of sales	(64.7%)	(61.6%)	
Other expenses	(1.9)	(2.0)	(5.0%)
EBIT	15.7	56.0	(72.0%)
% of sales	2.3%	8.2%	
Amortisation/depreciation	69.4	68.0	2.1%
% of sales	10.0%	10.0%	
EBITDA	85.1	124.0	(31.4%)
% of sales	12.3%	18.2%	
Gains or losses on fixed asset disposals / other	(15.2)	(0.5)	n.m.
Restructuring costs	(80.3)	0.0	n.m.
Impairment reversal /(losses)	(4.6)	(2.0)	130.0%
Net financial income/(expense)	(5.3)	(4.6)	15.2%
Profit /(loss) before taxes	(89.7)	48.9	n.m.
Corporate income tax	56.0	27.5	103.6%
Net profit for the year	(33.7)	76.4	(144.1%)
Normalised profit for the year	31.0	77.8	(60.1%)
Earnings per share (EUR) (1)	€(0.19)	€0.45	•
Normalised earnings per share (EUR) (1)	€0.18	€0.46	
Number of employees at the year end	2,936	2,871	2.3%

<sup>(1)</sup> Number of shares at the reporting date

- Net sales amount to €692.9 million, a 1.5% increase compared with the previous year, thanks to the new launches (particularly Eklira, which with sales totalling €84.1 million is the Group's best-selling product). In geographic terms, sales have diminished mainly in the Spanish market as a result of regulatory measures approved in preceding years. In Europe and the Middle East sales fell by 7% and in America, Asia and Africa the rose by 11% due mainly to shipments of aclidinium bromide to the commercial partner in the US (Forest). Taking all the above into account, overseas sales account for 62% of the Group's total.
- Other income has decreased by 40% as expected, since in 2012 €70 million was received in relation to the regulatory approval of aclidinium bromide in the USA and the European Union (by the FDA and EMA).
- The gross margin has risen by almost five percentage points as a result of the greater importance of the Company's own products (due basically to the contribution of Eklira).
- R&D expenditure has decreased due to the completion of the pivotal Phase III studies on the
  combination of aclidinium bromide and formoterol during the first half of the year, in accordance with
  the pre-established development schedule. In contrast, overheads and administration expenses rose
  due to the investment in new launches, particularly Eklira and Constella.
- As a result of the aforementioned changes, EBIT and EBITDA decreased by 72.0% and 31.4%, respectively compared with the same period in the previous year.
  - The heading "Gains or losses on fixed asset disposals / other" includes €8.4 million relating to the acquisition costs for Aqua (which have been normalised).



- Restructuring costs relate to the Group's best estimate of the costs associated with the reorganisation on a European scale mentioned above (which have also been normalised).
- Corporate income tax is positive due to the effect of R&D deductions (in line with trends in R&D investment).
- Net results reflect a loss of €33.7 million, although once impairment losses, restructuring costs and the Aqua acquisition costs are normalised, the Net Normalised Profit amounts to €31 million (60.1% lower than 2012).

### 3. Corporate development

During the year the following corporate performance agreements were entered into:

**Aqua acquisition:** On 17 December Almirall announced the acquisition of a 100% interest in Aqua Pharmaceuticals, LLC ("Aqua"), a private company specialising in dermatological prescription products which was mainly owned by RoundTable Healthcare, a US venture capital company focused on the health industry.

Under the terms of the agreement, Almirall acquired Aqua through an initial cash payment of USD 305 million plus an additional USD 22.6 million relating to the long-term amortisation of certain tax assets. Additional payments of up to USD 75 million may arise if certain regulatory and commercial objectives are met during 2014 and 2015.

The acquisition was financed through a USD 350 million bridging loan. The definitive financing of the operations had yet to be decided on at 31 December 2013.

# 4. Balance sheet. Financial position

A robust balance sheet with borrowing capacity

€million	December 2013	% of BS	December 2012
Goodwill	336.2	19.0%	270.3
Intangible assets	595.1	33.6%	358.2
Property, plant and equipment	161.3	9.1%	157.0
Non-current financial assets	23.3	1.3%	8.8
Other non-current assets	322.1	18.2%	251.4
Total non-current assets	1,438.0	81.1%	1,045.7
Inventories	97.7	5.5%	92.4
Trade receivables	99.5	5.6%	98.8
Cash at bank and in hand	89.2	5.0%	52.3
Other current assets	48.3	2.7%	66.9
Total current assets	334.7	18.9%	310.4
Total assets	1,772.7		1,356.1
Equity	888.3	50.1%	923.7
Bank loans	281.4	15.9%	0.0
Non-current liabilities	232.4	13.1%	183.0
Current liabilities	370.6	20.9%	249.4
Total equity and liabilities	1,772.7		1,356.1

The Group's balance sheet at 31 December 2013 reflected the following:

Goodwill and intangible assets include the assets arising from the purchase of Aqua, amounting to approximately €66.7 million and €246.9 million, respectively.

Other non-current assets includes the tax credits attributable mainly to the R&D deduction and the tax credits for losses. These will be applied in future years.



Equity includes the €0.3 million capital increase as a result of the payment in shares of the flexible dividend (2.4 million new shares were issued). Of the €26.7 million approved by the shareholders as a dividend, €0.8 million has been paid in cash, leading to a cash saving for the group of some €26 million. Taking into account the financing for the Aqua purchase operation, equity now represents 50% of total assets

Non-current assets have increased as a result of the deferred taxes arising from the difference between the local carrying value and the consolidated amounts of the assets relating to the Agua acquisition.

Current liabilities have risen due to the inclusion of Aqua's balance sheet figures and the liability recorded as a result of the reorganisation on a European scale referred to above.

### 5. Financial risk management and use of hedging instruments

The Group uses financial instruments to partially hedge its exposure to financial risk in relation to both interest rate risk and foreign currency risk.

#### Interest rate risk

In the past, in order to eliminate the uncertainties arising from fluctuations in the interest rates on the Group's long-term bank borrowings, the Group arranged certain hedging transactions. These loans expired in 2012 and therefore at the end of 2013 there are no interest rate hedges.

During 2012 the Parent Company entered into a credit facility available for up to €125 million, for which there is no interest rate hedging.

At the end of December 2013, a bridging loan of USD 350 million was entered into for the purchase of Aqua Pharmaceuticals LLC.

### Exchange rate risk

The Group is exposed to foreign currency risk on certain transactions arising from its ordinary business. This relates mainly to revenue received in USD from sales of finished goods, payments in USD for clinical trials, raw materials purchases and the payment of royalties in JPY, as well as collections and payments made by the Mexican, UK, Polish, Canadian and Danish subsidiaries in local currencies.

In the case of collections the risk represents 17% of revenue and other income, and in the case of payments 20% of procurements and other operating expenses.

The Group analyses foreseeable collections and payments in foreign currency and the performance and trend thereof on a quarterly basis. In 2013 the Group reduced its exposure to foreign currency risk in higher volume transactions through the arrangement of one-off exchange insurance to cover payments in yen for the purchase of raw materials and to cover cash inflows in dollars, mainly in respect of collections. Similarly, cash surpluses in foreign currency have been sold in order to avoid exposure to the volatility of the currency market and its resulting impact on the income statement.

At the end of the year, the Group acquired a subsidiary in the USA. The operation was financed in the same currency as the acquisition.

# Liquidity risk

The Group calculates its cash requirements using two fundamental forecasting tools that differ in terms of timescale.

On the one hand, a one-year monthly cash budget is set based on the projected financial statements for the current year. On the other, a shorter-term cash budget is set (at three months), which is updated monthly on the basis of the invoices registered, shipping notes confirmed or orders processed. Cash surpluses are generally invested in very short-term financial assets.

The Group manages its liquidity risk prudently, maintaining sufficient cash and marketable securities and arranging credit facilities to cater for the projected needs.

Lastly, medium- and long-term liquidity planning and management is based on the Group's Strategic Plan spanning a five-year time frame.



### 6. Risk factors

- 1. Price reduction, limitations on volume or difficulties in approval or reimbursement of new products owing to decisions by the health authorities.
- 2. Critical products not approved or delays in their approval by the European Medicines Agency or the Food & Drug Administration (FDA).
- 3. Negative impact on the Company's assets as a result of the difficult situation in Europe.
- 4. Competitive environment hinders the growth of new products.
- 5. Restrictions on new releases due to problems in the supply chain.

### 7. Treasury shares

At 31 December 2013 the parent company held no treasury shares.

# 8. Events after the balance sheet date

On 23 January 2014 the majority shareholder Grupo Plafín, S.A.U. carried out a placement with qualified investors of a package of 8,700,000 shares in Almirall, S.A., representing 5.0303% of the share capital. The placement price was €11.75 per share (€102,225 thousand for all the shares).

### 9. Outlook for 2014

The Group expects to accelerate sales growth in terms of a high double-digit percentage, albeit less than 20%. Given the current product catalogue, recent international expansion and the launch plan, international sales are expected to reach about 70% in 2014.

Other income is expected to be approximately half that of 2013, given the lower envisaged receipts as milestones are attained, and due to deferrals and 'upfronts' (or initial payment).

R&D expenditure for the year is expected be lower than in 2013 and represents approximately 14% of sales. Also, general and administrative expenses are expected to be on a level similar to 2013 following the consolidation of Aqua and the generation of savings associated with the restructuring plan announced in December.

Interest expense related to debt will be in the €20 million - €30 million range.

This will result in a normalised net profit (i.e. net profit without including extraordinary items) substantially higher than that achieved in 2013.

# 10. Corporate Governance Report

The Corporate Governance Report is set out in Appendix I of this report.



## 11. Capital structure. Significant ownership interests

At 31 December 2013 the parent company's share capital is represented by 172,951,120 shares with a par value of € 0.12 each, fully subscribed and paid in.

The shareholders with significant direct or indirect ownership interests in the share capital of Almirall, S.A., of more than 3% of the share capital, of which the parent company is aware, in accordance with the information contained in the official records of the Spanish National Securities Market Commission (CNMV) at 31 December 2013, are as follows:

Name or company name of direct holder of ownership interest	No. of shares	% ownership of ∰the Almirall ∰Group
Grupo Plafin, S.A.	80,129,287	46.33%
Todasa, S.A.	43,830,765	25.34%
Wellington Management Company, LLP	8,572,637	4.96%

At 31 December 2013, the parent company is unaware of other ownership interests of 3% or more of the parent company's share capital or voting power, or of interests lower than the percentage established, but that permit significant influence to be exercised.

### 12. Side agreements and restrictions on transfer and voting rights

The Group has entered into three side agreements, all of which were reported to the CNMV and which may be consulted in full on the following web site <a href="www.almirall.com">www.almirall.com</a>:

### Agreement entered into by Almirall, S.A. shareholders

A side agreement entered into by Mr Antonio Gallardo Ballart, Mr Jorge Gallardo Ballart, Mr Daniel Bravo Andreu, and Todasa, S.A.U. and Grupo Plafin, S.A.U. regulating, inter alia, certain preferential acquisition rights, and purchase and sale options, relating to the shares of Almirall, S.A.

### Agreement entered into by Inmobiliaria Braviol, SA shareholders

A side agreement entered into by Mr Antonio Gallardo Ballart, Mr Jorge Gallardo Ballart, Mr Daniel Bravo Andreu, Ms Margaret Littleton and Inmobiliaria Braviol SA, Danimar 1990 SL and Todasa SAU, regulating, inter alia, certain preferential acquisition rights and purchase and sale options relating to the shares of the aforementioned companies.

### Agreement between Jorge and Antonio Gallardo Ballart

A side agreement regulating the concerted action of the signatories in Almirall, S.A. and the inherent voting rights of their indirect ownership interest in the Company through Grupo Plafin, S.A.U., and Todasa, S.A.U.

There are no restrictions on the transferability of the parent company's shares or the exercise of the related voting rights under the Articles of Association.

### 13. Managing bodies, Board of Directors

### Appointment of directors

The directors are appointed (i) by proposal of the Appointments and Remuneration Committee, in the case of independent directors, and (ii) following a report by said Committee in the case of other directors, by the shareholders in General Meeting or by the Board of Directors in accordance with the provisions contained in the Spanish Companies Act 2010.

Newly appointed directors are required to following the parent company's orientation course for new directors so that they may acquire a sufficient knowledge of the parent company and its corporate governance rules.



As for the appointment of external directors, the Board of Directors ensures that the choice of candidates involves persons of recognised solvency, competence and experience. Particular care is taken in relation to those called upon to fill the positions of independent director envisaged in Article 6 of the Board Regulations.

Directors proposed for appointment must refrain from participating in discussions and votes concerning

Directors hold office for the term provided for that purpose by the General Meeting, which is equal for all and may not exceed six years, at the end of which they may be reappointed for one or more further periods of equal duration.

### Replacement of directors

Directors will cease to hold office when the period for which they were appointed has elapsed and when the relevant decision is adopted by the General Meeting, exercising the powers attributed to it by law or by the Articles of Association. In any event, the appointment of administrators will terminate when, once the term has expired, the following General Meeting has been held or the legal time limit for holding the General Meeting to approve the previous year accounts has expired.

The Board of Directors may propose the removal of independent directors before the expiry of the statutory period when a justifiable reason is appreciated by the Board, subject to a prior report by the Appointments and Remuneration Committee. In particular, it is understood that a justifiable reason exists when a director has breached the duties inherent to his position or has become involved in one of the prohibiting circumstances described in the definition of independent director contained in corporate governance guidelines applicable at the time.

Directors affected by removal proposals must refrain from participating in discussions and votes concerning them.

The directors shall report their resignation to the Board of directors and formalise, if considered appropriate by the same, their resignation in the following cases:

- a) Where they cease to hold the executive posts with which their appointment as directors was associated.
- b) Where they are involved to any of the incompatibilities or prohibitions stipulated by law.
- When seriously reprimanded by the Board of Directors for failing to discharge their obligations as directors.
- d) When their remaining on the Board could jeopardise or prejudice the interests, credit or reputation of the parent company or when the reasons for which they were appointed (for example, when a nominee director sells a shareholding in the parent company) cease to be applicable.
- e) In the case of independent directors, they may not remain as such for more than 12 consecutive years; therefore, once this period has elapsed, they must tender their resignation to the Board of Directors and formally withdraw.
- f) In the case of nominee directors, (i) when the shareholder they represent sells its entire shareholding and (ii) in the requisite number, when such shareholder reduces its shareholder to a level requiring the number of nominee directors to be reduced.

In the event that, due to resignation or for any other reason, a director leaves office before the end of his term, he shall explain the reasons in a letter sent to all Board members.

The Board of Directors may propose the removal of independent directors before the expiry of the statutory period when a justifiable reason is appreciated by the Board, subject to a prior report by the Appointments and Remuneration Committee. In particular, it is understood that a justifiable reason exists when a director has breached the duties inherent to his position or has become involved in one of the prohibiting circumstances described in the definition of independent director contained in corporate governance guidelines applicable at the time.



### Amendment of the Company's Articles of Association

Amendments to the Articles of Association are the responsibility of the shareholders and are regulated by Article 160 of the Spanish Companies' Act 2010. There are no special provisions in this respect in either the Articles of Association or the General Meeting Regulations.

### Powers of the members of the Board of Directors

Certain powers pertaining to the Board of Directors are vested in the Company's Chief Executive Officer, pursuant to a public deed executed before the Barcelona Notary Mr. Enrique Viola Tarragona on 17 May 2012.

Powers have been granted to Mr. Luciano Conde Conde by virtue of the public deed executed before the Barcelona Notary Mr. Salvador Carballo Casado on 21 June 2011.

Powers have been granted to Mr. Bertil Lindmark by virtue of the public deed executed before the Barcelona Notary Mr. Salvador Carballo Casado on 21 June 2011.

Powers have been granted to Mr. Jorge Gallardo Ballart by virtue of the public deed executed before the Barcelona Notary Mr. Enrique Viola Tarragona on 2 June 2011.

At the General Shareholders' Meeting held on 13 April 2007, the shareholders agreed unanimously, in the terms contained in the relevant resolutions and which are summarised here, to the following:

- 1. Authorise the Board of Directors of the parent company, as provided in Article 153.1) of the Spanish Companies Act 2010, so that, without prior consultation with the General Meeting, it may increase the share capital up to half of the parent company's capital at that time, taking into account in this respect the capital increases that could have been carried out under the Fifth and Thirteenth resolutions of the same General Meeting. This authority may be exercised within five years of the date of the resolution, on one or more occasions and in the amount and conditions, and at the time, freely decided in each case.
- 2. Delegate to the Board of Directors the power to issue debentures, bonds and other fixed-income securities of a like nature, whether simple or exchangeable for shares of the parent company, or of any other company whether or not it belongs to the parent company's Group and/or convertible in parent company shares. This delegation may also be used to issue promissory notes, preference shares (if legally admissible) and warrants (options to subscribe new shares or acquire existing shares in the parent company). The issuance of the securities covered by such delegation may be made on one or more occasions within a period of 5 years from the date of this resolution and for a total of one hundred million euros maximum.
- Authorise the parent company's Board of Directors to carry out the derivative acquisition of own shares on the terms indicated below:
  - a). The acquisition may be made by way of sale, exchange or payment in kind, in one or more instalments, provided that the shares acquired, added to those already held by the parent company, do not exceed five percent of share capital.
  - b). The price or consideration shall vary between a minimum equal to its nominal value and a maximum equal to the closing price of the parent company shares in the continuous market at the time of acquisition. The above notwithstanding, in the case of acquisitions of shares that might be agreed before the shares are admitted to quotation and in particular for the acquisition of treasury shares as part of a possible implementation of an employee tranche, the maximum price shall be the one determined for the retail tranche of the offering.
  - c). The authorisation shall be valid for 18 months as from the day following the date of the resolution.

Express authorisation is also granted for the acquisition of shares in the parent company by any of the subsidiary companies in the same terms resulting from this resolution.

Shares acquired as a result of such authorisation may be sold or redeemed, or used in the remunerative arrangements referred to in Article 75.1.3. of the Companies Act 2010.

4. Delegate, in the broadest terms, to the Board of Directors, including powers of substitution for any of its members, all such powers as may be necessary to interpret, execute and fully implement the resolutions adopted in said General Meeting; such powers of substitution were applied by the Board in



favour of the Chairman, Mr. Don Jorge Gallardo Ballart and the First Deputy Chairman Mr. Antonio Gallardo Ballart under resolutions adopted on 13 April and 11 May 2007, respectively.

# 14. Significant agreements

There are no significant agreements with regard to changes in the control of the parent company or between the parent company and its executives or employees with respect to indemnities for dismissal, resignation or public takeover bids.



# SCHEDULE I: Corporate Governance Report