



# Almirall S.A. and Subsidiaries (Almirall Group)

## **Consolidated Directors' report** (Year ended December 31, 2021)

*(Translation of a report originally issued in Spanish. In the event of discrepancy,  
the Spanish language version prevails)*

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## **1. Fiscal year summary: main achievements**

The 2021 financial year was still affected by the impact of the COVID-19 pandemic, although normality is gradually returning to normal in the various geographies where the Group's companies operate, as vaccination campaigns are progressing and mobility restrictive measures are being relaxed. However, the appearance of the new "Omicron" variant at the end of 2021 again added uncertainties, although it seems that its severity, despite the increase in cases, has been much less than in previous waves, so the impact on the Group's activity has not been significant for the time being. Despite this, the Group closed the year with an increase in net sales and a favorable business performance, especially in Europe.

Given the sector in which the Group operates, its activities are considered essential and therefore the activity has not been interrupted by the various measures taken since March 2020 (states of alarm or confinements), especially as regards the production activity of both the Group's production centers (located in Spain and Germany) and third-party manufacturers supplying certain products. There have been no shortages during this period.

Despite not having interrupted production activity, the Group's sales have been negatively impacted in products indicated for cold symptoms (due to social distancing measures and the use of masks) and products not indicated for chronic treatments have also been negatively impacted, mainly due to the restriction of people's mobility, which has had an impact both in terms of delay and cancellation of product promotion activities, as well as in the reduction of demand at global level in the different countries in which the Group operates.

In this context it should be noted that the impact of COVID-19 in the EU countries has been less than in the United States as a result of the type of product sold in each of these territories, being in the EU market and especially in the products related to chronic treatments those that have been less impacted and in the United States where the product portfolio is of the so-called non-essential products where the drop in sales was more pronounced in 2020. The year ending December 31, 2021 has seen a recovery in prescriptions in the US, while the EU has generally returned to pre-COVID 19 levels, with the exception of the aforementioned cold products. It should be noted that the market share of the Group's main products has not been significantly impacted and that most of the sales are in line with market developments.

From the point of view of R&D activities, there have been delays, not cancellations, in some activities related to clinical studies, given the restrictions on access to hospitals that made it difficult to recruit new patients. However, Management considers that there have been no significant delays that could affect the medium to long term. The registration process for Klisyri in the United States was completed in December 2020, while in the EU, approval was obtained from the European Medicines Agency (EMA) on July 19, 2021. As for Phase III Lebrikizumab, the development timeline remains on track with EMA registration submission in 2022 and subsequent approval and launch in 2023.

Promotional activities have been the most affected due to the confinement and the measures imposed to prevent contagion. As a result, various activities such as congresses, events and medical visits have been cancelled and/or postponed. In this regard, the Group has made an effort to advance in the digitalization of certain processes and activities in order to maintain the activity and, at the same time, comply with the social distancing measures and restrictions on access to medical centers.

Finally, support and administration activities have continued to be carried out by adopting certain labor flexibility measures in the different work centers and in accordance with the exceptional measures established in each country. In general, teleworking has been chosen in all those functions that allowed it without significant disruption.

The dividend proposed by the Board of Directors on February 18, 2021 was approved by the General Shareholders' Meeting held on May 7, 2021. The dividend payment has been instrumented as a flexible dividend in which shareholders have been offered a choice between receiving newly issued Parent Company shares or the cash amount equivalent to the dividend. The cash payment was chosen by 35.6% of the shareholders rights (resulting in a disbursement of EUR 11.7 million) and the remaining 64.4% opted to receive new shares at unit par value that were issued as a capital increase. On June 11, 2021, 1,661,175 new shares of the Parent Company were admitted to trading on the Barcelona, Madrid, Bilbao and Valencia stock exchanges.

From a liquidity standpoint, the Group ended the year with a cash position amounting to EUR 207.4 million (EUR 165.7 million at December 31, 2020). Such evolution is explained by:

- Solid cash flow from operating activities (EUR +233.8 million), thanks to the evolution of working capital items and the collection of corporate tax refunds mainly in Spain and the United States.
- Net payments from investing activities (EUR -57.2 million) resulting mainly from investments in the Group's production sites and various payments linked to licensing agreements as described in Note 9 to the Consolidated Annual Accounts, partially offset by royalty collections linked to the agreement with AstraZeneca.

- Net payments from financing activities (EUR -134.9 million) mainly as a result of the debt restructuring carried out in 2021 (EUR 150 million of a syndicated loan and EUR 250 million of the Convertible Bond were repaid and simple senior notes were issued for EUR 300 million) and the cash payment of the flexible dividend (EUR 11.7 million).

## **2. COVID-19 impacts**

Note 33 of the accompanying Consolidated Annual Accounts summarizes the main impacts of COVID-19 in year 2021.

## **3. Corporate development**

During the year ended December 31, 2021, the following corporate development agreements and relevant facts have taken place:

- On February 17, 2021 MC2 Therapeutics granted Almirall the marketing rights in Europe for Wynzora® cream for the treatment of plaque psoriasis. Wynzora® cream (50 µg / g calcipotriol and 0.5 mg / g betamethasone as dipropionate) received FDA approval in the United States on July 20, 2020 and completed the marketing authorization procedure (MAA) in Europe in July 2021.
- On March 16, 2021, it was announced that, following the 60-day data review period, Almirall decided not to exercise its option right to acquire Bioniz Therapeutics Inc. Under the terms of the Option Agreement, Almirall made an initial payment of \$15 million to Bioniz in exchange for an option to acquire all shares of Bioniz Therapeutics Inc. Following the decision not to exercise the option, Almirall will not be required to make any further payments based on this agreement.
- On May 21, 2021, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion regarding the regulatory approval of Klisyri® (tirbanibulin), indicated for the topical treatment of actinic keratosis (AK) on the face or scalp. Subsequently, final approval was obtained on July 19. In December 2020, Almirall's development partner, Athenex, Inc. received approval from the U.S. Food and Drug Administration (FDA) to market Klisyri® (tirbanibulin) in the United States.
- On July 1, 2021, Kaken Pharmaceutical granted Almirall exclusive rights to develop and commercialize efinaconazole topical solution in Europe. This active ingredient, an antifungal from the triazole family discovered by Kaken Pharmaceutical, is indicated for the treatment of onychomycosis, a fungal infection of the nail. Almirall plans to hold a meeting with the regulatory authorities prior to the application for marketing authorization of the product in Europe within the next 12 months.
- On August 16, 2021, the Group announced that Lebrikizumab produced a significant improvement of at least 75% in skin clearance in more than half of patients with moderate to severe atopic dermatitis (AD), as measured by the Eczema Area and Severity Index (EASI), in the Phase 3 ADvocate 1 and ADvocate 2 studies. In the top-line results of these two monotherapy studies in patients with AD, all primary and all major secondary endpoints, including skin clearing and improvement in itching, were met at week 16 of treatment.
- On September 13, 2021 Almirall, S.A. agreed to carry out an issue of senior unsecured debentures, with a maximum aggregate nominal amount of EUR 250 million (extendable to EUR 300 million depending on market conditions) and maturing in 2026 (the "Debentures"). The Notes would be senior notes secured by joint and several personal guarantees provided by certain subsidiaries. This transaction was finally closed on September 22 for an amount of EUR 300 million and with a fixed interest rate of 2.125%. The main purpose of this issue was the payment of the Convertible Bond in the amount of EUR 250 million maturing on December 14, 2021.
- On November 1, 2021 AstraZeneca agreed to transfer the global rights to Eklira (aclidinium bromide), known as Tudorza in the US, and Duaklir (aclidinium bromide/formoterol) to Covis Pharma Group. Almirall will continue to receive milestone and royalty payments under the agreement initially signed with AstraZeneca. This transaction was finally completed on January 5, 2022.
- On December 14, 2021 Almirall and Ichnos Science announced the exclusive license agreement for ISB 880, an IL-1RAP antagonist. Under the agreement, Almirall has acquired global rights to develop and commercialize this monoclonal antibody for autoimmune diseases. Ichnos will retain the rights to antibodies targeting the IL-1RAP pathway for oncology indications.
- On December 21, 2021, the Group announced that Lebrikizumab significantly improved disease severity when combined with topical corticosteroids (TCS) in people with moderate to severe atopic dermatitis (AD)

in a third pivotal Phase III trial (ADhere). At week 16, the study met all primary and key secondary endpoints.

#### **4. Evolution of key figures in the consolidated income statement**

- Operating income amounted to EUR 836.5 million (+2.7%) due to:
  - EUR 827.2 million (+2.4%), thanks to the growth of Ilumetri in Europe, the launch of Klisyri in 2021 (Germany and the United States, mainly) and the good performance of the domestic market, which was offset by the erosion of generics in the United States and lower deferred revenues linked to the licensing agreement with AstraZeneca.
  - Other income increased to EUR 9.3 million (+31.8%), mainly due to the change in the fair value of the financial asset linked to the agreement with AstraZeneca.
- R&D expenses for the year amounted to EUR 73.6 million (-6.7%), decreasing slightly due to several studies that ended in 2020, some delays in some activities due to COVID-19 and studies linked to the development of Lebrikizumab in the EU and sarecycline for China that have started in the last quarter of the financial year 2021.
- Operating expenses have seen an increase due to new launches (Klisyri in the US and Europe and the progressive launch of Ilumetri in the EU), combined with increased activity as restrictions linked to COVID-19 have been lifted.
- Depreciation and amortization decreased slightly to EUR 119.9 million (-2.6%) as a result of the impairment made in 2020 on certain US assets and, additionally, the impact of the US dollar exchange rate.
- The heading "Impairment losses on property, plant and equipment, intangible assets and goodwill" in the accompanying Consolidated profit and loss Statement includes in 2021 the impairment losses on certain assets in the United States, as explained in Note 9 to the accompanying Consolidated Annual Accounts.
- The heading "Net results on disposal of assets" includes the loss associated with the option paid in 2019 to Bioniz for the option to acquire all of its shares, since in March 2021 it was decided not to exercise this option, as explained in Note 9 of the accompanying Consolidated Annual Accounts.
- As a result of the above, the pre-tax result amounts to a loss of EUR 9.1 million, compared to a profit of EUR 79.2 million in the 2020 financial year.
- Finally, the Income Tax heading includes the impact of the amendment to the Spanish Corporate Income Tax Law, amounting to a loss of EUR 19.9 million, as explained in Note 22 to the accompanying Consolidated Annual Accounts.

#### **5. Consolidated balance sheet. Financial position**

The main variations of the Consolidated Balance sheet as of December 31, 2021 compared to December 31, 2020 are described below:

- Intangible assets decreased mainly as a result of the amortization for the year, the impairment and derecognition of assets related to the US market described above, partially offset by investments related to licensing agreements and the positive effect of the US dollar exchange rate on US assets.
- Inventories have decreased due to new launches and the building of safety inventories in previous years as a result of the reorganization of production between the Group's different sites.
- Trade debtors have increased mainly due to sales in the Spanish and German markets.
- Financial debt decreased mainly due to the repayment in advance of the syndicated loan (EUR 150 million) and the payment of the Convertible Bond (EUR 250 million), partially offset by the issuance of senior unsecured notes (EUR 300 million).
- Non-current liabilities (excluding financial debts) decreased mainly due to the recognition in the income statement of deferred income, as mentioned in Note 16 to the accompanying consolidated financial statements.

- Current liabilities (excluding financial liabilities) have increased due to the increase in trade payables and the EUR 20.8 million up-front related to the signing of the license agreement with Ichnos Science, which at December 31, 2021 was pending payment.

## **6. Financial risk management and use of hedging instruments**

### **Interest rate risk**

At December 31 most of the Group's debt is at a fixed rate, minimizing the risk of a possible increase in interest rates. As described in Note 17, the main debt instruments are as follows:

- On September 22, 2021, the Parent Company, has proceeded to the issuance of senior unsecured notes for an aggregate nominal amount of EUR 300 million, with an annual fixed interest rate of 2.125% and maturing on September 22, 2026.
- On July 17, 2020, the Parent Company entered into a revolving credit facility, amounting to EUR 275 million, for an initial term of 3 years with the possibility of an extension of 1 additional year (such renewal has been granted effective June 30, 2021, effective July 17, 2021, therefore maturing in July 2024) and intended for general corporate purposes. This policy accrues a variable interest rate tied to Euribor. At December 31, 2021, the Group had no amount drawn on this policy.
- On March 27, 2019, the Parent Company formalized a loan with the European Investment Bank (EIB) for up to EUR 120 million to finance its research and development efforts, with the aim of offering cutting-edge innovation and differentiated therapies in the area of medical dermatology. The first tranche of EUR 80 million was granted on April 17, 2019 at a fixed interest rate of 1.35%, with 32 equal principal repayments between April 17, 2021 and April 17, 2029, the latter being the final maturity. Due to the issuance of new debt, the interest rate is increased by 0.30% temporarily, resulting in an interest rate of 1.65%.

### **Foreign currency risk**

The Group is exposed to exchange rate risk in certain transactions derived from its activity. These are mainly collections in dollars corresponding to sales of finished products, collections and payments derived from the operation with AstraZeneca, payments in dollars derived from license agreements with Athenex, Dermira or Sun Pharma, payments in dollars for clinical trials, purchases of raw materials and royalty payments in yen and dollars. The most relevant foreign currency in which the Group operates is the US dollar.

The Group analyzes quarterly the forecasts of collections and payments in foreign currencies as well as their evolution and trend. During the last few years, the Group has reduced its exposure to exchange rate risk in those commercial transactions of greater volume, by contracting specific exchange rate insurance to cover payments in yen for the purchase of raw materials, and to cover cash inflows in USD for collections.

Until November 24, 2021, the Parent Company of the Group was the borrower of a loan between companies of the group, with Almirall, Inc., in USD. Said loan has not been hedged since July 1, 2020 it has been considered as more value of the investment and, therefore, the exchange differences generated from that moment have been recorded in the translation differences section of the equity (see Note 15). On November 24, 2021 Almirall, S.A. proceeded to capitalize the nominal amount of said loan together with the interest pending to be paid, therefore as from that date no additional exchange difference has been generated in the Parent Company.

### **Liquidity risk**

The Group determines cash requirements using two fundamental forecasting tools that vary in terms of their time horizon.

On the one hand, a one-year monthly cash budget is established based on the forecast financial statements for the current year, from which the variances are analyzed monthly. On the other hand, 24-month forecasts are set up, which are updated monthly.

On the other hand, medium and long-term liquidity planning and management is based on the Group's Strategic Plan covering a five-year time horizon.

Cash surpluses in foreign currency are invested in deposits in those cases where there is a provision to make payments in that currency, mainly US dollars.

The financing instruments include a series of "covenants" which in the event of non-compliance would imply the immediate enforceability of such financial liabilities. The Group periodically evaluates such compliance (as well as future expectations of compliance in order, where appropriate, to be able to take corrective action). As of December 31, 2021, all "covenants" are fulfilled, as mentioned in Note 17.

The Group performs prudent liquidity risk management, maintaining sufficient cash and marketable securities, as well as the hiring of credit facilities committed enough to meet the intended needs.

## **7. Risk factors**

Risk factors worthy of mention that may affect the achievement of the business objectives are the following:

- Price reductions or volume limitations for existing products and difficulties in obtaining the prices or reimbursement conditions requested for new releases by decisions of the health authorities, with the consequent impact on sales forecasts.
- Erosion of turnover and loss of market share due to the progressive entry of generics.
- Cyber-attacks or security incidents that may allow access to confidential information or cause a disruption of business activities.
- Impairment of intangible assets and goodwill due to income flows below those projected.
- Pipeline of R&D not sufficiently balanced and differentiated in its different phases to nourish the product portfolio.
- Prolonged and higher than expected impact of COVID-19.

Additionally, in Note 33 of the accompanying Consolidated Annual Accounts, additional risks related to COVID-19 are detailed, as well as in section 1.5 of the Non-financial Information Report where the Group's risk management system is explained.

## **8. Treasury shares**

The Parent Company maintains a liquidity contract with a financial intermediary, effective as of March 4, 2019, with the objective of increase and stability in the share price of the Company, within the limits established by the General Meeting of Shareholders and by current regulations, in particular, Circular 1/2017, of April 26, of the National Securities Market Commission, on liquidity contracts. Said contract assumes that the Parent Company owns, at December 31, 2021, treasury stock representing 0.08% of the share capital (0.09% at December 31, 2020) and a global nominal value of EUR 16.8 thousand and which have been registered in accordance with IFRS-EU. The average acquisition price of these shares has been EUR 11.3 per share. The shares of the Parent Company in its possession are intended to negotiate in the market.

## **9. Outlook for 2022**

The 2022 financial year is expected to see a continuation of the business progress seen in 2021, continuing the planned product launches and the development of the research pipeline. Note 33 of the accompanying Consolidated Financial Statements and this management report describe the main impacts of the 2021 financial year as well as the risks and uncertainties facing the Group.

With regard to new products, Klisyri is expected to be launched in 2022 in most of the European Union (following the launch in 2021 in Germany and the United Kingdom). In addition, Wyzora will also be launched in Europe and Ilumetri is expected to continue to grow in the various markets where it is present.

In terms of R&D activities, the company expects to complete Phase 3 of Lebrikizumab and subsequently file the registration for Europe in the second half of 2022. In addition, we expect to continue developing the pipeline in preclinical and clinical phases with innovative treatments for dermatology.

Finally, the Group's management continues to focus on opportunistic M&A transactions that fit in with the Group's commercial strategy, always with a prudent financial attitude.

## **10. Annual Corporate Governance Report**

The Annual Corporate Governance report is attached hereto as Annex II.

## **11. Capital structure. Significant ownership interests**

The share capital of the Parent Company as of December 31, 2021 is represented by 179,776,802 shares with a par value of EUR 0.12, fully subscribed and paid up (178,115,627 shares as of December 31, 2020).

In Note 15 of the attached Consolidated Annual Accounts the movement of capital during the year is detailed, the increase of which is due to the flexible dividend paid in the year.

Shareholders with significant ownership in the capital stock of Almirall, S.A. both direct and indirect, greater than 3% of the share capital, of which the Parent Company is aware, according to the information contained in the official records of the National Securities Market Commission as of December 31, 2021 and December 31 of 2020, are the following:

<i>Name of direct holder of the ownership interest</i>	<i>% interest 31/12/2021</i>	<i>% interest 31/12/2020</i>
Grupo Plafin, S.A.	40.9%	40.9%
Grupo Corporativo Landon, S.L.	18.8%	18.8%
Wellington Management	5.1%	-
Artisan Partners	3.6%	-
<b>Total</b>	<b>68.4%</b>	<b>59.7%</b>

On December 31, 2021 and 2020, the Parent Company is unaware of there being other ownership interests of 3% or more in the share capital or voting rights of the Parent Company, or other interests which, despite being less than this percentage, enable the holder to exercise a significant influence over the Parent Company.

## **12. Side agreements and restrictions on transferability and voting rights**

There is a shareholders' agreement, duly notified to the CNMV and whose full text can be consulted on the website [www.almirall.com](http://www.almirall.com), signed by Mr. Antonio Gallardo Ballart and Mr. Jorge Gallardo Ballart, which regulates the concerted action of its signatories in Almirall, S.A. and the exercise of the voting rights inherent to their indirect participation in the Company through the company Grupo Plafin, S.A.U. and Todasa, S.A.U. (now Grupo Corporativo Landon, S.L.).

The Articles of Association impose no restrictions on the transferability of the shares of the Company, and neither are there any restrictions on voting rights pursuant to the Articles of Association or regulations.

## **13. Governance bodies, Board of Directors**

### ***Appointment of Directors***

The directors are appointed (i) upon proposal by 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 General Shareholders' Meeting or by the Board of Directors in accordance with the provisions of the Spanish Companies Law.

Newly appointed directors are required to complete the Parent Company's orientation course for new directors so that they can rapidly build up sufficient knowledge of the Parent Company and of its corporate governance rules.

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

Directors proposed for re-appointment must refrain from participating in the deliberations and voting procedures concerning them.

Directors hold office for the term stipulated by the General Meeting, which is equal for all and may not exceed four years, at the end of which they may be re-elected one or more times for periods of the same maximum duration.

### ***Replacement of Directors***

Directors cease to hold office when the period for which they were appointed has elapsed and when a decision to this effect 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 directors expires when, once its term has elapsed, the following General Meeting has been held, or the legal time limit for holding the General Meeting to approve the accounts for the previous year has passed.

The Board of Directors may only propose the removal of an independent director before the expiry of the statutory term when there is due cause, acknowledged by the Board following a report by the Appointments and Remuneration Committee. In particular, due cause is understood to exist when a director has breached the duties inherent to his/her position or has come to be in any of the circumstances which bar him/her from holding this office, as described in the definition of independent director contained in corporate governance recommendations applicable at the time.

Directors who are the subject of removal proposals must refrain from participating in the deliberations and voting procedures concerning them.

The directors are required to tender their resignation to the Board of Directors and formalize such resignation, where the Board considers this appropriate, in the following cases:

- a) Where they cease to hold the executive posts with which their appointment as directors was associated.
- b) Where they find themselves in any of the situations of incompatibility or barring from office stipulated by law.
- c) When seriously reprimanded by the Board of Directors for failing to discharge their obligations as directors.
- d) When their remaining on the Board could jeopardize or prove detrimental to the interests, credit or reputation of the Parent Company or when the reasons for which they were appointed cease to apply (for example, when a nominee director sells their shareholding in the Parent Company).
- e) In the case of independent directors, they may not remain in such positions continuously for more than 12 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, similarly, (ii) in the requisite number, when such shareholder reduces its shareholding to a level which requires 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 their term, they are required to explain the reasons in a letter sent to all the Board members.

#### ***Amendment of the Company's bylaws***

Amendments to the bylaws are a competence of the General Meeting and are regulated by Article 160 of the Spanish Companies Law and other related legislation. There are no special provisions of relevance in this respect in either the bylaws or the General Meeting Regulations.

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

The Chief Executive Officer of the Company has delegated to him certain powers of the Board of Directors as per the deed authorized by the Notary Public of Barcelona Mr. Enrique Viola Tarragona on May 20, 2021.

Similarly, powers have been granted to Mr. Jorge Gallardo Ballart in the public deed executed before the Barcelona Notary Mr. Enrique Viola Tarragona on June 2, 2011.

#### **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 Directors and Managers or Employees with respect to indemnities for dismissal, resignation, or public takeover bids.

#### **15. Subsequent events**

On October 29, 2021, the Parent Company, AstraZeneca and Covis Pharma GmbH signed an agreement whereby AstraZeneca assigns to Covis Pharma GmbH the global rights of Eklira and Duaklir, which would be effective at the time when these companies complete the transaction, which finally occurred on January 5, 2022 (Note 12). As a result of this agreement, the Parent Company, in addition to continuing to receive royalty payments under the terms initially established with AstraZeneca, will receive a fixed amount of \$ 10 million on the date on which the transaction is completed and \$40 million in different tranches until September 2023, mainly linked to certain changes in the milestone structure initially established.

Additionally, at the date of preparation of these Consolidated Annual Accounts, the Board of Directors of Almirall, S.A. has agreed to propose to the General Shareholders' Meeting the distribution of a dividend charged to unrestricted reserves in the amount of EUR 33.8 million (equivalent to 0.19 euros per share). For the purpose of this dividend distribution, it is proposed to revert to the "Flexible Dividend" shareholder remuneration system, already applied in 2021. In this way, shareholders are offered an alternative that allows them to receive bonus shares of the Parent Company without limiting their possibility of receiving in cash an amount equivalent to the payment of the dividend as indicated in Note 4.

#### **16. Non-Financial Information Statement**

The Non-financial Information Statement is attached in Annex I of this document.

#### **17. Annual Remuneration Report**

The Annual Remuneration Report is attached as Annex III to this document.