

Barcelona, Spain  
 November 10<sup>th</sup> 2022

## Almirall's Nine-month 2022 Results

# Almirall achieves core net sales of €633.8 MM Euros in the first nine months of 2022 showing a solid 5.3% growth

- Almirall continues solid business momentum in Q3 with an acceleration of sales growth (+5.3% year-on-year) driven by the recently launched products and the strong performance of the European Dermatology portfolio
- Excellent momentum of the dermatology business in Europe, growing 21% year-on-year with key products delivering strong growth: solid performance of Ilumetri<sup>®</sup> underpinned by new countries' contribution with ongoing sales momentum, Wynzora<sup>®</sup> increased market share in key countries, and Klisyri<sup>®</sup> showed strong performance in EU countries where launched
- Total EBITDA reached €146.4 MM year-to-date (-19.2%), the comparison to last year is affected by product divestments in the first half of 2021 and deferred income which ended in 2021. In addition, the total EBITDA was also impacted in 2022 by higher investments in R&D and SG&A related to new and coming launches
- The Board of Directors has appointed Carlos Gallardo, Chairman of the Board of Directors, as interim CEO while the company identifies a permanent candidate to succeed Gianfranco Nazzi
- Lebrikizumab Marketing Authorization Application (MAA) has been accepted for evaluation by the European Medicines Agency (EMA), following phase 3 data
- Based on the good performance of the business so far, Almirall is reiterating its 2022 guidance

Almirall, S.A. (ALM), the global biopharmaceutical company based in Barcelona, has announced its 9M 2022 financial results.

### Financial highlights (€ rounded million)

	9M 2022	9M 2021	Variation
<b>Core Net Sales*</b>	<b>633.8</b>	<b>601.7</b>	5.3%
<b>Core EBITDA*</b>	<b>134.0</b>	<b>164.2</b>	(18.4%)
<b>Total EBITDA</b>	<b>146.4</b>	<b>181.2</b>	(19.2%)
<b>Net Income</b>	<b>10.9</b>	<b>(39.4)</b>	n.m
<b>Normalized Net Income</b>	<b>32.7</b>	<b>61.5</b>	(46.8%)

\* Core results excludes AstraZeneca and Covis contribution: Deferred Income and Other Income. From 2022 onwards, there is no difference between Core Net Sales and Net Sales as no additional Deferred Income from AstraZeneca/Covis is registered, the difference related to Core EBITDA and EBITDA is explained by the other income related to AstraZeneca/Covis.

## Summary of results

- **Core Net Sales\*** reached €633.8MM, a +5.3% year-on-year increase with a strong contribution from the sales of the dermatology portfolio in the European market. Total EBITDA declined 19.2% year-on-year to €146.4MM in line with expected performance, as 2021 had products divestments and deferred income. In addition, the total EBITDA was also impacted in 2022 by higher investments in R&D and SG&A related to new and coming launches.
- Almirall finished the third quarter with a strong and healthy balance sheet at 0.8x Net Debt to EBITDA thanks to the good cash flow generation and the reduction in the pension plans. **Normalized Net income** was €32.7MM which resulted in a **normalized earnings per share of €0.18 per share**.
- **R&D** investments at €71.6MM increased to 11.3% of Net Sales in-line with expectations. Almirall anticipates R&D expenses to reach around 12% of Net Sales for the full year due to the investment in phase 3b focused studies for Lebrikizumab, the Klisyri® large field studies as well as an increase in spending on earlier stage assets such as the Anti IL1-Rap and the IL-2 mutant fusion protein.
- **SG&A (Selling, General, and Administrative)** expenses were €308.9MM, 6.3% higher than last year as Almirall continues to invest in its newly launched products such as Wyzora®, Klisyri® in the US & EU, and Ilumetri® rollout in key countries.
- **Core Gross Margin\*** of 66.5% is broadly in line with expectations for this year and the next year.

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*We are pleased to see that we have had good business momentum in Q3, with our growth drivers showing very strong performance. Our Core business continues to perform well in line with our expectations, which puts us on target to achieve our 2022 Guidance.*

*During the third quarter, we received important news such as the EMA acceptance for filing of Marketing Authorization Application (MAA) for lebrikizumab based on the encouraging results of the analysis of Phase III studies ADvocate 1&2 and ADhere. This confirms that we continue to execute on pipeline commitments and are committed to the transformation of the company by preparing the business for future launches and supporting our mid-term growth acceleration prospects.*

*Last week we announced my appointment by the Board of Directors as interim CEO and the step down of Gianfranco Nazzi. While we have already set in motion a thorough search for this position, I will take over the management of the company alongside Almirall's strong management team. I am committed to driving and supporting Almirall's exciting journey towards leadership in medical dermatology and driving long-term shareholder value.*

**Carlos Gallardo, Chairman and Interim CEO**

### Psoriasis

**Ilumetri® (tildrakizumab)**, an anti-IL-23 biologic for moderate-to-severe plaque psoriasis, consolidates its solid performance year to date. Ilumetri® reached year-on-year sales growth of +55.6% versus 9M 2021 achieving year-to-date net sales of over €88.4 MM, though the company registered lower sequential growth in the third quarter due to the seasonality impact.

The product continues to show a solid performance in Europe, maintaining its leadership in countries like Germany, where the Anti-IL23 confirms its position while continuing to gain new patients within the biologics, despite recent launches of new Anti-IL-17s.

During the 31st EADV (European Association of Dermatology and Venereology) Congress Almirall presented the results from TRIBUTE, an interventional phase IV clinical study, which resembled real-life clinical practice. <sup>i</sup>

Almirall reinforces its position as the only European company with an entire portfolio of psoriasis products covering the treatment paradigm with the successful rollout campaign, in progress, of Wyzora®\* cream, a once-daily aqueous cream with a fixed combination of calcipotriene and betamethasone dipropionate (CAL/BDP) indicated for the topical treatment of mild to moderate psoriasis vulgaris in adults.

**Wyzora®\*** cream is formulated using PAD Technology, a topical formulation and drug delivery system that allows CAL and BDP to co-exist in an aqueous environment for the first time<sup>ii</sup>. During the 42nd Annual Fall Clinical Dermatology Conference that took place in Las Vegas, NV, data showing that PAD Technology leads to more efficient delivery of Calcipotriene (CAL) and Betamethasone Dipropionate (BDP) than CAL/BDP gel/topical suspension was presented.<sup>iii</sup>

Wyzora® achieved Sales of €5MM year to date and showed excellent traction in the first countries launched, with 11% market share achieved in both Germany and Spain. The product shows a positive uptake since its launch, reaching an increasing number of patients while receiving positive feedback regarding product efficacy and convenience. During Q3 Almirall launched Wyzora® in Austria, Denmark, and The Netherlands and the company is working on the rollout campaign of the product in new EU countries in the coming quarters.

*\*Wyzora® is authorized with this name in France, the UK, Spain, the Czech Republic, Denmark, Norway, Sweden, Finland, Germany, Portugal, Italy, Ireland, and The Netherlands. In Austria, it is authorized under a different tradename: Winxory®.*

### Actinic Keratosis (AK)

**Klisyri®\*** (tirbanibulin), a novel microtubule inhibitor for the topical treatment of actinic keratosis (AK) of the face or scalp, achieved a very good uptake and is gaining strong traction in the countries where launched. In Germany, where Klisyri® has been awarded the most innovative product of 2022 at the Pharma Trend Image & Innovation Awards<sup>iv</sup>, the product is expanding its penetration with increasing unit market share one year after launch.

During the third quarter, Klisyri® reached Net Sales of >€5 MM YTD in the EU underpinned by new country launches as Almirall continues to advance the roll-out of Klisyri® in Europe.

In the US, Klisyri® received a strong recommendation in the AAD guidelines update<sup>v</sup>. The product has gained penetration in the US AK topical market with over 53,000 prescriptions having been generated since its launch in February 2021.

Moreover, Almirall's ongoing work to drive demand and improve market access has achieved 70% growth in Medicare coverage.

*\* Klisyri® is licensed from Athenex.*

## Acne

**Seysara**<sup>®</sup> (sarecycline), an oral antibiotic for the treatment of acne, showed TRx volume recovery during the third quarter reaching pre-Covid levels (32% growth in Q3 2022 vs. Q3 2021; 33% growth 2022 vs 2021 YTD).

Furthermore, the product increased its market share to >5% share in the Oral Antibiotics market in the US. Almirall continues to focus its efforts on improving commercial productivity (TRx/HCP) and also increasing payer coverage. Seysara<sup>®</sup> made steady gains within commercial market access with over 74% of commercial lives now having payer access.

## Building next stage pipeline

### Atopic Dermatitis (AD)

During the 31st European Academy of Dermatology and Venerology (EADV) Congress Almirall new detailed results from Phase 3 monotherapy studies in atopic dermatitis (AD) were presented and showed investigational **lebrikizumab** provided robust and durable improvements in skin clearance and itch for patients who achieved a clinical response\* at Week 16 through one year of treatment.<sup>vi</sup>

Recently, Almirall announced that the European Medicines Agency (EMA) has accepted for evaluation the filing of the Marketing Authorization Application (MAA) for lebrikizumab for the treatment of moderate to severe atopic dermatitis. Approval in Europe is expected by late 2023.

### Onychomycosis

**Efinaconazole** is a triazole antifungal compound indicated for the treatment of mild-to-moderate fungal infection of the nail in adults and children (aged 6 years and older). Almirall has submitted regulatory filings under the European decentralized procedure. The German regulatory authority is acting as the Reference Member State. The outcome of the filing is expected to be known in 2023.

With the potential launch of this antifungal expected in 2023, assuming regulatory approval, Almirall will reinforce its onychomycosis franchise by complementing Ciclopoli<sup>®</sup>, Almirall's OTC product indicated to treat this condition.

## Acne

Phase 3 clinical trials are ongoing in China for the oral antibiotic **Seysara**<sup>®</sup> (**sarecycline**). Almirall started treating the first patients at the end of last year and is working towards an expected submission in 2023.

### Autoimmune dermatological diseases

In the third quarter, Almirall announced that it has entered into an exclusive licensing agreement with Simcere Pharmaceutical Group for Simcere's IL-2 mutant fusion protein (IL-2 mu-Fc) autoimmune drug candidate, **ALM223** (previously SIM0278). This molecule activates regulatory T-cells developed in-house by utilizing Simcere's protein engineering platform.

Under the agreement, Almirall will be granted an exclusive right to develop and commercialise ALM223 for all indications outside the Greater China region (Mainland China, Hong Kong, Macau and Taiwan). Simcere will retain all rights to develop and commercialise ALM223 within Greater China.

Almirall is also working on reinforcing its biologic pipeline and leading position in Medical Dermatology with its anti-IL-1-RAP monoclonal antibody. Almirall in-licensed exclusive global rights from Ichnos Science to develop and commercialise **ALM27134\***, a first-in-class fully human, high-affinity monoclonal antibody that targets human IL-1RAP and has the potential to treat underserved patients with a variety of autoimmune dermatological diseases. During Q3 Almirall also announced the initiation of the phase I study evaluating the safety, pharmacokinetics, pharmacodynamics, and clinical activity of ALM27134.

*\*Previously referred to as ISB 880*

## 2022 Full Year Guidance

Guidance maintained: Core Net Sales: mid-single-digit growth, Total EBITDA between €190 - €210 MM.

## Investor Calendar 2023

- Full year 2022 Financial Results – February 20th, 2023
- Q1 2023 Financial Results – 8th May 2023
- H1 2023 Financial Results – 24th July 2023
- 9M 2023 Financial Results – 16th November 2023

## About Almirall

Almirall is a global biopharmaceutical company focused on skin health. We collaborate with scientists and healthcare professionals to address patient's needs through science to improve their lives. Our Noble Purpose is at the core of our work: "Transform the patients' world by helping them realize their hopes and dreams for a healthy life". We invest in differentiated and ground-breaking medical dermatology products to bring our innovative solutions to patients in need.

The company, founded in 1943 and headquartered in Barcelona, is publicly traded on the Spanish Stock Exchange (ticker: ALM). Throughout its 79-year history, Almirall has retained a strong focus on the needs of patients. Currently, Almirall has a direct presence in 21 countries and strategic agreements in over 70, with about 1,800 employees. Total revenues in 2021 were €836.5MM.

For more information, please visit [almirall.com](https://almirall.com)

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<sup>i</sup> Costanzo et al. Tildrakizumab improves quality of life, treatment satisfaction and patient benefits in patients with moderate-to-severe chronic plaque psoriasis in conditions close to real clinical practice. Presented at 31st European Academy of Dermatology and Venereology (EADV) Sept

<sup>ii</sup> Praestegaard M, Steele F, Crutchley N. Polyaphron dispersion technology, a novel topical formulation and delivery system combining drug penetration, local tolerability and convenience of application. Accepted for publication in *Dermatology & Therapy*, 2022.

<sup>iii</sup> Crutchley N et al. PAD technology™- based CAL/BDP cream demonstrates superior human skin flux properties compared to topical suspension/gel. Poster presented at the 2022 Fall Clinical Dermatology Conference. October 20-23, 2022, Wynn Hotel, Las Vegas (USA).

<sup>iv</sup> <https://pharma-trend.com/pharma-award/#IP>

<sup>v</sup> Eisen DB, Dellavalle RP, Frazer-Green L, Schlesinger TE, Shive M, Wu PA. *Focused Update: Guidelines of care for the management of actinic keratosis*. *JAAD*. 2022

<sup>vi</sup> Blauvelt A, et al. *Efficacy and Safety of Lebrikizumab in Moderate-to-Severe Atopic Dermatitis: 52-Week Results of Two Randomized, Double-Blinded, Placebo-Controlled Phase 3 Trials (ADvocate1 and ADvocate2)*, Abstract presented at: *EADV 2022*. Abstract 3456