



Barcelona, Spain 22<sup>nd</sup> February, 2020

# Almirall's 2020 Full-Year Results

# Almirall delivers on latest 2020 guidance and sets growth targets for 2021

- The company delivered on its latest guidance despite a challenging year impacted by COVID-19 and the genericization of Aczone<sup>®</sup>: Net Sales €807.4 MM (-5.4%, flat excluding the Aczone<sup>®</sup> generic impact), Total Revenues €814.5 MM (-10.3%), EBITDA €238.3MM (-21.7%), all year-on-year and due to the expected generic competition to Aczone in the US and a reduction in milestones from AstraZeneca
- Almirall appointed Gianfranco Nazzi as the new CEO, effective May 1, 2021. Mr. Nazzi will bring continuity to the strategy as the business prepares for important launches to support future growth prospects
- A continued positive outlook for key growth drivers will be boosted in 2021 by the recent launch of Klisyri® (tirbanibulin) in the US, with the launch in Europe expected in the second half of 2021
- Almirall is advancing our strong late-stage pipeline aiming to unlock significant mid-term value. Key 2021 milestones are expected to include topline phase 3 lebrikizumab data and the anticipated approval in Europe for a psoriasis cream (calcipotriene and betamethasone dipropionate) commercialised under the tradename Wynzora<sup>®</sup> in US
- Introducing Core Guidance for 2021: Core Net Sales growth of mid-single-digit and Core EBITDA
  of €190-€210 MM (versus 2020 Core EBITDA of €181 MM) which equates to total EBITDA of
  approximately €215-€235 MM
- Dividend proposal of €0.19 per share will be submitted at the next Annual General Meeting May 7<sup>th</sup>

#### Financial highlights (€ rounded million)

	2020	2019	Variation	Variation (CER¹)
Total Revenues	814.5	908.4	(10.3%)	(10.3%)
<ul> <li>Net Sales</li> </ul>	807.4	853.1	(5.4%)	(5.3%)
• Other Income	7.1	55.3	(87.2%)	(87.5%)
Gross Profit	560.1	603.9	(7.3%)	(7.1%)
· % of sales	69.4%	70.8%		
EBITDA	238.3	304.2	(21.7%)	(21.6%)
Normalized Net Income	95.1	136.1	(30.1%)	(29.9%)

<sup>&</sup>lt;sup>1</sup> CER (Constant Exchange Rates): Excluding the effects of exchange rate fluctuations.

"2020 has been a challenging year given the impact of COVID-19 and the genericization of Aczone®, however, we have delivered the latest guidance with an EBITDA of €238.3 MM and Net Sales of €807.4 MM.

The pandemic has created an unprecedented situation and I am proud of our employees who have worked hard and continued to put the patient at the heart of everything we do. We maintained our unwavering commitment to patients and we ensured an uninterrupted supply of our medicines for patients in need throughout the pandemic.

To highlight our key products performance, Ilumetri® continued to perform strongly with increasing market share within the anti-IL23 class in Germany. Skilarence® performed within expectations having been impacted by COVID-19 related restrictions. Seysara® has seen a modest recovery from May 2020 having also been adversely impacted by COVID-19. We rely on growth in our key products to continue to improve our core EBITDA in 2021 and we expect Core Net sales to be boosted by new launches, like Klisyri® for actinic keratosis. Klisyri® was recently launched in the US and is expected to be launched in Europe in H2 2021, with global peak sales expected to reach €250 million in the future.

We have begun 2021 with the appointment of Gianfranco Nazzi as the new CEO of Almirall, effective May 1, 2021. We are sure that his wealth of international experience in the pharmaceutical sector will help Almirall achieve its objectives of sustained growth in its core business going forward.

We have also announced two important collaborations during the first weeks of 2021 with Tyris Therapeutics and MC2 Therapeutics that will reinforce our pipeline potential and will allow Almirall to expand its innovative options in Medical Dermatology. We will continue to make significant efforts to build and develop our pipeline of future products by maintaining an investment of around 10% to 12% of our annual Net Sales in R&D. Almirall is very well positioned and has all of the ingredients to grow our core business in the coming years."

Mike McClellan, CFO and Interim CEO.

Almirall, S.A. (ALM) the global biopharmaceutical company based in Barcelona, has announced its full-year 2020 financial results today.

#### **Summary results**

- Net Sales of €807.4 MM represents a decline of 5.4% year-on-year, impacted both by COVID-19 and the generic competition to Aczone<sup>®</sup>. Net sales excluding the impact of the Aczone<sup>®</sup> generic competition in the US were flat versus 2019.
- Total Revenues reached €814.5 MM, a 10.3% year-on-year decrease, and were additionally impacted by the expected significant decline in Other Income (-87.2%) due to the reduction in milestones from AstraZeneca.
- Gross Profit of €560.1 MM reflected a decline of -7.3% as expected relating to the generic competition to Aczone® in the US.
- Operating Cash Flow reached €165 MM (+95% growth vs. 9M 2020) and Financial Debt totalled €392.5 MM, ending with a net debt to EBITDA ratio of 1.6x.
- Research & Development expenses were €78.9 MM (-14.4%).



- Selling, General & Administrative expenses were €370.2 MM, with a 6.1% lower spend on sales & marketing largely due to COVID-19.
- **EBITDA** for 2020 was €238.3 MM, down 21.7% driven by the generic competition to Aczone® as well as the significant decline in Other Income.
- Normalised Net Income was €95.1 MM.
- Shareholders Equity represented 56.8% of Total Assets.

# **Key events in 2020**

**January 8**th. Almirall enters into an option agreement to acquire Bioniz Therapeutics and to establish a broad research agreement to further expand its innovative pipeline in Medical Dermatology.

**January 9**th. Almirall and WuXi Biologics sign strategic collaboration agreement for multiple bispecific antibodies targeting dermatology diseases.

**January 9**th. Almirall signs a strategic agreement with 23andMe to license rights of a bispecific monoclonal antibody that blocks all three isoforms of IL-36 cytokine.

**February 6**<sup>th</sup>. Almirall announces a partnership with Plug and Play to boost digital innovation in dermatology. **February 24**<sup>th</sup>. Almirall and Paratek enter into a License Agreement for Seysara® in China.

May 28<sup>th</sup>. Almirall, UC3M, and MEDINA Foundation launch a project to research new treatments for rare genetic diseases.

June 11th. Almirall enters the IBEX 35.

July 21th. Almirall joins the AMR Action Fund to support the fight against antimicrobial resistance.

**October 8**th. Almirall and the University of Dundee announce a multi-target research collaboration to develop novel Targeted Protein Degraders medicines.

**October 12<sup>nd</sup>.** Almirall announces approval of the reimbursed price for Ilumetri® (tildrakizumab) in France for the treatment of adult patients with severe chronic plaque psoriasis.

**October 30**th. Almirall announces first complete dataset in the IL-23p19 class and demonstrates llumetri® (tildrakizumab) long-term efficacy and safety through 5 years in patients with moderate-to-severe psoriasis.

November 9th. The Board of Directors appoints Carlos Gallardo as Vice President of the Board.

November 12<sup>th</sup>. Popit and Almirall announce new adherence tool to support psoriasis patients.

**December 24**th. Almirall announces FDA approval of Klisyri® (tirbanibulin), a new innovative topical treatment for actinic keratosis.

## Leading the future of medical dermatology through new launches and a strong portfolio

Almirall's performance during 2020 was affected by the pandemic's profound impact in the Medical Dermatology area. The reduction in the number of patient visits due to COVID related restrictions and the change in prescription habits have negatively impacted our sales performance, particularly in the US.

Although we recorded an increase in face-to-face interactions in Q3 as countries began easing restrictions, the start of the third wave of the pandemic in Europe in Q4 saw a return of tightened restrictions slowing down the normalization of patient visits to doctors and hospitals. We expect that COVID-19 will continue to impact H1 2021, but we expect healthcare systems to gradually return to normal by H2 2021 as mass vaccination programmes progress.

Klisyri® (tirbanibulin), a novel microtubule inhibitor, was approved by the US Food and Drug Administration (FDA) for the topical treatment of actinic keratosis (AK) of the face or scalp. The approval was based on the data from one of the largest phase 3 clinical study programs ever conducted for a topical AK treatment, which was recently published in the **New England Journal of Medicine (NEJM)**. Tirbanibulin demonstrated complete clearance of AK lesions at day 57 in treated face or scalp areas in a significantly higher number of patients than with vehicle. The results proved tirbanibulin's efficacy and also its tolerability and safety profile.

This topical ointment represents a significant step forward in AK's treatment due to its convenient 5-day application period, the shortest of any topical treatment for AK, and proven efficacy and safety profile.



In February 2021, Almirall launched **Klisyri®** for AK in the US and reinforced the US sales force. Klisyri® is under review by the European Medicines Agency (EMA) and its launch in the EU is expected in H2 2021, which will strengthen Almirall's European AK franchise.

**Ilumetri**<sup>®</sup>, an anti-IL-23 high-affinity humanized monoclonal antibody indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis, continues to demonstrate strong performance with sales growing +124% year-on-year to €44 MM. Monthly units in all countries are similar or above pre-COVID levels with excellent momentum in Germany, reaching the highest quarter unit volume since launch. Ilumetri<sup>®</sup> has increased its competitive position within the anti-IL-23 class, capturing 32% market share of new patients in its class in Germany, which is competing with anti-IL17's to become the winning class. At the end of 2020 Almirall launched Ilumetri<sup>®</sup> in France after establishing an experienced team and dermatologists are already prescribing it to patients. The product is also gaining traction in recent virtual launches like the ones conducted in Italy and Belgium.

The potential of Ilumetri® (tildrakizumab) was confirmed by the recent publication in the **British Journal of Dermatology** of a full 5-year pooled data analysis from two Phase 3 clinical studies, reSURFACE 1 and reSURFACE 2. This is first complete dataset analysis published in a medical journal on an anti-IL23p19 inhibitor. It demonstrated that patients who responded to tildrakizumab maintained a clinically significant response over 5 years and control of psoriasis was sustained with a reassuring safety profile.

2020 has been an atypical year for the US oral antibiotic market, including **Seysara**® our innovative oral antibiotic derived from tetracycline and specifically designed to treat acne in patients over the age of 9 years. Prescriptions have had a positive but modest recovery from May 2020 in line with the overall OAB market, however continue to be impacted from COVID-19 related restrictions limiting access to physicians by patients and our sales force.

In 2020, the FDA approved an important update to the Seysara® label, stating that the primary bacterium associated with acne (*P. acnes*) displayed a low propensity for the development of resistance to sarecycline (the active ingredient of Seysara®). We will continue to dedicate resources to support the new promotional campaign and medical education programs to further differentiate Seysara® based on this microbiology label and to enhance its access to patients.

Almirall's strategy for Seysara<sup>®</sup> includes future expansion into the Chinese market. We have received acceptance of the Clinical Trial Application in China and expect to initiate a phase 3 clinical trial in 2021 to demonstrate the drug's efficacy and safety for submission to the Chinese National Medical Products Administration (NMPA) in 2023. It is estimated that there will potentially be 13 million moderate-to-severe acne patients treated with oral antibiotics in the urban Chinese population by 2028, which represents a significant opportunity to launch an innovative product whose clinical development is largely de-risked. Seysara<sup>®</sup> represents the first dermatology product that Almirall plans to launch in the Chinese market, with a long-term view to building a strategic dermatology portfolio in China.

#### Focused on R&D to unlock a pipeline with significant mid-term potential

Almirall maintains a firm commitment to R&D and continues working hard to develop its pipeline to unlock the enormous growth potential of the Medical Dermatology business with exciting milestones expected in 2021. At present, Almirall's pipeline comprises 4 promising late-stage products and 13 preclinical programs. In addition, the company deploys a responsive and nimble strategy for identifying key acquisition, licensing and alliance opportunities that can contribute to achieving its goals and delivering long-term profitable shareholder value.

**Lebrikizumab** phase 3 clinical trials are ongoing and top line results are expected in H2 2021. In 2019, Almirall exercised its option with Dermira (which was subsequently acquired by Eli Lilly) to license the rights to lebrikizumab in Europe for atopic dermatitis. Lebrikizumab is an anti-IL-13 monoclonal antibody currently in development as monotherapy in patients from 12 years of age with moderate-to-severe atopic dermatitis,



a disease where there is a significant unmet need. Almirall believes lebrikizumab has best-in-class potential and offers an opportunity to improve efficiency, tolerability, and convenience for patients. Lebrikizumab's launch is expected for 2023, and Almirall anticipates potential peak sales for lebrikizumab in Europe of around €450 MM.

In 2020 and early 2021, Almirall announced several agreements, including the accords with **WuXi Biologics**, **23andMe**, **Popit**, **Tyris Therapeutics**, **Happify Health**, **and MC2 Therapeutics**, and the option agreement with the US biotech **Bioniz Therapeutics Inc**.

Recently, Almirall has announced an agreement with **MC2 Therapeutics** which granted Almirall exclusive European rights to market **Wynzora**® cream for the treatment of plaque psoriasis. Wynzora®, a topical calcipotriene/betamethasone DP combination cream developed using PAD<sup>TM</sup> formulation technology, received US FDA approval on July 20, 2020, and is currently in pre-registration for psoriasis in Europe. With the addition of this product to its portfolio, Almirall has strengthened its position in the EU psoriasis market with a complete portfolio of psoriasis products that covers the entire treatment paradigm.

In January 2021, Almirall and **Tyris Therapeutics**, a next-generation gene therapy company founded by Columbus Venture Partners, announced a strategic partnership to tackle orphan dermatological conditions using non-viral gene therapies. The companies aim to develop next-generation gene therapies with transformational potential for the treatment of rare genetic dermatology diseases.

Almirall has an option agreement with **Bioniz** and we are currently reviewing the phase 1/2 clinical study of BNZ-1. We expect to make a decision on the option in Q1 2021.

Almirall also reinforced its commitment to digital health with agreements with **Happify Health** and **Popit**. Almirall and the Finnish digital health start-up Popit announced a collaboration to provide a novel support solution for patients with psoriasis, which improves medication adherence and offers educational support for the patient. The recently announced strategic partnership between Almirall and Happify Health aims to develop evidenced-based digital solutions to improve the lives of patients with psoriasis based on cognitive behavioural therapy, positive psychology, and mindfulness.

#### **Conclusions and 2021 Outlook**

We delivered the latest Guidance despite a challenging year with impact from COVID-19 and the generic competition of Aczone®. Our key products and new launches will continue to grow our Core Net Sales and Core EBITDA in 2021. With the arrival of Gianfranco Nazzi as the new CEO, we will continue to drive our strategy as the business prepares for important launches to support future growth prospects. At Almirall, we are committed to developing our pipeline to unlock the significant potential to grow our core Medical Dermatology business with exciting milestones coming in 2021. We are also focused on leveraging our strong balance sheet for external opportunities to generate sustainable value for shareholders.

## **Board proposals to the Annual General Meeting: Dividend**

The AGM will be proposed a dividend of €0.19 per share for approval May 7<sup>th</sup> 2021.



#### 2021 Full Year Guidance vs. 2020

Core Net Sales: mid-single-digit growth (versus €755 MM in 2020).

Core EBITDA: between €190 - €210 MM (versus €181 MM in 2020) which equates to approximately €215 - €235 MM of total EBITDA.

#### **Investor Calendar 2021**

- Q1 2021 Financial Results 10<sup>th</sup> May 2021
- H1 2021 Financial Results 26<sup>th</sup> July 2021
- 9M 2021 Financial Results 8<sup>th</sup> November 2021

#### **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 publically traded on the Spanish Stock Exchange and is a member of the IBEX35 (ticker: ALM). Throughout its 77-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, through 13 subsidiaries, with about 1,800 employees. Total Revenues in 2020 were 814.5 million euros.

## For more information, please visit almirall.com

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