

# Almirall's Full-Year 2019 Results

## Strong operational performance with excellent pipeline progress

- **Delivered upgraded guidance: low double-digit Total Revenue growth and strong EBITDA margin improvement; Total Revenues +12%, Net Sales +13% and EBITDA +45% to €304 MM, all year-on-year**
- **Growth drivers continue to show positive momentum. In Europe, our psoriasis franchise growth continues to be driven by the performances of Ilumetri<sup>®</sup> and Skilarence<sup>®</sup>. In the US, Seysara<sup>®</sup> performed strongly and a revised co-pay card program has been implemented to optimize profitability from January 2020 onwards**
- **Increased innovation and progress in the pipeline: the Phase III study for Lebrikizumab (atopic dermatitis) has been initiated; Tirbanibulin (actinic keratosis) filling to be completed by end of Q1 2020; acquisition of China rights for sarecycline, Phase III initiation in 2020**
- **Strategic agreements recently signed with Bioniz, 23andMe and WuXi Biologics, that reinforce the pipeline in key medical dermatology diseases**

### Financial highlights (€ rounded million)

	2019	2018	Variation	Variation (CER <sup>1</sup> )
<b>Total Revenues</b>	<b>908.4</b>	<b>811.0</b>	12.0%	11.0%
• <b>Net Sales</b>	<b>853.1</b>	<b>756.9</b>	12.7%	11.8%
• <b>Other Income</b>	<b>55.3</b>	<b>54.1</b>	2.2%	0.2%
<b>Gross Profit</b>	<b>603.9</b>	<b>529.2</b>	14.1%	13.1%
• <b>% of sales</b>	<b>70.8%</b>	<b>69.9%</b>		
<b>EBITDA</b>	<b>304.2</b>	<b>209.5</b>	45.2%	43.4%
<b>Normalized Net Income</b>	<b>136.1</b>	<b>88.2</b>	54.3%	54.2%

We are pleased with our performance in 2019, having delivered the upgraded guidance, achieving an EBITDA of €304.2 MM and Total Revenues of €908.4 MM. In terms of pipeline, 2019 has been a transformative year, one which we believe will be a key enabler of future growth.

Our key brands in Europe, Skilarence® and Ilumetri®, continue to perform well, as does Seysara® in the US.

In 2019 we exercised the option for lebrikizumab that has the potential of being a best-in-disease product in atopic dermatitis and we have designed the Phase 3 lebrikizumab program to demonstrate such a profile. At the end of this quarter, we expect to announce the completed filing of Tirbanibulin in Europe and in the US.

We have started 2020 with three important announcements that further reinforce our pipeline potential. We have executed an option agreement to acquire Bioniz therapeutics, Inc. and we have signed two important agreements with 23andMe and WuXi Biologics. With these new agreements, Almirall expands its innovative options in medical dermatology, including therapeutic bi-specific antibodies.

For 2020 we expect Net Sales to grow low to mid single-digit and EBITDA to reach €260-280 MM. There are multiple moving parts this year. Overall we anticipate a steady increase in sales, as products continue their rollout across Europe and the US strategy for Seysara® to optimize profitability from January begins to bear fruit. We will be investing to support our recent launches and prepare for our future launches, which will lead to an increase in SG&A spend in 2020.

As we have previously flagged, there will be an adverse impact from the genericization of Aczone 7.5% and a significantly lower level of milestones and royalties from AstraZeneca, in line with the current lower sales level of our licensed products. Furthermore, we have decided to employ a conservative approach and we are including in our projections potential measures by the Spanish Government that may affect our business in Spain. For these reasons, we have provided the market with a relatively wide EBITDA range as part of our guidance.

**Peter Guenter, CEO**

[Almirall, S.A. \(ALM\)](#), a global pharmaceutical company based in Barcelona (Spain), has announced its full-year 2019 results today.

## Summary results

- **Total Revenues** reached €908.4 MM in 2019 vs €811.0 MM in 2018 (+11% CER) and comprised **Net Sales** of €853.1MM (+12% CER) and **Other Income** of €55.3 MM.
- **Gross Profit** of €603.9 MM reflected CER growth of 13%, driven by performance of key products.
- **Cash Position** at the close of 2019 was €117.4 MM whereas **Financial Debt** came to a total of €455.0MM, representing 18.6% of total assets.
- **Research & Development** expenses were €92.2 MM (+5% CER).
- **Selling, General & Administrative** expenses €394.1 MM (+5% CER, but a decline of 7% CER excluding depreciation and amortization).
- **EBITDA** at close of 2019 was €304.2 MM (+43.4% CER), delivering the upgraded guidance provided at H1, and following good performances from key brands and improved product mix driving an increase in gross margin.
- **Normalised Net Income** was €136.1 MM
- **Shareholders Equity** represented 52.5% of Total Assets.

## Key events in 2019

- **January, 4th.** Francesca Domènech Wuttke, new Chief Digital Officer and new member of the Management Board in Almirall.
- **January, 17th.** Novel oral antibiotic treatment Seysara<sup>®</sup> (sarecycline) now available in the US.
- **February, 12th.** Almirall and Dermira enter into option license agreement for European rights to lebrikizumab.
- **March, 4th.** Almirall enters into a definitive agreement to divest ThermiGen, its medical device aesthetics business.
- **March, 4th.** Almirall and Athenex announce positive topline results from two Phase III Studies of KSX2-391 ointment 1% featured in Late Breaker Program at the 2019 American Academy of Dermatology Annual Meeting.
- **April, 1st.** FDA approves Duaklir<sup>®</sup>, a new drug application for chronic obstructive pulmonary disease (COPD).
- **June, 25th.** Almirall exercises its option with Dermira to license rights to lebrikizumab in Europe for atopic dermatitis.
- **September, 16th.** Almirall announces CFO leadership transition: Mike McClellan to join Almirall on November 11th as new group CFO.
- **October, 9th.** Almirall announces initiation of Phase 3 Program evaluating lebrikizumab in patients with moderate-to-severe atopic dermatitis.
- **October, 11th.** Tildrakizumab confirms its long-term efficacy and safety with the longest IL23p19 data available.
- **October, 21st.** Duaklir<sup>®</sup> available in the US.
- **December, 3rd.** Volker Koscielny, new Chief Medical Officer and new member of the Management Board at Almirall.

## Almirall transformation underway: building a medical dermatology leader

Almirall's solid performance during 2019 was in particular marked by the strong takeup of **Skilarence<sup>®</sup>** and **Ilumetri<sup>®</sup>** in Europe.

**Skilarence<sup>®</sup>** is an oral systemic formulation for the treatment of patients with moderate-to-severe chronic plaque psoriasis and 2019 saw good initial market penetration achieved and significant market share capture in Germany and The Netherlands. It is currently marketed in the UK, Germany, the Netherlands, Spain, Italy, Ireland and Switzerland and it achieved Net Sales of €33 MM in 2019. We expect a more moderate rate of growth as of 2020 onwards.

**Ilumetri<sup>®</sup>**, an anti-IL-23p19 high-affinity humanized monoclonal antibody indicated for the treatment of adult patients with moderate to severe plaque psoriasis, continues its launch sequence. In 2019 there were additional market introductions in Austria, Switzerland, Netherlands and Spain and Net Sales in 2019 of €20 MM were recorded. Its rollout continues in Europe in 2020. **Ilumetri<sup>®</sup>** is considered the most cost-effective option of the new biologics\*.

In January 2019 in the US, Almirall launched **Seysara<sup>®</sup>**, an innovative oral antibiotic derived from tetracycline, and specifically designed for the treatment of acne in patients 9 years of age and older. Seysara<sup>®</sup> finished the

year with €23 MM of Net Sales and 6% volume market share in December 2019. Up to 6,200 dermatologists prescribed the drug and a total of 204,090 prescriptions were written in 2019. A revised co-pay card program has been implemented to optimize profitability from January 2020.

## Development of R&D and significant reinforcement of the pipeline with the latest agreements

Almirall has shown its commitment to dermatology with several agreements in 2019 and early 2020, including the license agreement with Dermira for Lebrikizumab, the agreements with 23andMe and WuXi Biologics or the option agreement with the US biotech Bioniz Therapeutics Inc.

In February 2019 Almirall announced that it had entered into an option and license agreement under which the company acquired an option to exclusively license rights to develop and commercialize Lebrikizumab for the treatment of atopic dermatitis and certain other indications in Europe. In June, Almirall exercised the option with Dermira for this drug. In January 2020, Eli Lilly announced its intention to acquire Dermira.

As a result of the agreement with **23andMe**, Almirall secured the rights to develop and globally commercialize the bi-specific antibody targeting IL-36, a member of the IL-1 family of cytokines and associated with various inflammatory diseases, including some dermatological disorders. 23andMe has licensed this bi-specific monoclonal antibody to Almirall to take advantage of the company's experience in medical dermatology and thus accelerate the development of this preclinical program. Almirall will continue with the development of the antibody with the aim of moving it into clinical trials in humans and subsequently commercializing it.

The second partnership is with the technology company **WuXi Biologics** through which Almirall will have access to the patented antibody platforms of the Chinese company, including WuXi Body, for the discovery of various novel bi-specific antibodies. This strategic agreement allows Almirall to develop products from the collaboration and retain ownership for medical use of the resulting components to achieve the company's goal of developing biologically based drugs to tackle skin diseases.

In addition, Almirall will be involved in the field of oncodermatology after signing a purchase option agreement with the US biotech company **Bioniz Therapeutics Inc.** Through this agreement, Almirall will obtain global rights to BNZ-1, an inhibitor that selectively blocks the activity of three cytokines of the same family: IL-2, IL-9 and IL-15, and which is currently in Phase 1/2 of development for refractory cutaneous T-cell lymphoma. If the option is exercised, Almirall would enter into a broader research agreement with Bioniz NewCo, using its multi-cytokine simultaneous inhibition platform, with the aim of obtaining at least 3 new candidates ready to start clinical phase.

Furthermore, Almirall confirms that the complete filings of Tirbanibulin (ALM14789) to the EMA and the FDA will take place during Q1 2020. ALM14789 is a topical drug for the treatment of actinic keratosis in adult patients developed by Athenex and licensed by Almirall. It's estimated to be launched in the US and the EU in the first half of 2021.

We have recently announced that we have acquired licencing rights for Seysara<sup>®</sup> in China. We are planning to submit Seysara<sup>®</sup> to the Chinese NMPA in 2023. It is estimated that there will be a potential 13 million moderate to severe treated acne patients in the urban Chinese population by 2028, a significant opportunity into which to launch an innovative product whose clinical development is largely derisked.

## Conclusions and 2020 Outlook

Almirall is undergoing a strategic transformation driven by innovative launches, in particular its European psoriasis franchise, **Skilarence**<sup>®</sup> and Ilumetri<sup>®</sup> and by **Seysara**<sup>®</sup> in the US. Despite a number of anticipated challenges in 2020 we remain extremely optimistic as to the continued strong growth and transformation of this business going forward. The strong growth potential comes from our innovative pipeline which, together with recent product launches, have a peak sales potential in excess of €1bn (versus Net Sales of only €853 MM in 2019). In addition, we remain focused on incremental external opportunities to generate sustainable value for shareholders and further boost growth prospects.

## Board proposals to the Annual General Meeting: Dividend

At the Annual General Meeting on May 6th, 2020, the Board of Directors will propose a gross dividend of €0.203 per share in a scrip dividend modality. In this way, its shareholders are offered an alternative that allows them to receive shares issued by the parent company without limiting their possibility of receiving in cash an amount equivalent to the payment of the dividend.

## 2020 Full Year Guidance vs. 2019

Net Sales: low to mid single-digit growth.

EBITDA: between €260-€280 MM.

## Investor Calendar 2020

- **Q1 2020:** May 11<sup>th</sup>
- **H1 2020:** July 27<sup>th</sup>
- **9M 2020:** November 9<sup>th</sup>

## About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying science to provide medical solutions to patients and future generations. Our efforts are focused on fighting skin health diseases and helping people feel better. We support healthcare professionals in their continuous improvements, providing our innovative solutions where they are needed.

The company was founded over 75 years ago and has its headquarters in Barcelona. It is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key source of value creation for society thanks to its commitment to its principal shareholders and its decision to help others by understanding their challenges and using science to provide solutions for real life. Total Revenues in 2019 were more than 900 million euros. Almirall has c. 1,800 employees.

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

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\* Technology appraisal guidance [TA575] Published date: 17 April 2019 <https://www.nice.org.uk/guidance/ta575/documents/html-content-3>