

Almirall delivers solid nine months 2021 results and tightens its upgraded guidance

Barcelona, Spain (ots/PRNewswire) -

- **Strong Core business performance with growth in Core Net Sales EUR601.7 MM (+6.2% year-on-year) and Core EBITDA reaching EUR164.2 MM, (+20.3% year-on-year) driven by positive contribution from Growth Drivers and a strong EU dermatology performance**
- **Key Growth Drivers underpinning increase in Core Net Sales. Strong performance from Ilumetri® with sales growing sequentially quarter-on-quarter and Klisyri® receiving positive feedback from dermatologists and patients, making steady gains month over month in the US market and showing strong early positive signals in the recent launch in Germany**
- **Top-line read out of lebrikizumab's data in August, with primary and all key secondary endpoints including itch, interference of itch on sleep and quality of life with people with moderate-to-severe atopic dermatitis met at Week 16 in two pivotal Phase 3 trials and safety profile consistent with prior studies**
- **Good progress of the remaining late-stage R&D pipeline. Klisyri® recently launched in Germany and the UK with the roll-out on track in the rest of the European market. Successful regulatory approval of Wynzora® in seven EU countries**
- **Tightening upgraded Guidance for 2021: Core Net Sales mid-single-digit growth and Core EBITDA between EUR200 MM (from EUR195 MM) and EUR215 MM**
- **Simplified capital structure after having successfully issued EUR300 MM Senior Notes maturing in 2026**

[Almirall, S.A. \(ALM\)](#), the global biopharmaceutical company based in Barcelona, has announced today its 9M 2021 financial results. The company reports a robust business performance year-to-date as it sees the continuation of the good momentum from its growth drivers and recent launches. Overall, the solid evolution of the Core business led to the Core EBITDA increasing by 20.3% from last year, reaching EUR164.2 MM for the 9-month period. The normalized net income excluding, among others, the intangible impairments booked in Q2 is slightly down compared to last year reaching EUR61.4 MM.

The company delivered a very strong Operating Cash Flow generating EUR161.4 MM.

During this quarter, Almirall has successfully issued EUR300 MM Senior Notes maturing in 2026. The new bonds, which will bear an annual interest of 2.125% payable semi-annually, will be used to repay EUR250 MM of convertible bonds that come due at the end of the year. The simplified capital structure brings longer maturity profile and flexibility for additional inorganic growth.

Almirall reiterates its upgraded sales guidance for 2021 (Core Net Sales mid-single-digit growth) and tightens the Core EBITDA range by increasing the base level to EUR200 MM from EUR195 MM (EUR200 MM - EUR215 MM).

Financial highlights (EUR rounded million)

	9M 2021	9M 2020	Variation
Core Net Sales	601.7	566.8	6.2%
Core EBITDA	164.2	136.5	20.3%
Net Income	(39.4)	57.1	n.m.
Normalized Net Income	61.4	74.2	(17.2%)
Operating Cash Flow	161.4	38.1	n.m.

Summary of 9M results

- **Core Net Sales*** reached EUR601.7 MM, a 6.2% year-on-year increase
- **Core EBITDA*** increased 20.3% year-on-year to EUR164.2 MM
- **Normalised net income** EUR61.4 MM, a 17.2% year-on-year decrease
- **Net Loss** of EUR39.4 MM due to the impairment of EUR103 MM for the carrying value of the intangible asset for Seysara® (EUR69 MM), the US Legacy Portfolio (EUR22 MM), and the Bioniz option payment which was not exercised (EUR12 MM) as announced at H1 results
- **Operating Cash Flow** reached EUR161.4 MM

*Core business excludes AstraZeneca contribution: Deferred Income and Other Income

"We are pleased to see that the Core business continues to deliver well with a strong operational performance in line with our expectations. There is excellent momentum moving forward into Q4, where we are confident that Almirall's growth drivers will keep their strong trajectory. The company is well positioned for long-term growth as it unlocks the value of the late-stage pipeline and executes on its transformation by preparing the business for important launches. We are therefore confident in meeting our upgraded Guidance for 2021 and have tightened upwards the Core EBITDA base level."

Gianfranco Nazzi, CEO

Growth Drivers Performance

Psoriasis

Ilumetri[®], an anti-IL-23 high-affinity humanized monoclonal antibody indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis, has had a strong year-to-date performance with sales growing sequentially as new country launches gain momentum and contribute to the overall growth to achieve a Net Sales of over EUR20MM during Q3.

Even though there is tough competition within the anti-IL23 class in Germany, the product has a strong market share in the country, increasing to 29% within the class. In addition, there has been positive momentum and contribution of new country launches in France, Spain, Italy, Austria, and Switzerland, and the latest in Portugal.

During the [European Academy of Dermatology and Venereology 2021 \(EADV\) Congress](#), Almirall presented the design of the POSITIVE study, which will assess the improvement of the overall wellbeing of patients treated with Ilumetri[®] in a real-world setting.

Actinic Keratosis (AK)

Klisyri[®] (tirbanibulin), a novel microtubule inhibitor for the topical treatment of actinic keratosis (AK) of the face or scalp, has been launched in Germany and the UK during this quarter after receiving approval from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and the European Commission. Klisyri[®] is doing very well in Germany, achieving 5,200 prescriptions during the first month after launch and more than half of wholesalers having already placed orders.

The rollout of this product in Europe follows its launch in the US in February of this year and enhances Almirall's leadership in the EU market.

Market growth is anticipated to be driven by several factors, including ageing populations and the rising prevalence of the disease, in part due to environmental factors, such as increased sun exposure. AK is one of the most common diagnoses made by dermatologists in Europe with a prevalence of approximately 18% of the population and higher for adults over the age of 60[i]. In this context, the commercialization of Klisyri[®] is an important addition to dermatologists' options to treat AK and marks another milestone achieved by Almirall in its mission to bring new and innovative solutions to AK patients around the world.

In the US, the product continues to make steady gains month by month. It has gained penetration in the AK topical market, with more than 15,000 prescriptions generated since its launch and a market share above 2.5%. The company expects to make good progress on commercial and Medicare coverage this year and in 2022.

Acne

Seysara[®], an innovative oral antibiotic derived from tetracycline and specifically designed to treat acne, has continued to make modest gains in TRx with an improvement in the OAB market share and an increase in 40% of Net Sales year-on-year. Almirall's strategy remains the same, to rebuild the TRx and increase market share as reps increase their face-to-face interactions with physicians once there is a normalization from Covid.

The company will continue to dedicate resources to further differentiate Seysara[®] based on the Microbiology label, which is an important factor that Almirall is able to leverage with physicians to differentiate the product.

Late-stage pipeline & Near-term Launches

Atopic Dermatitis (AD)

Lebrikizumab, an anti-IL13 monoclonal antibody for the treatment of moderate-to-severe atopic dermatitis (AD), led to significant improvements with at least 75 percent skin clearance in more than half of people with moderate-to-severe atopic dermatitis, as measured by EASI (Eczema Area and Severity Index), in Advocate 1 and Advocate 2 Phase 3 clinical trials. In the top-line results published from these two monotherapy studies released this quarter, primary and all key secondary endpoints, including skin clearance and itch improvement, were met at Week 16. The full results from these two studies will be disclosed at future congresses in 2022. Data from a Phase 3 combination study (Adhere) of lebrikizumab with topical corticosteroids in patients with AD will be available later this year. Lebrikizumab has the potential to be best-in-class therapy for treating AD in a class where it has been published that AD is an IL-13 dominant disease.

AD is an immune-mediated chronic skin condition with a significant impact on the wellbeing and quality of life of patients. Despite recent treatment advances, there remains a high unmet need for medicines that provide effective and well tolerated treatment options.

The development schedule remains on schedule with submission to the European Medicines Agency (EMA) expected in 2022 and subsequent approval and release estimated to be obtained in 2023.

Psoriasis

Wynzora[®]'s decentralised procedure is advancing successfully with regulatory authorizations granted in Austria, Czech Republic, Denmark, France, Norway, Spain and the United Kingdom.[ii] This should allow expected launches in the EU to happen from early 2022 onwards.

Wynzora[®] cream is a combination of 50 µg/g calcipotriol and 0.5 mg/g betamethasone as dipropionate, which is a well-established topical treatment for mild to moderate psoriasis vulgaris in adults. It uses PAD(TM) technology, which allows optimal delivery of the active ingredients to the target issue.

The product has a clear strategic fit within Almirall's portfolio providing a full range of psoriasis products that covers the patient journey and strengthening its position in the EU psoriasis market. Almirall is the only pharma company with a full portfolio of psoriasis products.

Onychomycosis

Efinaconazole, is a triazole antifungal indicated for the treatment of onychomycosis, a fungal infection of the nail. Almirall plans to use existing studies to get approval in Europe and the company is already working on preparations for a planned pre-submission meeting.

The product has been marketed in Japan since 2014 under the trade name of Clenafin® and it has also been launched in the United States, Canada, Korea, Taiwan, Hong Kong and Macau under the trade name of Jublia®.

Acne

As for the launch of the oral antibiotic **Seysara® in China**, Almirall is working towards the start of the phase 3 trials as planned in Q4, having already received the acceptance of the Clinical Trial Application.

Guidance for 2021

Full year Core Guidance. Core Net Sales* mid-single-digit growth, Core EBITDA* between EUR200 - EUR215 MM (previously EUR195 - EUR215 at H1)

**Core business excludes AstraZeneca contribution: Deferred Income and Other Income*

Investor Calendar 2021

- Full year 2021 Financial Results - February 22nd, 2022

[i] Lucas R, McMichael T, Smith W, Armstrong B. Solar ultraviolet radiation: Global burden of disease from solar ultraviolet radiation: World Health

[ii] Wyzora® has received marketing authorization in Czech Republic, Denmark, France, Norway, Spain and the UK with the name Wyzora® and with the name Winxory in Austria.

Logo: https://mma.prnewswire.com/media/1217694/Almirall_Logo.jpg

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