

# STALLERGENES GREER REPORTS SOLID GROWTH AND CONTINUED RECOVERY IN 2017, DELIVERING ON FULL YEAR GUIDANCE

- Net sales reached €265 million in constant currency and €260 million in reported currency, a growth of 40% year-over-year and in line with narrowed guidance issued in August 2017¹
- EBITDA of €21.9 million a significant turnaround compared to a loss of €67.9 million in 2016
- Advanced house dust mite candidate STAGR320 with the completion of patient enrolment in Phase III trial, release
  of Phase III paediatric trial data in Japan, and acceptance of New Drug Submission by Health Canada
- Announced positive results from BREATH, first real-world evidence studies on the long-term effectiveness of grass pollen sublingual immunotherapy treatment compared to symptomatic drugs

**London (UK), March 22, 2018** – Stallergenes Greer, a biopharmaceutical company specializing in treatments for respiratory allergies, today announced its full year results for the year ended 31 December 2017.

	H	H1 (unaudited)		H2 (unaudited)			Full Year (audited)		
(in €million)	2017	2016	% change	2017	2016	% change	2017	2016	% change
Net sales	129.6	78.0	66%	130.6	108.2	21%	260.2	186.2	40%
Gross profit	83.4	34.7	140%	82.4	66.3	24%	165.8	101.1	64%
Gross margin	64%	45%	19 points	63%	61%	2 points	64%	54%	10 points
EBIT	(3.5)	(58.5)	n.a.	(1.9)	(37.5)	n.a.	(5.4)	(96.0)	n.a.
Net profit/(loss)	(8.9)	(39.0)	n.a.	(1.0)	(21.5)	n.a.	(9.9)	(60.5)	n.a.
EBITDA	6.3	(45.1)	n.a.	15.7	(22.9)	n.a.	21.9	(67.9)	n.a.
EBITDA margin	5%	n.a.	n.a.	12%	n.a.	n.a.	8%	n.a.	n.a.

## **FY 2017 Financial Highlights**

Fereydoun Firouz, Chairman and Chief Executive Officer of Stallergenes Greer, commented:

"2017 was a pivotal year and the results we delivered are evidence of the Group's transformation which began two years ago. We met our financial guidance and returned to a positive EBITDA representing a €90 million swing over 2016. We reached key innovation milestones, including the completion of patient enrolment in a Phase III trial for our house-dust mite tablet candidate, STAGR320, and the publication of real-world data from the BREATH studies, which notably demonstrated that Oralair® improved control of allergic rhinitis and may have a preventive effect on allergic asthma onset and progression compared to symptomatic treatments.

We made significant progress commercially, delivering a 40% increase in net sales year-over-year as a result of recapturing market share across our product portfolio in all European geographies and continuing to hold market leadership in the U.S. subcutaneous treatment market.

In 2018, we will continue to focus on commercial execution, optimizing our current product portfolio to gain further market share, and developing new offerings to expand allergy immunotherapy penetration in market segments where we see growth opportunities. Our operational plan is focused on driving top line growth, improving profitability, continuing our innovation path and upgrading our technical operations capabilities."

<sup>&</sup>lt;sup>1</sup> Guidance for 2017 was stated as "total revenue"; there is no material difference between "net sales" and "total revenue". Net sales stated in "constant currency" were determined using the same exchange rates as the half-year 2017 results.



Full-year net sales increased 40% as a result of market share gains in European and International markets and sales growth of the sublingual product category

Net sales by region: Europe and International grew significantly; Leading position held in the U.S.

	H1 (unaudited)		H2 (unaudited)			Full Year (audited)			
(in €million)	2017	2016	% change	2017	2016	% change	2017	2016	% change
Southern Europe	53.7	17.8	202%	65.3	44.3	47%	119.0	62.1	91%
North & Central Europe	18.5	10.7	73%	15.2	12.4	22%	33.7	23.1	45%
International	11.8	4.7	151%	7.8	7.4	6%	19.6	12.1	63%
United States	45.6	44.8	2%	42.3	44.1	(4)%	87.9	88.9	(1)%

The 40% increase year-over-year in net sales reflects the continued recapture of share in European markets and success in new international markets following the temporary suspension of production and distribution at our Antony site in late 2015, which impacted sales in 2016. As of 31 December 2017, Oralair holds 38% of the grass tablet market in France, a 13-percentage point gain over 2016, and 34% of the grass tablet market in Germany, a 3-percentage point gain over last year. In addition, the Group holds a market leadership position in Russia, Poland, the Balkans and the Middle East, and regained share in Czech Republic and Slovakia. Sales growth and market share gains were the result of a refocused commercial organization and improved product supply lead time.

In local currency (US\$), revenue in the U.S. was up 1% in 2017. In the grass tablet market, Oralair nearly doubled its share from December 2016 while the overall market declined by 5% year-over-year<sup>3</sup>. In the subcutaneous immunotherapy market, Stallergenes Greer maintained its leading position with a strong demand that exceeded supply.

Net sales by product category: Staloral® drove 83% growth in sublingual; Subcutaneous grew 3%

		H1 (unaudited)		H2 (unaudited)			Full Year (audited)		
(in €million)	2017	2016	% change	2017	2016	% change	2017	2016	% change
Sublingual <sup>4</sup>	76.9	27.3	182%	79.8	58.4	37%	156.7	85.7	83%
Subcutaneous <sup>5</sup>	36.9	34.2	8%	33.5	33.8	(1)%	70.4	68.0	3%
Other products <sup>6</sup>	10.8	11.1	(3)%	12.1	10.0	21%	22.9	21.1	9%
Veterinary	5.0	5.4	(7)%	5.2	6.0	(14)%	10.2	11.4	(11)%

Full year 2017 sublingual product sales increased 83% to €156.7 million from full year 2016, primarily due to the performance of Staloral, which saw total sales increase 98%, or €61.7 million, compared to 2016. The growth was mainly driven by market share gains and, to some extent, by the industry-wide shortage of subcutaneous immunotherapy treatments in Europe, which resulted in switching of some patients to sublingual therapy. Within the sublingual category, total tablet sales in 2017 reached €30.5 million compared to €21.4 million in 2016, mainly driven by Oralair market share growth in established markets. In the U.S., Oralair market share gained 15 points from 16% in 2016 to 31% in 2017. However, the market is growing more slowly than expected.

In the subcutaneous product category, the Group reported 2017 sales of €70.4 million, a 3% increase compared to 2016, driven by growth in European and International markets while the U.S. market remains flat. Sales from the other product

<sup>&</sup>lt;sup>2</sup> Source: IMS MIDAS

<sup>&</sup>lt;sup>3</sup> Source: Symphony Health Solutions and US Specialty Pharmacy aggregated data internal data audit

<sup>&</sup>lt;sup>4</sup> Product category includes oral drops (Staloral) and tablets (Oralair and Actair®)

<sup>&</sup>lt;sup>5</sup> Product category includes Named Patient Prescription products and bulk allergens

<sup>&</sup>lt;sup>6</sup> Product category includes diagnostic and ancillary products



category grew 9% year-over-year to €22.9 million, and veterinary sales declined 11% to €10.2 million compared to 2016, due to increased competition in this segment.

#### Operational efficiencies delivered margin improvement

The Group's full year 2017 gross margin of €165.8 million represented 64% of net sales, compared to 54% in full year 2016. The improvement is largely due to a global commitment to cost management and a result of ongoing operational efficiency initiatives. In addition, 2016 margins were impacted by costs incurred during the temporary suspension of production and distribution as well as the product recall in 2015.

The Group reduced its net loss from €60.5 million in 2016 to a net loss of €9.9 million in 2017, and reported a positive 2017 EBITDA of €21.9 million, compared to an EBITDA loss of €67.9 million in 2016. EBITDA increased overall by €89.8 million fuelled by a €74.0 million increase in sales and a decline in Selling, General and Administrative expenses of 11%, from €148.2 million in 2016 to €131.9 million in 2017. In 2018, the Group will continue to recalibrate operating expenditures and will further review areas where efficiencies can be made, including the Group's footprint and overhead costs. This commitment resulted in a decision to reduce its administrative offices in the U.K., France and the U.S.

As a result of the business recovery and robust measures to contain costs, Stallergenes Greer continues to have a solid balance sheet. At 31 December 2017, the Group's shareholders' equity represented 83% of the balance sheet total.

As part of our annual reviews, the Group has performed an impairment analysis of its intangible assets and goodwill in accordance with IAS 36 (Impairment of Assets) for its cash-generating units (CGU's). Based on our long range business plan and related sensitivity scenarios around it, the value-in-use of each CGU exceeds its carrying value and therefore no impairment of goodwill has been recorded in the consolidated Group accounts.

#### Group continues to invest in innovation to fuel long-term growth

Stallergenes Greer is committed to developing innovative therapies for major respiratory allergies and invested €45.6 million in R&D in 2017, primarily to fund STAGR320, the Group's Phase III global multi-centre clinical trial for house dust mite (HDM)-induced allergic rhinitis. In July 2017, Stallergenes Greer announced completion of patient enrolment. With more than 1,600 patients enrolled, this study is the largest conducted study to assess the efficacy and safety of a sublingual immunotherapy tablet treatment.

This followed Stallergenes Greer's announcement in January 2017 of positive top-line results from its Phase III study for paediatric HDM-induced allergic rhinitis in Japan. Results from this study supported the March 2017 submission of a new drug application for paediatric use of Actair (Stallergenes Greer's commercial name for STAGR320 in registered markets) in Japan, which was approved post-period in February 2018.

In September 2017, the Group received market approval to commercialize STAGR320 in New Zealand under the Actair brand name and in October 2017, Health Canada accepted for review the New Drug Submission for STAGR320.

In addition to STAGR320, in June 2017, Stallergenes Greer published results from BREATH (Bringing Real-World Evidence to Allergy Treatment for Health), the first global, real-world evidence studies demonstrating the long-term benefits of sublingual immunotherapy to control allergic rhinitis and may reduce the risk of the onset and progression of allergic asthma.

#### **Investments in Quality and Technical Operations to continue**

The AIT industry's manufacturing model is based on that of a compounding pharmacy, with processes that must be continuously updated to meet evolving regulatory requirements and comply with the latest Good Manufacturing Process (GMP) biological manufacturing standards. To address this and to ensure product quality and patient safety for all released and distributed products, Stallergenes Greer has made significant investments in its Technical Operations and Quality capabilities over the past two years, including modernizing manufacturing processes and facilities.



As a result of these efforts and the Group's ongoing commitment to quality, Stallergenes Greer successfully completed three U.S. Food and Drug Administration (FDA) inspections in 2017 at its U.S. facilities. Investments in Lenoir and San Diego will continue in 2018.

In France, the Group made significant progress on operational systems upgrades at its Antony facility, resulting in the reduction of the average product lead time to less than seven days<sup>7</sup> compared to the industry standard of two to three weeks. In addition, work has continued to enhance quality control methods used for product manufacturing and release. Meanwhile, an inspection conducted in the fourth quarter of 2017 by the National Agency for Medicines and Health Products Safety (ANSM) in France resulted in the issuance of an injunction received on 4 January 2018. The injunction was primarily related to the quality management system and processes at the Antony facility, mostly for the production of subcutaneous products. The remediation plan is well underway and the Group is committed to working with the French authorities. Shipment delays and temporary shortages of subcutaneous products are expected in European and International markets through 2018.

#### 2018 Business outlook

Stallergenes Greer made substantial progress in 2017 and will continue to make strategic decisions in order to improve its competitiveness and solidify its business fundamentals. This includes investing in growth opportunities and delivering cost efficiencies across the organization. The Group expects continued progress in 2018, both through sales growth and strengthened profitability. Stallergenes Greer expects:

- net sales to grow mid-single digit percent in constant currency, and
- EBITDA to be higher than 2017

# Stallergenes Greer plc recognized non-cash impairment with no impact on Group consolidated accounts

As part of our annual reviews, Stallergenes Greer plc has performed an impairment analysis of its "investments in subsidiary undertakings" on its statutory accounts based on the latest long range business plan and related sensitivity scenarios around it and an impairment of €234 million was recorded. The impairment in the statutory accounts for Stallergenes Greer plc has no impact on the Group consolidated accounts, its 2017 operating result, EBITDA or Equity<sup>8</sup>.

# **Webcast and Conference Call Information**

Stallergenes Greer will host an Investors and Analysts meeting today, 22 March 2018. The event will be available via live webcast at 10:30 am GMT / 11:30 am CET / 6:30 am EDT. The webcast will be available via the following link: https://edge.media-server.com/m6/p/ptqhwgnv and on the company's website, <a href="http://stallergenesgreer.com/financial-calendar-events">http://stallergenesgreer.com/m6/p/ptqhwgnv</a> and on the company's website, <a href="http://stallergenesgreer.com/financial-calendar-events">http://stallergenesgreer.com/financial-calendar-events</a>.

Please connect at least 15 minutes prior to the conference to register, download and install any necessary audio software.

#### **Financial Calendar**

- 16 April 2018: 2017 Annual Report Publication
- 7 June 2018: Annual General Meeting
- 30 August 2018: H1 2018 Results

#### **ABOUT STALLERGENES GREER PLC**

Headquartered in London (UK), Stallergenes Greer plc is a global healthcare company specializing in the diagnosis and treatment of allergies through the development and commercialization of allergy immunotherapy products and services.

<sup>&</sup>lt;sup>7</sup> Not including backorders

<sup>&</sup>lt;sup>8</sup> For more information, please refer to note 4.5 in the Stallergenes Greer plc, Company financial statements - www.stallergenesgreer.com.



Stallergenes Greer plc is the parent company of GREER Laboratories, Inc. (whose registered office is in the US) and Stallergenes SAS (whose registered office is in France).

#### TRADING INFORMATION

Name: Stallergenes Greer

ISIN: GB00BZ21RF93 1 - Ticker: STAGR

ICB Classification: 4577

LEI: 213800CYVZA7GJQEME86

Market: Euronext Paris regulated market

Additional information is available at http://www.stallergenesgreer.com.

This document (including information incorporated by reference in this document), oral statements made and other information published by the Company contain statements that are or may be forward-looking with respect to the financial condition and/or results of operations and businesses of the Company. These statements can be identified by the use of forward-looking terminology such as "believe," "expects," "project," "estimated," "forecast," "should," "plan," "may" or the negative of any of these, or other variations thereof, or comparable terminology indicating expectations or beliefs concerning future events. These forward-looking statements include risk and uncertainty because they relate to events and depend on circumstances that will occur in the future. Without being exhaustive, such factors include economic situations and business conditions, including legal and product evaluation issues, fluctuations in currencies and demand, and changes in competitive factors. These and other factors are more fully described in the Company's 2016 annual report published on 28 April 2017 on the Company's website www.stallergenesgreer.com. Actual results may differ from those set forth in the forward-looking statements, due to various factors. Save as required by applicable law, neither the Company nor any other person assumes any obligation to update these forward-looking statements or to notify any person of any such update.

### **CONTACTS**

**Communications and Investor Relations** 

Natacha Gassenbach Tel: +1 (617) 225 8013

Email: natacha.gassenbach@stallergenesgreer.com

Caitlin Stefanik

Tel: +1 (857) 331 4117

Email: caitlin.stefanik@stallergenesgreer.com

**Media Relations Agency** 

Havas Worldwide Paris (Europe)

Lucas Heral +33 6 77 01 47 49

E-mail: lucas.heral@havas.com

**Investor Relations Agency** 

FTI Consulting

Arnaud de Cheffontaines Tel: +33 1 47 03 68 10

Email: stalleregenesgreer@fticonsulting.com



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The financial information set out above does not constitute the Group's financial statements for the period-ended 31 December 2017 but are derived from those statements. The annual report for 2017 will be made public on or before 30 April 2018 and delivered to the UK Companies House on or before 30 June 2018. The auditor has reported on those statements. Their report was unqualified, did not draw attention to any matters by way of emphasis and did not contain statements under Section 498 (2) or (3) Companies Act 2006 or equivalent preceding legislation. While the financial information included in this preliminary announcement has been computed in accordance with International Financial Reporting Standards (IFRS), this announcement itself does not contain sufficient information to comply with IFRS.

The Group published full financial statements that comply with IFRS that are available on its website at http://stallergenesgreer.com/annual-report.

The financial statements were approved by the Board of Directors on 21 March 2018.



# Consolidated income statement as of 31 December 2017

€thousands	31 December 2017	31 December 2016
Net sales <sup>1</sup>	260,195	186,247
Other revenues	36	141
Total revenues	260,231	186,388
Cost of goods sold	(94,458)	(85,331)
Gross margin	165,773	101,057
Distribution costs	(11,413)	(11,783)
Selling and marketing expenses	(60,624)	(63,943)
Administrative expenses	(57,588)	(67,316)
Other general expenses	(2,281)	(5,154)
Selling, general and administrative expenses	(131,906)	(148,196)
Research and Development expenses (R&D)	(45,630)	(52,783)
R&D related income	6,412	7,379
Net R&D expenses	(39,218)	(45,404)
Operating loss (EBIT) before transformation costs	(5,351)	(92,543)
Transformation costs	-	(3,506)
Operating loss (EBIT)	(5,351)	(96,049)
Financial income	20	609
Financial expenses	(1,817)	(699)
Net financial expense	(1,797)	(90)
Loss before tax and associates	(7,148)	(96,139)
Income tax	(2,145)	35,773
Share of loss from associated companies	(578)	(156)
Loss for the period attributable to:		
Owners of the parent	(9,871)	(60,522)
Non-controlling interest	_	_
Group share of net loss	(9,871)	(60,522)

<sup>1.</sup> The 2017 net sales figure includes a €5,112k unused reversal of the recall provision against sales.



# Consolidated balance sheet as of 31 December 2017

€thousands	31 December 2017	31 December 2016
Goodwill	195,187	216,550
Other intangible assets	70,913	90,428
Property, plant and equipment	69,138	80,304
Non-current financial assets*	3,957	6,011
Deferred tax assets	26,754	35,377
Other non-current assets	237	-
Non-current assets	366,186	428,670
Inventories	56,793	63,786
Trade receivables	33,199	41,826
Current financial assets*	684	13
Other current assets	9,231	8,810
Current income tax receivable	611	529
Research tax credit and subsidies receivable	22,708	15,468
Cash and cash equivalents	50,849	71,262
Current assets	174,075	201,694
Total assets	540,261	630,364
Share capital	19,788	19,788
Share premium	539	539
Merger and contribution premium	342,149	342,149
Revaluation reserve	(236)	-
Retained earnings	85,086	126,733
Group shareholders' equity	447,326	489,209
Non-controlling interests	_	_
Total shareholders' equity	447,326	489,209
Provision for employee retirement obligations and related benefits	3,442	4,488
Non-current provisions	514	1,651
Non-current financial liabilities	6,318	6,753
Deferred tax liabilities	6,283	17,750
Non-current liabilities	16,557	30,642
Trade payables	19,793	26,658
Current provisions	2,115	3,180
Current financial liabilities	12,204	16,366
Income tax payable	1,313	1,217
Other current liabilities	40,953	63,092
Current liabilities	76,378	110,513
Total equity and liabilities	540,261	630,364

<sup>\*</sup>The liquidity contract of the Group for €670k at 31 December 2017 (31 December 2016: €742k) has been reclassified from non-current financial assets to current financial assets.



# Consolidated cash flow statement as of 31 December 2017

€thousands	31 December 2017	31 December 2016
Cash flow from operating activities		
Group share of net loss	(9,871)	(60,522)
Share of undistributed earnings from investments accounted for using the equity method	578	156
Tax	2,145	(35,773)
Net financial result	1,798	90
Amortisation and depreciation charges	23,404	27,682
Change in provision	(1,904)	(1,096)
Share-based compensation	2,429	1,117
Capital losses from disposal of assets	4,466	578
Financial losses excluding interests	(35)	56
Operating cash flow before changes in working capital	23,010	(67,712)
Current income tax paid	(3,768)	4,612
Change in subsidies and R&D tax credit receivables	(7,240)	(7,066)
Change in working capital of operating activities	(16,231)	(7,244)
Change in deferred income	11	(675)
Net cash flow from operating activities	(4,218)	(78,085)
Cash flow from investing activities		
Purchase of non-current assets	(12,643)	(22,015)
Acquisition of investments in consolidated undertakings, net of cash acquired	(1,403)	_
Proceeds from sale of non-current assets <sup>1</sup>	5,269	19,509
Change in working capital of investment activities	(1,400)	(2,547)
Net cash flow from investing activities	(10,177)	(5,053)
Free cash flow after investing activities	(14,395)	(83,138)
Cash flow from financing activities		
Proceeds from issuance of ordinary shares	_	_
Treasury shares transactions	(72)	20
Net financial interest paid	(1,407)	(583)
Use / (repayment) of bank overdrafts	(227)	(133)
Repayment of borrowings	(15,054)	(17,018)
Proceeds from borrowings	12,095	22,115
Net cash flow from financing activities	(4,665)	4,401
Change in cash and cash equivalents	(19,060)	(78,737)
+ cash and cash equivalents – opening balance	71,262	150,183
+/- effect of translation adjustment on foreign currency denominated cash	(1,353)	(184)
= cash and cash equivalents – closing balance	50,849	71,262

<sup>1.</sup> Included within proceeds from sale of non-current assets are the proceeds from sale of the DBV Technologies shares of  $\leq$ 16,834k in 2016.