# STALLERGENES GREER ANNOUNCES ITS 2015 FULL YEAR RESULTS

- FY 2015 Group net sales of €81.7m<sup>1</sup>, unaudited pro forma sales of €272.9m
- A new global leader in allergy immunotherapy with a strong vision, corporate identity and brand, created from the merger in September 2015
- Strong US performance, with unaudited pro forma FY15 sales up +36%
- Legacy technical issues with manufacturing in France caused temporary suspension of production and distribution and voluntary product recall in Q4 2015, resulting in significant negative impact on 2015 financial results
- RESTART, the Group's back-to-market plan of action for EU and International markets, underway
- Board of Directors does not recommend the payment of a dividend in this first year of trading

## DATE: April 27, 2016

London (United Kingdom) - Stallergenes Greer plc (the "Company") (Euronext Paris: STAGR), a biopharmaceutical company specializing in treatments for respiratory allergies, today announced its full year results for 2015. The results were reviewed and agreed by the Company's Board of Directors on 26 April 2016.

	2H15 results			FY15 results			
	Unaudited	Pro forma (unaudited)		Audited	Pro forma (unaudited)		
€m, except margin in %	2015	2015 2014		2015	2015	2014	
Sales	69.0	89.2	151.7	81.7	272.9	312.5	
EBIT	(65.7)	(74.8)	25.7	(73.9)	(31.8)	62.2	
Operating margin	-	-	16.9%	-	-	19.9%	
Net profit/(loss)	(41.6)	(37.4)	21.6	(49.3)	(8.8)	47.6	

## FY15 Financial Highlights

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

"In 2015, Stallergenes Greer became a new global biopharmaceutical company focused on enabling people to live life beyond allergy. During the first half of 2015, the Group delivered double-digit year-overyear sales growth on a pro forma basis. However, we were challenged in the second half of the year by an operational setback at our plant in Antony, France, resulting in the temporary suspension of production, distribution and subsequent voluntary recall of products. The impact of these unexpected

<sup>&</sup>lt;sup>1</sup> Net sales of €81.7m include Stallergenes Greer Holdings Inc. Group from 8 May 2015 and the Stallergenes Group from 8 September 2015. Net sales also include the full impact of the temporary suspension and voluntary product recall including a provision against sales of €24m.



events were significant and, as a consequence, our Board of Directors does not recommend the payment of a dividend in this first year of trading.

Now a fully integrated organisation led by a new global leadership team, we are continuing to develop the strong foundations which will enable us to build confidently on our leadership position in Europe and in the US. With our defined business strategy, new structures, state of the art systems and a focused R&D pipeline we will now pursue innovation and maximize growth opportunities.

We entered 2016 stronger and are working to regain the trust of all of our stakeholders. This year, we will execute against our strategy with four priorities in mind: Invest in our manufacturing and supply chain capabilities; generate demand for our products in conveying our comprehensive product portfolio value proposition; build a competitive and innovative product pipeline; and further build our new Company by attracting, developing and retaining top talent.

This is a substantial undertaking. Yet, I am confident that we have the determination and grit needed to move beyond the short-term challenges of late 2015 and deliver long-term value for both small and large shareholders. We have learned many lessons about the business we took leadership of last year, emerging stronger, united and truly wiser than before, knowing we can realize our therapeutic ambitions and play a crucial and growing global role in enabling people to live a life beyond allergy."

### Stallergenes Greer's 2015 Reporting Scope Evolution

Stallergenes Greer's FY15 financial results reflect the changes to the company's structure after the merger completed on 8 September 2015. The Company which became Stallergenes Greer plc was incorporated in December 2013. On 12 May 2015, it acquired the Greer Group and merged with the Stallergenes Group on 8 September 2015. The audited numbers reflect the result of each entity based on the date it joined the Group as illustrated in the chart below. The Group has also published unaudited pro forma consolidated figures to provide a more complete and comparable understanding of the Group's performance.

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Conso	lidated F	inancial	Stateme	nts							
Stallerge	enes Greer I	Plc – 1 Janua	ary – 31 De	cember							
				Greer	Group – 12	May – 31 C					
								8			
Proforma	a consolida	ted financia	statement	ts 1 January	- 31 Decen	nber					

## Stallergenes Greer's 2H15 and FY15 Financial Summary

The Group reported sales of €81.7m in FY15. Unaudited pro forma net sales were €272.9m, a 13% decline from €312.5m in FY14 (-16% at constant exchange rates), a consequence of a temporary suspension of production and distribution following the implementation of a new Enterprise Resource Planning (ERP) system and of the voluntary product recall initiated in December 2015.



	2	H15 result	6	FY15 results			
	Unaudited	Unaudited Pro forma (unaudited)		Audited Pro forma (una		(unaudited)	
€m	2015	2015	2014	2015	2015	2014	
Southern Europe	15.4	28.0	86.8	16.0	127.2	178.7	
North & Central Europe	9.7	14.8	23.5	9.9	47.2	54.6	
International markets	3.4	6.2	11.5	3.7	17.5	19.9	
US	40.5	40.2	29.9	52.1	81.0	59.3	
Total	69.0	89.2	151.7	81.7	272.9	312.5	

## FY15 Geographical Turnover

## European Business

Southern Europe FY15 sales were reported at €16.0m. Unaudited pro forma net sales were €127.2m, a 29% contraction from €178.7m in FY14 due to the impact of the temporary shutdown of production and distribution at the Antony plant and the voluntary product recall.

North and Central Europe FY15 sales were reported at €9.9m. Unaudited pro forma net sales were €47.2m, a 13% contraction from €54.6m in FY14, also due to the temporary suspension of production and distribution at the Antony plant and the voluntary product recall.

## International Business

Stallergenes Greer's International FY15 reported sales reached €3.7m while unaudited pro forma net sales totalled €17.5m compared to €19.9m in FY14. The decline is mainly due to the temporary suspension of production and distribution activities at the Antony plant. In FY15, the Group performed strongly in Russia. In Canada, Stallergenes Greer built the foundations for a post-merger expansion to distribute its full portfolio, including Greer Laboratories Extracts.

## US Business

In 2015, Stallergenes Greer performed strongly in the US with total reported sales of €52.1m. The Group's US unaudited pro forma net sales increased 36% to €81.0m (14.7% at constant exchange rate) from €59.3m in FY14. US activities have not been affected by the temporary suspension of production and distribution at the Antony plant.

Stallergenes Greer expanded its US presence in FY15 to capitalize on the expected long-term market potential of allergy immunotherapy (AIT). The Group established its new US headquarters in Cambridge, Massachusetts and invested in its technical and commercial capabilities.

Stallergenes Greer's allergen extract business delivered a solid performance in FY15 with a 14% growth<sup>2</sup> versus FY14. The Company continues to build the foundations supporting ORALAIR<sup>®</sup>'s performance in FY16. AIT treatment adoptions continued to be dominated by allergen extracts in the region; consequently, ORALAIR<sup>®</sup>'s sales were below initial expectations.

<sup>&</sup>lt;sup>2</sup> In local currency



	2H15 results			FY15 results			
	Unaudited	Pro forma (	(unaudited)	Audited	Pro forma (unaudited)		
€m	2015	2015	2014	2015	2015	2014	
Sublingual	21.1	37.5	101.4	21.1	159.4	213.8	
Subcutaneous	31.0	27.2	39.3	40.3	77.3	77.1	
Other	10.8	18.3	7.5	12.5	24.9	14.7	
Veterinary	6.1	6.2	3.5	7.8	11.3	6.9	
Total	69.0	89.2	151.7	81.7	272.9	312.5	

## FY15 Turnover per Product Type

## Sublingual Products

Stallergenes Greer's sublingual products, including tablet products ORALAIR<sup>®</sup> and ACTAIR<sup>®</sup> as well as the STALORAL<sup>®</sup> liquid drop, reported €21.1m in sales in FY15. On an unaudited pro forma basis, sales decreased significantly to €159.4m in FY15 from €213.8m in FY14, mainly due to the temporary suspension of production and distribution at the Antony plant and the voluntary product recall in H2 FY15. In some markets, including the US and Germany, the Group is currently strengthening its market positions. In November 2015, Stallergenes Greer also announced the launch of ACTAIR<sup>®3</sup> in Japan through its exclusive partner Shionogi & Co., Ltd.

## **Subcutaneous Products**

Subcutaneous product sales, including ALUSTAL<sup>®</sup>, PHOSTAL<sup>®</sup> and Greer Extracts were reported at €40.3m while unaudited pro forma net sales totalled €77.3m, stable compared to FY14. The subcutaneous line benefited from a strong growth in the US offset by the adverse impact related to the suspension of production and distribution at our Antony plant.

## **Other Products**

Other products include diagnostics and ancillary products, with total reported sales of €12.5m in FY15. On an unaudited pro forma basis, net sales increased by 69% to €24.9m in FY15 from €14.7m in FY14.

## **Veterinary Products**

The Group is now reporting financial information for veterinary products, a new product category resulting from the merger with Greer Laboratories. Sales were reported at €7.8m while unaudited pro forma net sales increased by 64% to €11.3m from €6.9m. Veterinary sales benefited from a strong market demand and a favorable USD/EUR exchange rate.

#### **Business Highlights**

#### **Creation of Stallergenes Greer plc**

In September 2015, the merger of Stallergenes and Greer Laboratories was completed, leading to the creation of Stallergenes Greer plc, a fully integrated global biopharmaceutical company focused on enabling people with allergies to live normal lives. There is a strong and compelling rationale behind the merger, which gives the Group direct access to the US market and generates new growth synergies for the Company.

<sup>&</sup>lt;sup>3</sup> ACTAIR<sup>®</sup> - immunotherapy tablets for the treatment of House Dust Mite (HDM) induced respiratory allergy



In addition, Stallergenes Greer's global headquarters were established in London, with the goal of creating a central geographic base that links continental Europe and the US, providing the Group access to high-quality academic, scientific and technological capabilities and a large capital market. As previously mentioned, the Group established its new US headquarters in Cambridge, Massachusetts, a major hub for life science innovation in North America. This new geographical presence will act as a catalyst to develop new scientific partnerships, enhancing our existing research and development programs.

## **Technical Challenges**

Stallergenes Greer launched a new end-to-end Enterprise Resource Planning (ERP) system in August 2015. After the ERP launch, the Group experienced a range of technical issues, leading to operational disruptions. In December 2015, complying with the French Health Authority (ANSM), the Group suspended production and distribution, and as a precautionary measure, recalled NPPs in France and a few other countries. Corrective actions and stringent risk management processes resulted in the resumption of production and distribution in March 2016.

## Research & Development Pipeline

Stallergenes Greer is committed to creating innovative treatments for major respiratory allergies and investing 18-20% of sales in research and development. Currently, more than 1,400 patients are enrolled in sublingual clinical studies worldwide. In FY15, Stallergenes Greer initiated its HDM tablet Phase III global multi-center clinical trial for allergic rhinitis. In Japan, the Japanese cedar pollen program with Shionogi & Co., Ltd. showed positive Phase II trial results and discussions are currently underway with the Group's partner regarding the optimal development of this program. The Group is also evaluating the US market opportunity of our ragweed sublingual candidate for a potential submission in H1 FY16.

## **Operating and Financial Review**

The Group's FY15 reported sales were €81.7m. Unaudited pro forma net sales were €272.9m, a 13% decline from €312.5m in FY14 (-16% at constant exchange rate). The Group's FY15 unaudited pro forma gross margin of €182.9m represented 67.0% of net sales, compared to 73.5% in FY14, a direct consequence of the temporary suspension of production, distribution and the product recall, while costs continued to be incurred.

Stallergenes Greer published a FY15 unaudited pro forma operating loss before transformation costs of €19.4m, versus a profit of €66.8m in FY14. This result includes investments in the establishment of the London headquarters, the Group's US commercial organization, the resolution of the temporary suspension of production and distribution and the voluntary product recall. Reported transformation costs of €9.2m relate predominantly to the acquisition of the Greer Group and its merger with the Stallergenes Group. The total unaudited pro forma transformation costs were €12.4m, including €3.2m incurred by Stallergenes SA in advance of the merger. The Group considers these costs non-recurring exceptional items.

In FY15, the Group reported €20.9m in R&D costs on an audited basis, representing 26% of net sales. On a pro forma basis, the Group invested €52.4m or 19% of sales in R&D in FY15, compared to €50.8m in FY14 (16%). This investment relates to ongoing clinical development programs, notably the development of STG320 (ACTAIR<sup>®</sup>) in allergic rhinitis. The R&D related income of €1.3m is primarily a research tax credit received in France. On a pro forma basis, the R&D related income was €19.5m for FY15, compared



to €20.1m in FY14, including a €10m milestone payment received from Shionogi & Co., Ltd. upon marketing authorization of ACTAIR<sup>®</sup> in Japan. Further milestone income was recognized during the pro forma FY15 period based on the progress of the Japanese cedar phase II clinical program.

As of 31 December 2015, the Group's financial position remained sound with net assets of €540.0m. The Group also had cash and cash equivalents of €150.2m and an outstanding debt balance of €17.7m. This net cash position enables the Group to make the necessary investments to relaunch the product portfolio in the EU and International markets (RESTART plan).

#### Dividend

In FY16, Stallergenes Greer will continue prioritizing investments for its future growth. Therefore, the Board of Directors does not recommend to pay a dividend to shareholders for FY15 at the Annual General Meeting of 9 June 2016.

### **2016 Significant Events**

#### Production and Distribution in EU and International markets

On 1 February 2016, the Company received authorization to restart the production and distribution of ORALAIR<sup>®</sup>, ACTAIR<sup>®</sup> and ALYOSTAL<sup>®</sup> Venom.

On 10 March 2016, the Company received authorization to restart the production and distribution of its Named Patient Products (NPP), STALORAL<sup>®</sup>.

#### **RESTART Action Plan in European and International Markets**

Stallergenes Greer has implemented the RESTART action plan to relaunch its product portfolio in all European and International markets. RESTART is designed to regain the Company's global leadership by focusing on production, logistics capabilities and commercial excellence. RESTART's first achievement was the resumption of production and distribution at the Company's Antony plant.

#### **Research & Development**

On 5 April 2016, the Company received the approval for ACTAIR<sup>®</sup> from the Australian health authorities.

On 27 April 2016, the Company announced that its partner, Shionogi & Co., Ltd., reported positive results for the phase II clinical study of its sublingual immunotherapy tablet for the treatment of seasonal allergic rhinitis induced by Japanese Cedar pollen (STAGR120).

### 2016 Business Outlook

Stallergenes Greer's FY15 consolidated accounts show a solid balance sheet and a strong cash position of €150.2m. This allows the Group to continue to invest in the RESTART program and in its production facilities in a disciplined approach. Meanwhile, encouraging new prescription trends lead us to a cautiously optimistic outlook for FY17.



As production capabilities and distribution ramp up in Antony to meet customer demand, the Group is monitoring sales and operating expenses on an ongoing basis and financial guidance will be provided during Q3,16.

### Webcast and Conference Call Information

The company will host an investor and analyst conference in Paris, France on 28 April 2016. The event will also be available via live webcast at 2pm CET / 1pm BST / 8am EDT. The webcast will be available via the link below:

#### http://edge.media-server.com/m/p/7y63ad9m

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

#### **Financial Calendar**

- 29 April 2016 Annual Report Filing
- 9 June 2016 Annual General Meeting
- 25 August 2016 1st semester 2016 Results
- November 2016 Strategy and R&D Day



## 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. Stallergenes Greer plc is the parent company of GREER Laboratories, Inc. (whose registered office is in the U.S.) and Stallergenes S.A.S. (whose registered office is in France).

#### **Trading information:**

Name: Stallergenes Greer

ISIN: GB00BZ21RF93 1 - Ticker: STAGR

ICB classification 4577

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 our prospectus filed with the French Autorité des marchés financiers on September 3, 2015. 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.

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The consolidated income statement and balance sheet as of 31 December 2015 are audited. The pro forma consolidated income statement is unaudited. The condensed consolidated financial information contained in this announcement does not constitute statutory accounts within the meaning of Section 434 of the Companies Act 2006. The information has been extracted from the consolidated financial statements for the year ended 31 December 2015 approved by the Directors on 26 April 2016. The report of the auditors on those accounts was unqualified and did not contain an emphasis of matter paragraph nor any statement under Section 498 of the Companies Act 2006. The financial statements will be delivered to the Registrar of Companies after the Annual General Meeting. This financial information has been prepared in accordance with the Disclosure and Transparency Rules of the Financial Conduct Authority. In preparing this financial information management has used the principal accounting policies as set out in the Group's annual financial statements for the year ended 31 December 2015.



## Condensed consolidated income statement as of 31 December 2015

€ thousands	2015	2014
Net sales*	81,748	
Other revenue	74	_
Total revenues	81,822	_
Cost of goods sold	(37,966)	_
Gross margin	43,856	_
Distribution costs	(8,561)	_
Selling and marketing expenses	(32,639)	_
Administrative expenses	(44,112)	(51)
Other general expenses	(3,568)	(6)
Selling, general and administrative expenses	(88,880)	(57)
Loss before R&D	(45,024)	(57)
Research and development costs (R&D)	(20,929)	_
R&D-related income	1,301	-
Net R&D costs	(19,628)	_
Operating loss before transformation costs	(64,652)	(57)
Transformation costs	(9,211)	_
Operating loss	(73,863)	(57)
Financial income	79	_
Financial expenses	(359)	_
Net financial expense	(280)	-
Loss before tax and associates	(74,143)	(57)
Income tax	24,889	_
Share of loss from associated companies	(27)	_
Loss for the year	(49,281)	(57)
Attributable to minority interests		
Group share of net loss	(49,281)	(57)

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## Condensed consolidated balance sheet as of 31 December 2015

€ thousands	31 December 2015	31 December 2014
Goodwill	210,844	
Other intangible assets	101,716	_
Property, plant and equipment	78,059	_
Non-current financial assets	19,835	_
Deferred tax assets	4,447	_
Non-current assets	414,901	-
Inventories	59,362	_
Trade receivables	29,669	_
Current financial assets	2	_
Other current assets	14,034	3
Income tax receivable	17, 608	_
Cash and cash equivalents	150,183	58
Current assets	270,858	61
Total assets	685,759	61
	31 December	31 December
€ thousands	2015	2014
Share capital	19,788	75
Share premium	539	—
Merger premium	343,904	_
Revaluation reserve	(1,158)	()
Retained earnings	176,908	(57)
Total shareholders' equity	539,981	18
Provision for employee retirement obligations and related benefits	5,333	_
Non-current provisions	758	-
Deferred tax liabilities	25,692	
Non-current liabilities	31,783	-
Trade payables	27,612	43
Current provisions	4,922	-
Current financial liabilities	17,669	-
Income tax payable	1,549	_
Other current liabilities	62,243	_
Current liabilities	113,995	43
Total equity and liabilities	685,759	61

# Unaudited pro forma consolidated income statement

In EUR m	2015	2014
Net sales*	272.9	312.5
Other revenue	0.2	0.2
Total revenues	273.1	312.7
Cost of goods sold	(90.2)	(82.8)
Gross margin	182.9	229.9
Selling, general and administrative expenses	(169.4)	(132.4)
(Loss)/profit before R&D	13.5	97.5
Research and development costs (R&D)	(52.4)	(50.8)
R&D-related income	19.5	20.1
Net R&D costs	(32.9)	(30.7)
Current operating (loss)/profit before transformation costs	(19.4)	66.8
Transformation costs	(12.4)	(4.6)
Operating (loss)/profit	(31.8)	62.2
Financial income	0.9	3.2
Financial expenses	(0.7)	(0.6)
Net financial income	0.2	2.6
(Loss)/profit before tax and associates	(31.6)	64.8
Income tax	22.9	(17.2)
Share of profit (loss) from associated companies	(0.1)	-
Net (loss)/profit for the year	(8.8)	47.6
Attributable to minority interests	0.0	0.0
Net (loss)/profit for the year	(8.8)	47.6

\* Net sales for 2015 reflect the impact of the temporary suspension and product recall including a provision against sales of €24m.