

#### Q1 2013 Financial Results and Business Update

May 7<sup>th</sup> 2013



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# Q1 Highlights and Business Update

Daniel Martinez, CFO



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#### **Q1** Results and Business update in summary

- Positive Phase III pivotal studies of Aclidinium + Formoterol combination
- Regulatory filings in the US (FDA) and EU (EMA) planned in Q4 2013
- Solid progress of Eklira<sup>®</sup> sales in EU and US
- Constella<sup>®</sup> launched in Germany, later this month in the UK
- Q1 Results on track to achieve yearly guidance
- Save the Date: Almirall's Investor Day in Barcelona (Sep 9<sup>th</sup> or 10<sup>th</sup>)



# **Q1 2013 Financial Results**

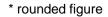
#### Daniel Martinez, CFO



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### **Q1 2013 Financial Highlights**

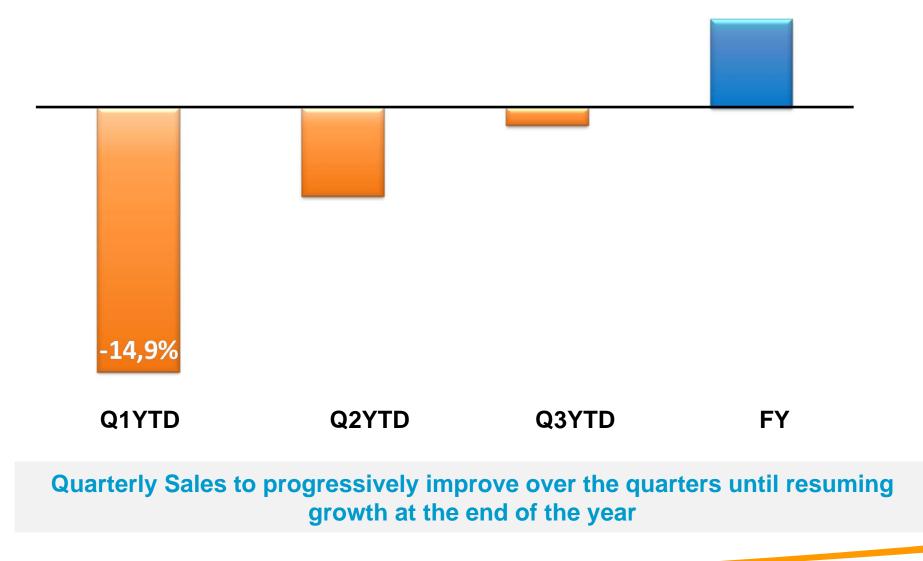
- Quarterly figures in line with expectations
- Sales performance to progressively improve over the quarters until resuming growth at the end of the year
- Strong improvement in Gross Margin (64,6% vs 61,9%) sustainable going forward driven by Eklira<sup>®</sup>
- 14% increase in SG&A spend in Q1 as guided to support new launches, lower increase expected at the end of the year (vs 2012)
- Cash position: €36MM
- Financial guidance reiterated
- Scrip dividend of €0,15\* per share approved by AGM





### **Quarterly improvement of Sales during 2013**

(proportions are only indicative)





#### **Income Statement**

€rounded million	YTD Mar 2013	YTD Mar 2012	% var
Total Revenues	198,3	220,9	(10,2%)
Net Sales	170,3	200,2	(14,9%)
Other Income	28,0	20,7	35,3%
Cost of Goods	(60,3)	(76,2)	(20,9%)
Gross Profit	110,0	124,0	(11,3%)
% of sales	64,6%	61,9%	
R&D	(28,3)	(38,0)	(25,5%)
% of sales	(16,6%)	(19,0%)	
SG&A	(104,9)	(91,8)	14,3%
% of sales	(61,6%)	(45,9%)	
Other Op. Exp	(1,3)	0,0	n.m.
% of sales	(0,8%)	0,0%	
EBIT	3,5	14,9	(76,5%)
% of sales	2,1%	7,4%	
Depreciation	16,6	16,4	1,2%
% of sales	9,7%	8,2%	
EBITDA	20,1	31,3	(35,8%)
% of sales	11,8%	15,6%	
Sale of noncurrent assets / Other	0,0	(0,4)	(100,0%)
Net financial income / (expenses)	(1,0)	(1,4)	(28,6%)
Profit before tax	2,5	13,1	(80,9%)
Corporate income tax	7,7	5,2	48,1%
Netincome	10,2	18,3	(44,3%)
Normalized Net Income	10,2	18,3	(44,3%)
Earnings per share (€)	0,06 €	0,11 €	
Normalized Earnings per share (€)	0,06 €	0,11 €	
Nu. of employees end of period	2.907	2.745	5,9%

#### ✓ Guidance reiterated

 Strong improvement in Gross Margin sustainable going forward driven by Eklira<sup>®</sup>

 Higher SG&A to support new launches in Q1



#### **Financial guidance 2013 reiterated**

	2013 (vs 2012)			
Net Sales	Return to growth			
Total Revenues*	Slight decline			
R&D	Return to more normal levels			
SG&A	Near term significant increase to suppor new product launches			
Corporate Tax	Negative Tax effective rate envisaged			
Normalized Net Income	Impact in 2013 due to investment in new products launches. Rapid growth thereafter.			

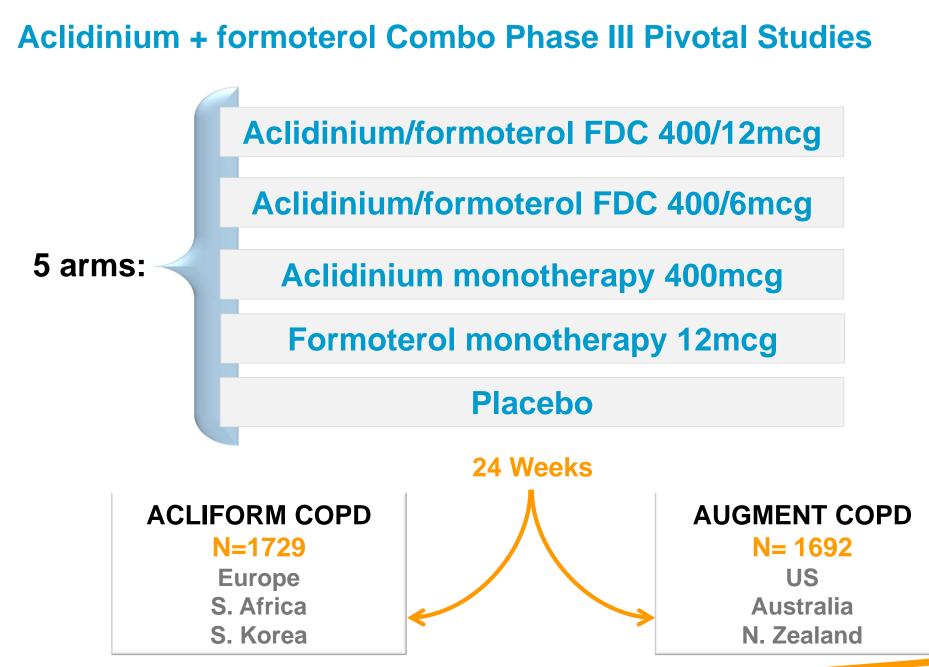


# **R&D** highlights

#### Bertil Lindmark, CSO



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FDC = Fixed Dose Combination



## **Co-primary endpoint data for 400/12mcg dose**

		1-h Post dose FEV <sub>1</sub>		Trough FEV <sub>1</sub>	
		vs. aclidinium 400mcg	vs. placebo	vs. formoterol 12mcg	vs. placebo
ACLIFORM	400/12mcg	125mL	299mL	85mL	143mL
COPD	P-values	<0.0001	<0.0001	<0.0001	<0.0001
AUGMENT	400/12mcg	108mL	284mL	45mL	130mL
COPD	P-values	<0.0001	<0.0001	0.01	<0.0001



#### **Combination rule has been achieved with 400/12mcg**

Two co-primary endpoints, designed to take in account the different contributions of the individual components in terms of efficacy, developed in consultation with FDA/EMA to meet the Combination Rule:

- The first co-primary endpoint consisted of the comparison between the fixed dose combinations of aclidinium/formoterol 400/12mcg and 400/6mcg versus aclidinium alone in change from baseline in FEV<sub>1</sub> at 1 hour post-dose at week 24.
- The second co-primary endpoint consisted of the comparison between the fixed dose combinations of aclidinium/formoterol 400/12mcg and 400/6mcg versus formoterol alone in change from baseline in morning predose trough FEV<sub>1</sub> at week 24.



## Symptom control is a critical component of COPD therapy

#### TDI (Transitional Dyspnea Index) – Breathlessness

- It measures dyspnea based on daily activities
- Three dimensions of dyspnea are assessed:
  - 1. Functional Impairment: impact of the breathlessness on daily activities
  - 2. Magnitude of Task: type of task that causes breathlessness
  - 3. Magnitude of Effort: level of effort needed to evoke breathlessness

#### SGRQ (Saint George's Respiratory Questionnaire) – Quality of life

- It evaluates the Health Status by measuring the impact on overall health, daily life and perceived well-being in respiratory diseases.
- It consist of 50 items (questions) divided in 3 dimensions (sections I, II and III):
  - I. Symptoms frequency and severity (cough, sputum production,...)
  - II. Activity (physical activities caused or limited by breathlessness)
  - III. Impact on quality of life (social and psychological disturbances)



#### **Competitive quality of life data points in TDI and SGRQ**

- Both studies included secondary endpoints, which analyzed to date were change from baseline vs placebo at 24 weeks in TDI and in SGRQ.
- Positive outcomes were seen with the two combinations achieving the MCID (Meaningful Clinical Important Difference) of a one point change (p<0.0001) in TDI in both studies, and a four point change (p<0.0001) in SGRQ in the AUGMENT/COPD study.</li>
- Additional analyses, including those on pooled data, will be presented at future scientific meetings.



#### **Combo Phase III topline results wrap-up**

- Positive and consistent spirometric results of 400/12mcg in both pivotal studies.
- Combination rule, as defined with the US/EU regulators, met with the 400/12mcg dose.
- Aclidinium + Formoterol combination is well tolerated.
- Strong supportive secondary endpoint data.
- Regulatory filings in the US (FDA) and EMA (EU) are planned in Q4 2013.

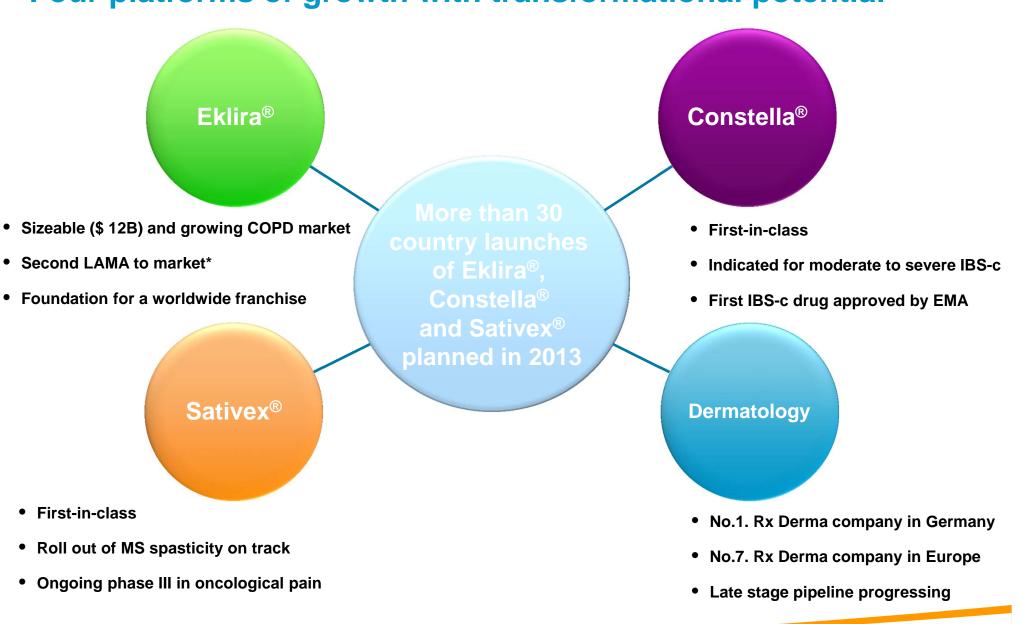


# **Growth platforms**

Senior Director Global Marketing & Medical Affairs



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🖲 Almirall

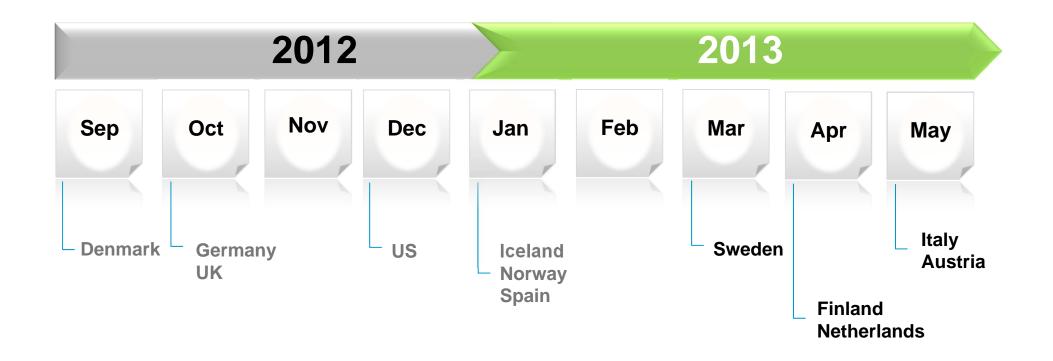
#### Four platforms of growth with transformational potential

\* In the US and some European countries

# Eklira<sup>®</sup> Genuair<sup>®</sup> / Bretaris<sup>®</sup> Genuair<sup>®</sup> & Tudorza<sup>™</sup> Pressair<sup>™</sup>

### Launches in 2012 and 2013 YTD







## **Aclidinium evolution in EU countries**

Includes Eklira® and Bretaris®

	Market share among LAMA <sup>1</sup>	% Share of Voice COPD drugs <sup>2</sup>
Germany	4,0%	26%
UK	<1%	17%
Spain	7,1%	28%

<sup>1</sup> In values

<sup>2</sup> Source: Cegedim-Reportive

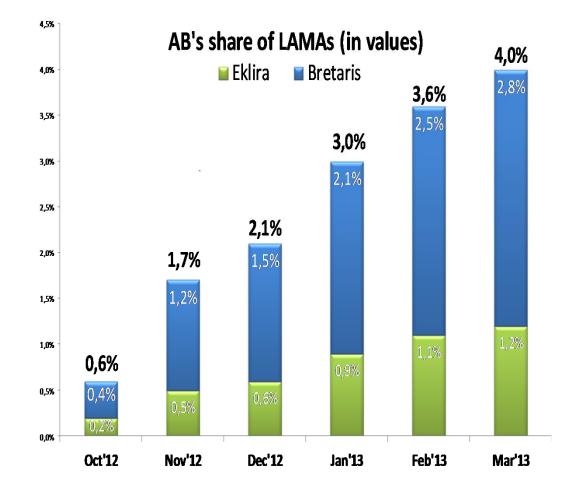
COPD Drugs Include: LAMA, ICS, LABA, LABA+ICS, SAMA, SABA+SAMA, PDE-4 inh



## Eklira<sup>®</sup> Genuair<sup>®</sup> / Bretaris<sup>®</sup> Genuair <sup>®</sup>

Sales evolution in Germany





- Eklira<sup>®</sup> promoted by Almirall and Quintiles
- Bretaris<sup>®</sup> promoted by Berlin Chemie (Menarini)
- Market research shows value proposition and Genuair<sup>®</sup> inhaler are well accepted, including twice-daily dosing regimen
- Other new LAMA had 6% share of LAMAs in March







- As expected, slower uptake than in other EU Top markets due to local formulary reviews plus the impact of the recent NHS reorganization from PCT to GP led CCG's
- So far, 47% of the targeted PCT have assessed Eklira<sup>®</sup> in their formularies, with a 83% of successful inclusion rate
- Formularies that include Eklira<sup>®</sup> account for over 40% of total LAMA targeted prescriptions
- Both Eklira<sup>®</sup> and other new LAMA have a similar market share among LAMAs (less than 1%)

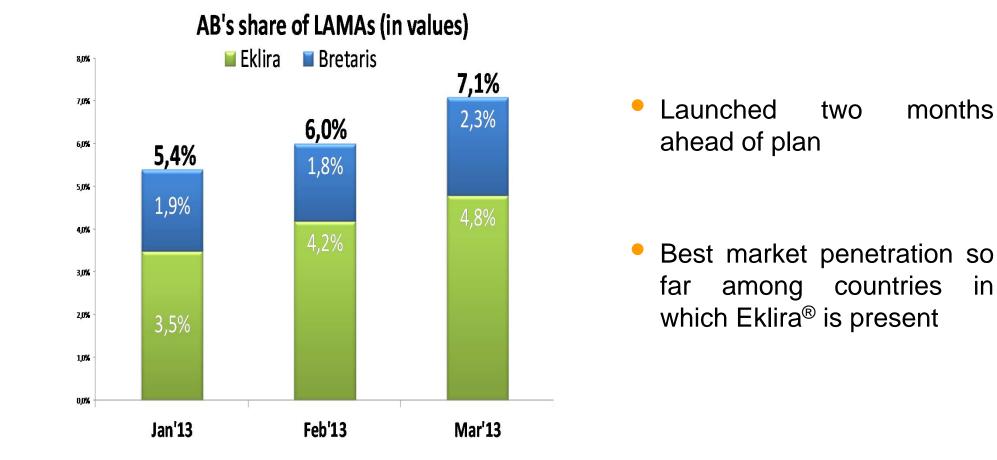
NHS = National Health Service | PCT = Primary Care Trust | CCG = Clinical Commissioning Groups



## Eklira<sup>®</sup> Genuair<sup>®</sup> / Bretaris<sup>®</sup> Genuair<sup>®</sup>

Sales evolution in Spain





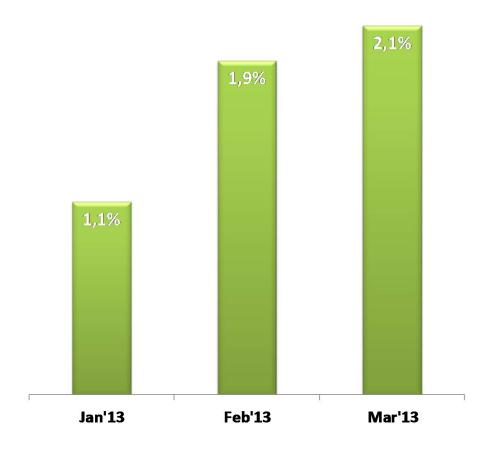


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#### **US: Tudorza<sup>™</sup> Pressair<sup>™</sup> evolution (I)**



#### AB's share of LAMAs (in values)



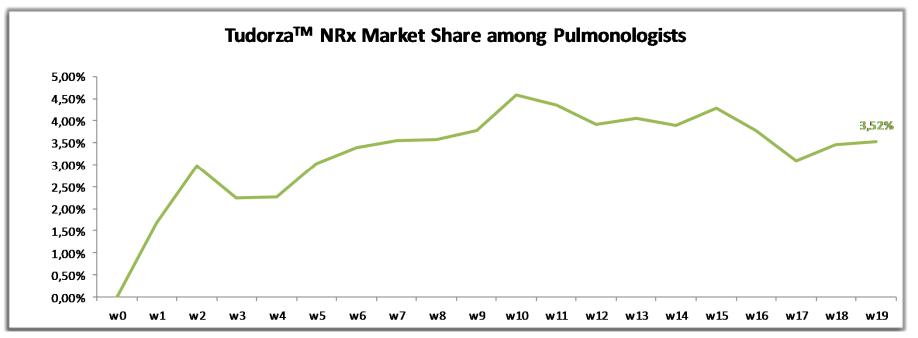
- Steady evolution of Tudorza<sup>™</sup> since its launch last Dec 15th
- More than 78,000 prescriptions
- 15,289 physicians have used Tudorza<sup>™</sup> so far (and 700 adding each week); by year end 50,000 expected
- 1,500 strong sales force has reached 75% of the 80,000 targeted physicians



Source: IMS Mar-13

#### **US: Tudorza<sup>™</sup> Pressair<sup>™</sup> evolution (II)**





- NRx market share is again climbing after the holiday period
- New to Brand Rx share, which measures the "dynamic market" and is a reliable predictor of future demand, is a healthy multiple of prescription market share
- Market research indicates Pressair<sup>™</sup> (Genuair<sup>®</sup>) inhaler and day-1 efficacy especially persuasive

Source: IMS Mar-13



#### Other key geographies for aclidinium



- Canada regulatory feedback expected in Q2
- Canada currently the 5th largest LAMA market worldwide
- Launch anticipated this year, copromotion between Almirall and Forest

- Positive results from bridging study with Eklira<sup>®</sup> carried out by Kyorin
- The Combination with formoterol is being developed in parallel with Eklira<sup>®</sup>
- Japan currently the 4th largest LAMA market worldwide

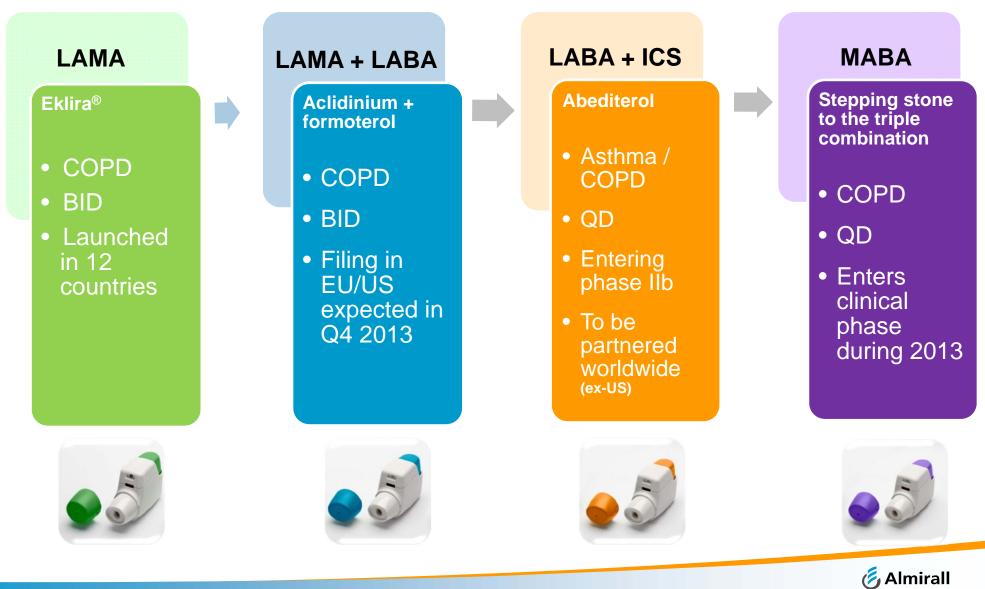


#### **Commercial execution wrap-up**

- Positive uptake of Eklira<sup>®</sup>, now launched in 12 countries up until May with further launches planned for 2013
- Our partners Forest and Menarini have given us the global commercial footprint to compete successfully
- Constella<sup>®</sup> now launched in Germany with UK and Nordics to follow later this month
- Sativex<sup>®</sup> launching Q3 in Italy
- Together with Eklira<sup>®</sup>, Constella<sup>®</sup> and Sativex<sup>®</sup> Almirall has more than 30 individual country launches planned for 2013 – these launches in Europe, Canada and Mexico will drive the transformation of our portfolio



## **Our respiratory franchise moving forward**





#### Daniel Martínez, CFO



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## **2013: Beginning the transformation**

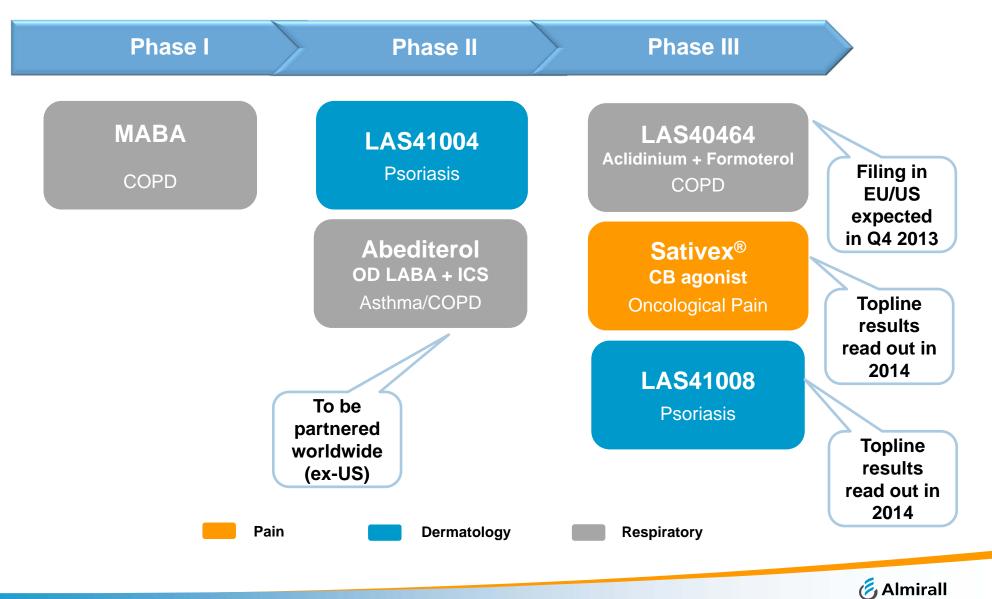
Executing on platforms of growth	<ul> <li>Positive Eklira<sup>®</sup> uptake</li> <li>Excellent market access in EU and US</li> <li>Roll out of Sativex<sup>®</sup>, Constella<sup>®</sup> and Derma</li> </ul>
Progressing our pipeline	<ul> <li>Positive combo pivotal trials</li> <li>Combo filing planned in 2013 in US and EU</li> <li>Abediterol and MABA to reinforce respiratory franchise</li> </ul>
Finance & Investors	<ul> <li>Guidance reiterated</li> <li>Solid cash position</li> <li>Almirall's Investor Day: Sep 9<sup>th</sup> or 10<sup>th</sup> in Barcelona</li> </ul>



# Appendixes

## A pipeline with significant upside

Preclinical projects not included



#### **Balance Sheet**

€rounded million	March 2013	% of BS	December 2012
Goodwill	270,1	20,3%	270,3
Intangible assets	354,2	26,6%	358,2
Property, plant and equipment	152,4	11,4%	157,0
Financial assets	12,6	0,9%	8,8
Other non current assets	260,1	19,5%	251,4
Total Non Current Assets	1.049,4	78,8%	1.045,7
Inventories	92,4	6,9%	92,4
Accounts receivable	101,0	7,6%	98,8
Cash & equivalents	35,9	2,7%	52,3
Other current assets	53,0	4,0%	66,9
Total Current Assets	282,3	21,2%	310,4
Total Assets	1.331,7		1.356,1
Shareholders equity	937,8	70,4%	923,7
Financial debt	0,0	0,0%	0,0
Non current liabilities	173,9	13,1%	183,0
Current liabilities	220,0	16,5%	249,4
Total Equity and Liabilities	1.331,7		1.356,1



#### **Cash Flow**

	YTD	YTD	
€rounded million	Mar 2013	Mar 2012	
Profit Before Tax	2,5	13,1	
Depreciation and amortisation	16,6	16,4	
Change in working capital	(34,6)	(29,5)	
Other adjustments	7,9	30,4	
Cash Flow from Operating Activities (I)	(7,6)	30,4	
Financial Income	0,1	1,3	
Investments	(7,9)	(4,6)	
Divestments	0,2	0,1	
Other cash flows	0,0	0,0	
Cash Flow from Investing Activities (II)	(7,6)	(3,2)	
Finance Expense	(1,2)	(2,4)	
Dividend distribution	0,0	0,0	
Debt increase/ (decrease)	0,0	(59,4)	
Other cash flows	0,0	0,5	
Cash Flow from Financing Activities	(1,2)	(61,3)	
Cash Flow generated during the period	(16,4)	(34,1)	
Free Cash Flow (III) = (I) + (II)	(15,2)	27,2	



#### **Zoom in – Other Income**

Includes: €5.4 MM of co-development revenues €11.4 MM linked to upfront and milest		klira®)	
€rounded million	YTD Mar 2013	YTD Mar 2012	% var
Co-development agreements	16,8	12,3	37,0%
Co-promotion agreements	3,9	3,6	9,6%
Product promotion collaboration	1,2	3,9	(67,8%)
Other	6,1	0,9	574,5%
Total Other Income	28,0	20,7	35,7%
Includes Actonel <sup>®</sup> , Cipralex <sup>®</sup> , Conbriza <sup>®</sup> , Libertek <sup>®</sup> and Xarelto <sup>®</sup>		4 MM of capitations and set of the set of th	



### Sales breakdown by Region and by main Therapeutic Area

	€rounded million	YTD Mar 2013	YTD Mar 2012	% var
	Spain	68,8	86,2	(20,3%)
By Region	Europe & Middle East	69,1	77,3	(10,6%)
	America, Africa & Asia Pacific	30,5	31,8	(4,2%)
	Corporate	2,0	4,8	(58,7%)
	Total	170,3	200,2	(14,9%)
	€rounded million	۲٦ Mar	D YTD 2013 Mar 201	% var
	Respiratory		55,3 55	1 <i>0,2%</i>
By Main	Gastrointestinal and Metabolism		32,8 37	7 (12,9%)
	Dermatology		32,8 32	
Therapeutic	CNS		23,1 28	1 7
Area	Cardiovascular		10,1 22	1 . ,
	Osteomuscular		9,8 12	1 7
	Urological Other therepoulting appendiction			3 (19,1%)
	Other therapeutic specialties Total		2,3 6 170,3 200	3 (64,1%) 2 (14,9%)



#### **Breakdown of the core business**

€rounded million		YTD Mar 2013	YTD Mar 2012	% Var
Ebastel <sup>®</sup> and others (ebastine)	•	21,0	26,8	(21,7%)
Eklira <sup>®</sup> and others (aclidinium bromide)		20,1	11,6	73,7%
Almogran <sup>®</sup> and others (almotriptan)	•	15,6	21,0	(26,0%)
Plusvent <sup>®</sup> (salmeterol & fluticasone)		12,2	14,8	(17,2%)
Tesavel <sup>®</sup> & Efficib <sup>®</sup> (sitagliptin)		11,1	10,7	4,0%
Solaraze® (diclofenac sodium) & Actikerall® (5-FU/SA)		7,4	7,1	3,7%
Airtal <sup>®</sup> and others (aceclofenac)		6,5	7,7	(15,2%)
Parapres <sup>®</sup> (candesartan cilexetile)		5,4	12,1	(55,2%)
Balneum <sup>®</sup> (urea oil)	•	5,0	5,1	(1,9%)
Decoderm <sup>®</sup> and others (flupredniden)		5,2	4,8	7,3%
Almax <sup>®</sup> (almagate)		4,1	4,4	(6,8%)
Pantopan <sup>®</sup> (pantoprazole)		3,7	4,2	(11,7%)
Cleboril <sup>®</sup> (clebopride)		3,2	2,9	9,3%
Elecor <sup>®</sup> (eplerenone)		2,7	4,0	(32,0%)
Opiren <sup>®</sup> (lansoprazole)	•	2,5	3,0	(16,6%)
Other		44,5	59,8	(25,7%)
Total Net Sales		170,3	200,2	(14,9%)

n.m.: no meaningful



#### **2013 Investor Calendar**

Event	Release date
Q2 / H1 2013 Financial results	29 <sup>th</sup> July
Investor Day	9 <sup>th</sup> or 10 <sup>th</sup> September
Q3 2013 Financial results	11 <sup>th</sup> November



For further information, please contact: Jordi Molina Investor Relations Ph. +34 93 291 3087 jordi.molina@almirall.com

Or visit our website: www.almirall.com



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