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Full-Year Report 2009

## UCB: Solid foundation for sustainable growth

- Multiple approvals and launches: Cimzia<sup>®</sup> for RA in the U.S. and EU, Vimpat<sup>®</sup> for epilepsy in the U.S. and in the EU, Neupro<sup>®</sup> for new patients in Parkinson's disease and RLS in the EU
- Total revenue decreased as expected by 13% to EUR 3.1 billion due to the full-year impact of generic competition to Keppra<sup>®</sup> in the U.S. and divestitures
- Strong underlying profitability (recurring EBITDA) of EUR 698 million (-5%) well in line with company guidance (more than EUR 680 million) and reflecting the significant impact of generic competition to Keppra<sup>®</sup> in the U.S., mostly compensated by lower operating expenses as a result of UCB's focus on its core activities
- Net profit after minorities increased to EUR 513 million in 2009 from EUR 42 million in 2008, reflecting higher non-recurring income stemming from capital gains and overcompensating non-recurring charges relating to the debt refinancing and organizational changes
- Increased gross dividend of EUR 0.96 per share recommended by Board of Directors
- Outlook 2010: total revenue expected to reach approximately EUR 3.0 billion; underlying profitability (recurring EBITDA) expected to end the year at approximately EUR 700 million; Core EPS (earnings per share) expected to reach approximately EUR 1.76

**Brussels (Belgium), 2 March 2009 – 7:00 AM (CET) - regulated information -** UCB announced today its consolidated full year 2009 financial results. 2009 was a year of execution and delivery. The company reached a turning point through new drug approvals and launches as well as the transformation of its organization. UCB achieved major development and regulatory milestones and reduced and refinanced the existing debt with a new financing structure reflecting an improved maturity profile. With all this, UCB created a strong basis for sustainable future growth.

"UCB is progressing to become a patient-centric global biopharmaceutical leader as we delivered three new medicines Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> in five indications to patients living with serious diseases of the central nervous system and immunology. Our financial results are on track and our debt is successfully re-financed. Another pillar of UCB's sustainable growth will be the realization of the full potential of our core products: Cimzia<sup>®</sup>, which we expect to reach peak sales of at least 1.5 billion Euro, Vimpat<sup>®</sup> with expected peak sales of at least 1.2 billion Euro and Neupro<sup>®</sup> with estimated peak sales of at least 400 million Euro," said Roch Doliveux, Chief Executive Officer, UCB. "With the



recent appointment of Ismail Kola as Executive Vice President, UCB & President of UCB NewMedicines™, we have underlined our commitment to a successful breakthrough phase bringing new medicines to the development pipeline and fostering further sustainable growth."

### **Financial performance for the full year 2009**

Absorbing the first full year impact of generic competition to Keppra® (*levetiracetam*) in the U.S., total revenue decreased by 13% to EUR 3 116 million. Net sales amounted to EUR 2 683 million or 11% lower than the period before partially compensated by the good performance of Keppra® in Europe and by the new product launches of Cimzia®, Vimpat® and Neupro®.

Cimzia® (*certolizumab pegol*), for Crohn's disease (CD) and, since late-May 2009 and October 2009, respectively approved in the U.S. and in Europe for patients suffering from moderately to severely active rheumatoid arthritis (RA), reached net sales of EUR 75 million after EUR 10 million in 2008. The new anti-epileptic drug, Vimpat® (*lacosamide*), available in Europe since September 2008 and launched in the U.S. in June 2009 as an add-on therapy for the treatment of partial-onset seizures, reached net sales of EUR 46 million. Neupro® (*rotigotine*) in Parkinson's disease (PD) and restless legs syndrome (RLS) showed net sales of EUR 61 million, (+5%) following the return to the European market<sup>1</sup> for all patients with PD in June 2009 and its simultaneous introduction as a treatment option for RLS in Europe.

The anti-epileptic drug Keppra® (including Keppra®XR) reached net sales of EUR 913 million which is 28% lower than last year, due to post-patent expiry erosion in North America (-58%), extending market leadership in Europe (+25%), and a decrease of 21% in the "Rest of World" driven by the divestiture to GSK. Zyrtec® (*cetirizine*), for allergy, increased net sales by 8% to EUR 268 million, reflecting a decrease of 16% in European sales due to a less severe pollen season compared to last year, an increase of 37% in Japan due to a severe pollen-season and the successful launch of paediatric indications and new formulations. Xyzal® (*levocetirizine*), for allergy, made net sales of EUR 132 million (-23%) outside the U.S. due to a less severe pollen season compared to last year in most European countries. Tussionex™ (*hydrocodone polistirex* and *chlorpheniramine polistirex*) reached net sales of EUR 147 million, at the same level as last year. Venlafaxine XR, a product to treat major depressive and social anxiety disorders, reached net sales of EUR 109 million in the U.S. UCB holds exclusive rights from Osmotica to market and sell venlafaxine XR in the U.S. Metadate™ CD (*methylphenidate HCl*), for attention deficit and hyperactivity disorder, made net sales of EUR 72 million, a decrease of 6%. This product is sold under the trademark Metadate™ CD in the U.S. (EUR 69 million) and was sold under the trademark Equasym™ XL in Europe and Rest of World (EUR 3 million in total (-78%) following its divestment to Shire in early 2009). Net sales for other products decreased 16% to EUR 726 million, with the main factors being U.S.

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<sup>1</sup> A deviation from the approved product specification leading to the recall of the product in the U.S. was announced in March of 2008 and, since June 2008, Neupro® supply in Europe was limited to patients already established on the drug. To address this issue, UCB has implemented a cold-chain storage and distribution system in Europe. Since the end of June 2009, Neupro® is again available to all patients in Europe with PD and also newly available in Europe as a treatment option for RLS.



products facing generic competition, the maturity of the portfolio and divestitures made early in the year.

Royalty income & fees amounted to EUR 227 million, down by EUR 169 million (-43%) compared to 2008 when a one-time intellectual property settlement increased this line by EUR 205 million. Excluding the settlement related income, royalty income & fees would have increased by 19% in 2009 supported by Toviaz® (*fesoterodine*) royalties (EUR 41 million) and by biotechnology intellectual property royalties. Other revenue for the full year of 2009 amounted to EUR 206 million, up by 15%. The increase in contract manufacturing sales to EUR 94 million (+125%) is mainly the result of the agreements with GSK and Shire announced early this year where UCB continues to manufacture the products divested. Profit-sharing with sanofi-aventis on Xyzal® in the US generated EUR 47 million (+19%).

Gross profit of EUR 2 091 million is 15% lower than 2008 following the decrease of net sales and increased royalty expenses and amortisation charges for the newly launched products.

Operating expenses reached EUR 1 638 million in 2009, 15% lower than last year, reflecting lower marketing & selling expenses (-16%) driven by the SHAPE programme with substantially lower expenses in non-core areas more than off-setting the higher marketing & selling investments behind the new products launches; lower research & development expenses (-12%) as late stage pipeline projects are approved and launched; and lower general & administrative expenses (-17%) also resulting from the SHAPE programme.

Recurring EBITDA is down by 5% to EUR 698 million reflecting the decline in revenue and gross profit, reflecting the significant impact of generic competition to Keppra® in the U.S., partially off-set by the reduction in operating expenses. In addition, recurring EBIT is down by 15% to EUR 453 million mainly due to the higher amortisation of intangible assets relating to the newly-launched products.

Non-recurring income and expenses amounted to income of EUR 384 million. This includes restructuring charges to EUR 73 million for the organisational changes in Belgium and the UK announced in November 2009 and the exit from the primary care sector in the U.S. announced in January 2010. The impairment amounted to EUR 126 million reflecting the already announced impairment charge from the closure of the development project CDP323 and the reduction in value of other tangible assets. This was overcompensated by gain on disposals amounting to EUR 594 million before tax mainly from the divestitures of commercial operations and product distribution rights to GSK, Shire and Eumedica, announced in February 2009.

Net financial expenses were EUR 162 million, an increase of EUR 6 million including significant one-time charges resulting from re-financing of debt. In late 2009, UCB used the opportunity of an improving capital market to re-finance its debt. This led to a more diversified lender base and an improved maturity profile.

Income tax expenses reached EUR 168 million. The average tax rate on recurring activities is 31%. Net profit after minority interests for the year reached EUR 513 million,



which is EUR 471 million above prior year, reflecting higher non-recurring income. Adjusting for the after-tax impact of non-recurring items and financial one-time items and for the after-tax contribution from discontinued operations, adjusted net profit reached EUR 226 million, which is 16% below the EUR 270 million in 2008.

### **Balance Sheet and Cash Flow**

As of 31 December 2009, UCB's total liabilities and shareholders equity were at EUR 9 120 million compared to EUR 9 524 million at year-end 2008. Total equity increased by 10% to EUR 4,417 million, representing 48% of the total balance sheet. The company's net debt position decreased by EUR 691 million to EUR 1,752 million compared with December 2008, mainly resulting from the inflow of cash from the divestitures earlier in 2009.

Cash flow from operating activities reached EUR 295 million (-19%), impacted by payments related to the SHAPE programme, inventory for new product launches and a reduction of trade receivables and payables. Cash flow from investing activities was EUR 473 million, due to divestitures made in 2009. Cash flow from financing activities was an outflow of EUR 736 million, driven by 2008 dividend payments (-EUR 167 million) and the repayment of debt.

### **Dividend**

The Board of Directors recommends a gross dividend of EUR 0.96 per share (net dividend of EUR 0.72 per share, +4%), reflecting UCB's dividend policy, consistent with the long term growth prospects of the Company, offering gradual increase in dividend, and as far as possible not to reduce it, irrespective of the short term income variations.

### **R&D update**

2009 saw a good number of development and regulatory milestones achieved, creating a strong basis for the future.

UCB announced first results from its Phase III studies of brivaracetam in epilepsy. One study met its primary efficacy endpoint while the second study did not. A third safety and tolerability study confirmed brivaracetam was well tolerated. Based on further analysis as well as discussions with the European and US Health authorities, patients and key opinion leaders, the decision has been made to conduct one additional Phase III trial.

There are no prescription medicines approved yet for fibromyalgia in Europe. Given the strong Phase III data with Xyrem<sup>®</sup> (sodium oxybate) now available, UCB feels motivated to move forward with this indication in Europe. Consequently, UCB is in discussions with the European authorities on this topic.

After completion of a detailed analysis of the full Phase IIb study data, the decision has been made to move forward with epratuzumab in systemic lupus erythematosus (SLE). A Phase III clinical trial programme is planned to start in 2010. Full Phase IIb data abstracts have been accepted for the World Lupus Congress in June 2010.

The initial clinical trial results of the study designed for EU involving patients taking certolizumab pegol for the induction of remission in patients with moderate to severe Crohn's disease (CD) were numerically superior at all time points, but the primary



endpoint for the overall population was not achieved. Given the European regulatory requirements, an approval for CD in Europe is not achievable with these results. However, UCB intends to move ahead in ulcerative colitis, a major unmet medical need in inflammatory bowel diseases (IBD).

In the area of central nervous system, a new compound was introduced to the Phase I program: UCB2892, a H3 antagonist with potential for cognitive disorders.

### **Outlook 2010**

In 2010, UCB expects to continue to bring its new products, Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> to patients while optimising its other business.

Total revenue is expected to reach approximately EUR 3.0 billion in 2010. This reflects full annualised generic erosion of Keppra<sup>®</sup> in the U.S and the loss of exclusivity for Keppra<sup>®</sup> in the E.U. in the second half of 2010, impacts by the divestitures made early 2009 and further erosion of mature products. These impacts should be partially offset by the growth of the newly launched products Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup>.

In 2010, UCB's recurring EBITDA is expected to reach approximately EUR 700 million.

Core EPS 2010 are expected to reach approximately EUR 1.76 versus EUR 1.74 in 2009 (based on EUR 180 million non-diluted shares). Core EPS (earnings per share) are calculated to reveal the inherent sustainable value of the net profit. For this calculation, per share net profit after minorities is adjusted for the after tax effects of non-recurring items (e.g. impairment and restructuring charges, extraordinary income, one-time financial or tax related expenses) and for the after tax impact of amortisation charges of intangible assets.



**FY 2009 – Financial highlights**

**A full financial report on the consolidated results is available on the UCB website:**

<http://www.ucb.com/investors/calendar/2009/2009-Full-Year-Financial-Results>

€ million	Actual		Variance	
	2009	2008	Actual rates	Cst rates
<b>Revenue</b>	<b>3 116</b>	<b>3 601</b>	<b>-13%</b>	<b>-14%</b>
Net sales	2 683	3 027	-11%	-12%
Royalty income & fees	227	396	-43%	-39%
Other revenue	206	178	15%	13%
<b>Gross profit</b>	<b>2 091</b>	<b>2 455</b>	<b>-15%</b>	<b>-16%</b>
Marketing & selling expenses	-781	-928	-16%	-18%
Research & Development expenses	-674	-767	-12%	-11%
General & administrative expenses	-189	-228	-17%	-15%
Other operating income/expenses(-)	6	-1	n.s.	n.s.
<b>Recurring EBIT (REBIT)</b>	<b>453</b>	<b>531</b>	<b>-15%</b>	<b>-15%</b>
Non recurring income/expenses(-)	384	-418	n.s.	n.s.
<b>EBIT (operating profit)</b>	<b>837</b>	<b>113</b>	<b>&gt;100%</b>	<b>&gt;100%</b>
Net financial expenses	-162	-156	4%	4%
<b>Profit before income taxes</b>	<b>675</b>	<b>-43</b>	<b>n.s.</b>	<b>n.s.</b>
Income tax expenses	-168	30	n.s.	n.s.
<b>Profit from continuing operations</b>	<b>507</b>	<b>-13</b>	<b>n.s.</b>	<b>n.s.</b>
Profit from discontinuing operations	7	55	-88%	-88%
<b>Net profit (after minority interests)</b>	<b>513</b>	<b>42</b>	<b>&gt;100%</b>	<b>&gt;100%</b>
Recurring EBITDA	<b>698</b>	<b>733</b>	<b>-5%</b>	<b>-6%</b>
Adjusted Net Profit (after minority interests)	<b>226</b>	<b>270</b>	<b>-16%</b>	<b>-18%</b>
Core Profit	<b>314</b>	<b>335</b>	<b>-6%</b>	<b>-7%</b>
Capital expenditures (incl. intangible assets)	87	179	-51%	
Net financial debt	1 752	2 443	-28%	
Cash flow from operating activities	295	366	-19%	
<b>Number of shares - non-diluted</b>	<b>180</b>	<b>180</b>		
<b>EPS (€ per non-diluted share)</b>	<b>2.85</b>	<b>0.24</b>		
<b>Core EPS (€ per non-diluted share)</b>	<b>1.74</b>	<b>1.86</b>		

The statutory auditor has issued an unqualified report dated 1 March 2010 on the company's consolidated accounts as of and for the year ended 31 December 2009, and has confirmed that the accounting data reported in the accompanying press release is consistent, in all material respects, with the accounts from which it has been derived.

**For further information**

Antje Witte, Investor Relations UCB  
T +32.2.559.9414, [antje.witte@ucb.com](mailto:antje.witte@ucb.com)

Richard Simpson, Investor Relations, UCB  
T+32.2.559.9494, [richard.simpson@ucb.com](mailto:richard.simpson@ucb.com)



Michael Tuck-Sherman, Investor Relations, UCB  
T +32.2.559.9712, [michael.tuck-sherman@ucb.com](mailto:michael.tuck-sherman@ucb.com)

Nancy Nackaerts, External Communications, UCB  
T +32.473.864.414 or +32.2.559.92.64, [nancy.nackaerts@ucb.com](mailto:nancy.nackaerts@ucb.com)

**Conference call details**

**08.00 (CET) - Press conference:**

Find the link to the conference call with presentation webcast on <http://www.ucb.com/media-room/events-presentations/2010/2009-full-year-results-press-conference> - Should you encounter any problems, call Genesys +32(0)24048800 and refer to meeting number **758749**.

**09.00 (EST) / 14.00 (GMT)/15.00 (CET) – Analyst meeting:**

Find the link to the conference call with presentation webcast on <http://www.ucb.com/investors/calendar/2009/2009-Full-Year-Financial-Results>

Dial-in details:

U.S. 1 866 546 4358

U.K. 0808 238 7377

Belgium 0800 75 772

Step 1: Dial the access number

Step 2: The operator will ask for your name

Step 3: The operator will direct you to the call

**About UCB**

UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 9 000 people in over 40 countries, UCB produced revenue of EUR 3.1 billion in 2009. UCB is listed on Euronext Brussels (symbol: UCB).

**Forward looking statement**

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.