Half-Year Report 2009

# UCB progress: new product launches and financials on track

- Multiple launches: Cimzia<sup>®</sup>/RA in the U.S., Vimpat<sup>®</sup>/epilepsy in the U.S. and in the EU, Neupro<sup>®</sup>/new patients Parkinson's disease and Neupro<sup>®</sup>/RLS in the EU
- Total revenue decreased as expected by 6% to EUR 1.6 billion: net sales declined by 10% to EUR 1.4 billion as a consequence of generic competition to Keppra<sup>®</sup> in the U.S., partially compensated by the strong performance of Keppra<sup>®</sup> in Europe and the new product launches of Vimpat<sup>®</sup> and Cimzia<sup>®</sup>. Royalty income increased by 35% to EUR 114 million supported by the launch of Toviaz<sup>®</sup>. Other revenue increased by 44% to EUR 103 million due to the good performance of Xyzal<sup>®</sup> in the U.S. and higher contract manufacturing sales
- Underlying profitability (recurring EBITDA) increased by 1% to EUR 363 million reflecting generic competition more than compensated by significantly lower operating expenses as a result of SHAPE
- Reported net profit after minorities almost quadrupled to EUR 516 million from EUR 108 million in 2008, of which EUR 455 million attributed to capital gains on divestitures
- Phase II trials for CDP7851 in fracture healing and postmenopausal osteoporosis (PMO) initiated
- Outlook 2009 confirmed: Full year total revenue expected to reach between EUR 3.1 - 3.3 billion; underlying profitability (recurring EBITDA) expected to end the year greater than EUR 680 million; net profit as reported increased to EUR 550 million

Brussels (Belgium), 31 July 2009 – 7:00 AM (CET) - press release, regulated information - UCB announced today its consolidated half year 2009 financial results. The first half year of 2009 is marked by progress with clinical development, operational and financial performance, and by a record number of product launches.

"Our Half-Year Report 2009 records significant progress for UCB. With multiple product launches underway showing already promise, we at UCB now have the future in our hands," said Roch Doliveux, Chief Executive Officer, UCB. "We are focusing on the successful commercialization of our major new products Cimzia®, Vimpat® and Neupro® in order to bring benefit to patients living with severe disease. At the same time, we are striving for improved efficiency and more partnerships to strengthen our performance and to continue transforming UCB into the next generation biopharma leader."



## Financial performance in the first half year 2009

New product launches partially compensated the impact of generic competition to Keppra<sup>®</sup> (*levetiracetam*) in the U.S. Total revenue decreased as expected by 6% to EUR 1 596 million.

Net sales amounted to EUR 1 379 million or 10% lower than the period before. The antiepileptic drug Keppra® reached net sales of EUR 465 million which is 22% lower than last year, due to post-patent expiry erosion in North America (-50%), extending market leadership in Europe (+26%), and an increase of 9% in the Rest of World. Zyrtec® (cetirizine), for allergy, increased net sales by 28% to EUR 169 million, reflecting the successful launch in Japan of the pediatric indications and new formulations as well as a severe pollen season. Xyzal® (*levocetirizine*), for allergy, made net sales of EUR 82 million (-21%) outside the U.S. due to a less severe pollen season in most European countries. With a mild cough and cold season in the U.S., Tussionex™ (*hydrocodone polistirex* and *chlorpheniramine polistirex*) reached net sales of EUR 67 million (-8%). Metadate™ CD (*methylphenidate HCI*), for attention deficit and hyperactivity disorder, reached net sales of EUR 42 million (+15%). This product is sold under the trademark Metadate™ CD in the U.S. (EUR 39 million) and was sold under the trademark Equasym™ XL in Europe and Rest of World (-59% following its sale to Shire in early 2009).

Cimzia® (certolizumab pegol), for Crohn's disease (CD) and, since late-May 2009, approved in the U.S. for patients suffering from moderately to severely active rheumatoid arthritis (RA), reached net sales of EUR 24 million. The new anti-epileptic drug, Vimpat® (lacosamide), available in Europe since late 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 23 million. The Parkinson's patch Neupro® (rotigotine) showed net sales of EUR 27 million (-25%) as a result of a deviation from the product specification leading to the U.S. recall announced in March of 2008 and, since June 2008, Neupro® supply in Europe being limited to patients already established on the drug. To address this issue, UCB has implemented a cold-chain storage and distribution system in Europe with all stocks of Neupro® replaced with product that is refrigerated from manufacturer to patient. Since the end of June 2009, Neupro® is again available to all patients in Europe with idiopathic Parkinson's disease and also newly available in Europe as a treatment option for the symptomatic treatment of adult patients with idiopathic moderate to severe restless legs syndrome (RLS).

Royalty income & fees amounted to EUR 114 million, up by 35% as a result of Toviaz® (fesoterodine) royalties and of biotechnology intellectual property. Other revenue for the first half of 2009 amounted to EUR 103 million, up by 44%. Profit-sharing with sanofiaventis from the US\$92 million Xyzal® sales in the U.S. generated EUR 24 million (+28%), contract manufacturing sales increased by 120% to EUR 44 million as a result of the agreements with GSK (divestiture of commercial operations and product distribution rights for selected smaller markets) and Shire (divestiture of Equasym®) announced early this year and were supported by milestone payments received.



Gross profit of EUR 1 087 million is 10% lower than 2008 with cost of sales increasing by 7% to EUR 509 million driven by higher royalty expenses, product mix changes and amortisation of intangible assets relating to newly-launched products.

Operating expenses reached EUR 841 million in 2009, 11% lower than last year, reflecting lower marketing & selling expenses (-7%) driven by the SHAPE programme with substantial lower expenses in non-core more than off-setting the significant higher marketing & selling investments in core business areas; lower research & development expenses (-13%), due to pipeline progress producing approvals and launches of new products like Vimpat<sup>®</sup> and Cimzia<sup>®</sup>, and lower general & administrative expenses (-17%) resulting from the SHAPE programme.

As a result, recurring EBITDA is up by 1% to EUR 363 million reflecting the decrease in revenue and gross profit off-set by a corresponding reduction in operating expenses. Recurring EBIT is down 7% to EUR 246 million impacted by higher amortisation of intangible assets related to newly-launched products.

Restructuring & non-recurring income amounted to EUR 461 million. The non-recurring items include SHAPE programme restructuring charges of EUR 5 million, impairment on intangible assets of EUR 95 million reflecting the already announced impairment on the development project CDP323, and gains on divestitures of commercial operations and product distribution rights (to GSK, Shire and Eumedica, announced in February this year).

Net financial expenses were EUR 55 million a decrease of EUR 14 million due to lower interest rates and some foreign exchange gains. Income tax expenses reached EUR 137 million. The average tax rate on recurring activities is 29%. Net profit for the year reached EUR 516 million, i.e. EUR 408 million above prior year, reflecting the higher non-recurring income. Adjusting for the after-tax impact of non-recurring items and financial one-offs and for the after-tax contribution from discontinued operations, adjusted net profit reached EUR 135 million, which is 6% below the EUR 143 million of adjusted net profit in 2008.

# **Balance Sheet and Cash Flow**

As of 30 June 2009, UCB's total liabilities and shareholders equity was almost stable with EUR 9 439 million compared to EUR 9 524 million at year-end 2008. Total equity increased by 9% to EUR 4 396 million, representing 47% of the total balance sheet. The company's net debt position as of 30 June 2009 decreased by 11% to EUR 2 166 million compared to December 2008. This results from the inflow of cash from the divestitures closed earlier this year.

Cash flow from operating activities amounted to an outflow of EUR 45 million, impacted by changes in working capital, compared to an inflow of EUR 185 million in the first half 2008. Cash flow from investing activities was EUR 477 million, due to divestitures closed earlier this year. Cash flow from financing activities was an outflow of EUR 356 million, driven by dividend payments (-EUR 163 million) and the net change of borrowings (-EUR 192 million).



#### **Outlook 2009 confirmed**

Full year total revenue is expected to reach between EUR 3.1 - 3.3 billion. The underlying profitability (recurring EBITDA) is expected to end the year greater than EUR 680 million and net profit as reported increased to EUR 550 million.

# R&D update

UCB's collaboration with Amgen to develop CDP7851 ("sclerostin antibody" also known as AMG 785), a novel anabolic therapy for bone loss disorders, is progressing. Following encouraging first-in-human data, in June UCB and Amgen initiated a Phase II study in postmenopausal osteoporosis (PMO) investigating the effect of the drug compared to placebo in the treatment of approximately 400 postmenopausal women with low bone mineral density. UCB and Amgen are also initiating a phase II study to investigate the effect of the drug compared to placebo in fracture healing. Phase II is expected to complete in 2012.

Thanks to regulatory authority approvals, UCB is able to launch new products in the U.S. and the EU:

Cimzia® for adult patients suffering from moderate to severe rheumatoid arthritis (RA) was approved by the U.S. FDA in May. Cimzia® was immediately made available for patients in an exclusively designed, patient-friendly prefilled syringe resulting from the UCB partnership with OXO®. In June, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) issued a positive opinion on the use of Cimzia® in moderate to severe active rheumatoid arthritis in adults. Confirmation by the European Commission is expected in the next couple of months.

Vimpat<sup>®</sup> was launched in the U.S. for the add-on treatment of epilepsy in adults in the first week of June. This new antiepileptic drug with a novel mechanism of action helps address a critical unmet medical need for the many people living with uncontrolled epilepsy.

Since the end of June, Neupro® in Europe has been available to all patients with Parkinson's disease and is also being introduced for the treatment of moderate to severe restless legs syndrome (RLS). At the end of July, UCB submitted extensive information on Neupro® and the cold-chain distribution system to the FDA. UCB is in dialogue with the FDA and is hoping to make Neupro® available to U.S patients during 2010, subject to FDA approval of the cold-chain.

Toviaz<sup>®</sup> (*fesoterodine fumarate*) was launched by Pfizer in the U.S. in the first week of April for the treatment of overactive bladder. Toviaz<sup>®</sup> was launched in Europe by Pfizer mid-2008. UCB is entitled to receive royalties on the combined sales of Toviaz<sup>®</sup> and Pfizer's tolterodine product franchise.



## HY 2009 - Financial highlights

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

## http://www.ucb.com/investors/2009-Half-Year-Financial-Results

For the six months ended 30 June <sup>1</sup> € million	Actual		Variance	
	2009	2008	Actual rates	Cst rates
Revenue	1 596	1 691	-6%	-9%
Net sales	1 379	1 535	-10%	-14%
Royalty income & fees	114	84	35%	38%
Other revenue	103	72	44%	37%
Gross profit	1 087	1 214	-10%	-16%
Marketing & selling expenses	( 421)	( 455)	-7%	-14%
Research & Development expenses	(323)	(370)	-13%	-14%
General & administrative expenses	(99)	(119)	-17%	-18%
Other operating income/(expenses)	2	( 6)		
Recurring EBIT (REBIT)	246	263	-7%	-18%
Non recurring income/(expenses)	461	(39)		
EBIT (operating profit)	707	224	215%	189%
Net financial expenses	(55)	( 69)		
Profit before income taxes	652	155	321%	283%
Income tax expenses	(137)	(48)		
Profit from continuing operations	515	107	381%	339%
Profit from discontinuing operations	1	1		
Net profit (after minority interests)	516	108	376%	335%
Recurring EBITDA	363	358	1%	-8%
Adjusted net profit <sup>2</sup>	135	143	-6%	-21%
Capital expenditures (including intangible assets)	34	73		
Net financial debt	2 166	2 443		
Cash flow from operating activities	( 45)	185		
Number of shares - non-diluted	180	180		
EPS (€ per non-diluted share)	2.86	0.59		
Adjusted EPS (€ per non-diluted share)	0.75	0.79		

<sup>&</sup>lt;sup>1</sup> Except for the net financial debt, where 2008 relates to the situation as published in the audited consolidated financial statements as at 31 December 2008.

The statutory auditor has issued an unqualified review report dated 30 July 2009 on the company's condensed consolidated interim financial statements as of and for the six month period ended 30 June 2009, and has confirmed that the accounting data reported in the press release is consistent, in all material respects, with the accounts from which it has been derived

# For further information

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#### About UCB

UCB, Brussels, Belgium (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 10 000 people in over 40 countries, UCB produced revenue of EUR 3.6 billion in 2008. 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

Adjusted for after- tax impact of one-off items and after-tax contribution from discontinued operations.



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.

Upon the publication of the 2009 half-year financial results, UCB will organise a press conference at 10.00 CEST and an analysts' and investors' conference call/webcast at 15.00 CEST.

#### 10.00 CEST - Press conference

The press conference will take place at 10.00 CEST and is supported by a conference call (+/- 45')

#### Dial-in details

To enter the call, you will need to dial one of the following numbers:

Belgium +32 (0)2 290 14 07
France +33 (0)1 7099 3208
Germany +49 (0)695 8999 0507
U.K. +44 (0)20 7162 0077

You will be connected to an operator who will transfer you to the UCB conference call. The conference ID number is **839417**. No password is required. To allow for registration, please dial-in at least 5-10 minutes before the conference is due to start. The presentation is available for download here

Should you have questions regarding this event, please contact:

Cindy Maas, External Communications Specialist - +32 2 559 9274 - cindy.maas@ucb.com

# 15.00 CEST - Analysts' and investors' conference call/webcast

The conference call will take place at 15.00 CEST and will last approximately one hour.

#### Dial-in details

To enter the call, you will need to dial one of the following numbers:

Belgium +32 (0)2 290 14 07
France +33 (0)1 7099 3208
Germany +49 (0)695 8999 0507
U.K. +44 (0)20 7162 0077
U.S. +1 334 323 6201

You will be connected to an operator who will transfer you to the UCB conference call. The conference ID number is **839435**. No password is required. To allow for registration, please dial-in at least 5-10 minutes before the conference is due to start

# Webcast details

To access the webcast, click here.

A replay of the conference call will be available a few hours after the call has ended.

Should you have questions regarding this event, please contact:

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