UCB News

UCB Half-Year Report 2023, Brussels (Belgium), 27 July 2023 – 7:00 (CEST) – regulated information

UCB now at the inflection point – ready to start a new phase of growth

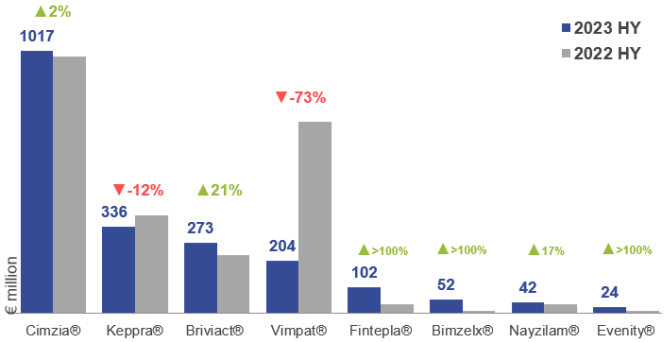
- Revenue reached € 2.6 billion (-11%; -13% CER[1]), net sales were € 2.4 billion (-12%; -14% CER[1])
- Underlying profitability (adj. EBITDA[2]) was € 801 million (-2%; -9% CER[1]), 31% of revenue
- CIMZIA® continued growth, VIMPAT® generic erosion as anticipated, FINTEPLA®, EVENITY® and BIMZELX® with strong launches; Zogenix becoming earnings accretive
- 4 approvals and launches: FINTEPLA® in Lennox-Gastaut syndrome (LGS) in the EU, BIMZELX® in psoriatic arthritis (PsA) and across the full spectrum of axial spondyloarthritis (axSpA) in the EU, RYSTIGGO® in generalized myasthenia gravis (gMG) in the U.S.; 10 regulatory filings under review in the U.S., the EU and Japan
- Financial guidance for 2023 confirmed: Revenue expected to reach € 5.15 - 5.35 billion, adjusted EBITDA[2] 22.5 - 23.5% of revenue, Core EPS[3] of € 3.40 - 3.80

"We had a robust first half 2023, delivered good product growth and strong launches while absorbing the impacts from the anticipated loss of exclusivity for E KEPPRA® and VIMPAT®. These impacts are receding, and we have now reached the inflection point with overall company growth going forward," **Jean-Christophe Tellier, CEO UCB commented**. *"We are pleased to serve more than 10 000 people living with psoriasis around the globe where BIMZELX® is available for patients. BIMZELX® now captures greater than one third of new prescriptions of IL17 products for psoriasis. We are working with the U.S. agency FDA and are expecting action for bimekizumab in Q3 2023. We are looking forward to bringing our newly U.S. approved RYSTIGGO® to people living with generalized myasthenia gravis. We like to thank our employees and partners for their great efforts and together, we are working towards our strong long-term growth and our ambition to create value for all stakeholders, now and into the future."*

UCB's HY 2023 financial results

€ million	2023 HY	2022 HY	Act	CER[1]
Revenue	2 589	2 925	-11%	-13%
Net sales	2 378	2 705	-12%	-14%
Adj. EBITDA[2]	801	814	-2%	-9%
Number of shares (m)	189	190	0%	
Core EPS[3] (€)	2.63	3.15	-16%	-27%

Top product net sales



[1] CER = constant exchange rates
[2] adj. EBITDA = adjusted Earnings Before Interest, Taxes, Depreciation and Amortization charges
[3] Core EPS = core earnings per share

Inspired by patients.
Driven by science.

HY 2023 revenue reached € 2.6 billion (-11%; -13% CER[1]). **Net sales** reached € 2.4 billion (-12%; -14% CER[1]). This reflects the anticipated generic erosion of VIMPAT® in the U.S. and the EU and of E KEPPRA® in Japan. The growth of the UCB product portfolio was driven by CIMZIA®, BRIVIACT®, BIMZELX®, FINTEPLA® and EVENITY®.

Underlying profitability (adjusted EBITDA[2]) reached € 801 million (-2%; -9% CER[1]), reflecting lower revenue and lower operating expenses. These were driven by higher marketing and selling expenses, lower research and development expenses, lower general and administrative expenses and significantly higher other operating income – also supported by a one-time income from a product sale. The adjusted EBITDA ratio for the first six months of 2023 (in % of revenue) reached 31%, compared to the first six months 2022 with 28%.

Profit amounted to € 311 million (-22%; -33% CER[1]). **Core EPS[3]** were € 2.63 after € 3.15 in the first six months 2022.

Sandrine Dufour, CFO UCB says: *"We are pleased to deliver healthy financial results for the first six months 2023 and to confirm our financial guidance for 2023. We see the inflection point in the net sales performance, leaving the loss of exclusivity impacts behind us and bringing company growth. We successfully integrated Zogenix which is becoming earnings accretive as expected. The second half of the year is planned to be marked by significant investments behind the ongoing and upcoming launches."*

Regulatory and Clinical Pipeline Update

UCB continuously innovates and strives to find new ways to deliver solutions to people living with severe immunological and neurological diseases, with an unprecedented regulatory and clinical pipeline, set to help people live their best possible lives.

UCB is expecting action from the U.S. agency for bimekizumab in Q3 2023.

In June, the European Commission granted marketing authorization for **BIMZELX® (bimekizumab)** for the treatment of adult patients with active psoriatic arthritis (PsA) and adult patients with active axial spondyloarthritis (axSpA).

In July, the European Medicines Agency (EMA) has accepted for review the marketing authorization application of **bimekizumab** for the treatment of adults with moderate to severe hidradenitis suppurativa (HS).

In June, fenfluramine was filed with the Japanese regulatory authority for the treatment of patients with Lennox-Gastaut syndrome (LGS) and orphan drug designation was granted in May 2023.

In February, the regulatory agency in Japan accepted the filing for review of **rozanolixizumab** for the treatment of adults with generalized myasthenia gravis (gMG).

In June, FDA granted marketing authorization for **RYSTIGGO® (rozanolixizumab-noli**) for the treatment of gMG. Rozanolixizumab is a subcutaneous (SC) monoclonal antibody targeting the neonatal Fc receptor (FcRn) for the treatment of adults with gMG who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

In June, **E Keppra® (levetiracetam)** was approved in Japan for the treatment of partial-onset epileptic seizures in young patients (1m-4years of age)

All other clinical development programs are continuing as planned.

Net sales break-down by product

Due to rounding, some financial data may not add up in the tables.

€ million	2023 HY	2022 HY	Act	CER[1]
U.S.	655	644	2%	1%
Europe	210	209	0%	1%
Japan	15	23	-36%	-31%
International markets	137	118	16%	19%
Total Cimzia®	1 017	994	2%	2%

CIMZIA® (certolizumab pegol) serving people living with inflammatory TNF-mediated diseases is showing a stronger volume growth than the anti-TNF market – based on differentiation and driven by continued growth in the U.S. and strong growth in international markets. In Japan, order pattens by partner Astellas led to lower net sales in the first half of 2023. The underlying prescription trend, however, is positive.

€ million	2023 HY	2022 HY	Act	CER[1]
U.S.	75	71	6%	5%
Europe	101	105	-4%	-4%
Japan	51	86	-41%	-36%
International markets	109	118	-8%	-2%
Total Keppra®	336	380	-12%	-9%

KEPPRA® (levetiracetam) for people living with epilepsy reported lower net sales. The generic erosion in Japan started early January 2022 and was stronger than expected due to multiple generics and governmental support for generic levetiracetam. The erosion continued during the first six months of 2023, however, at a slower pace than expected. The loss of exclusivity in the U.S. and Europe occurred more than 10 years ago.

€ million	2023 HY	2022 HY	Act	CER[1]
U.S.	211	174	21%	20%
Europe	53	43	23%	23%
International markets	10	8	17%	19%
Total Briviact®	273	225	21%	20%

BRIVIACT® (brivaracetam) is available for people living with epilepsy and showed significant growth in all regions. Briviact® has a different mode of action from Vimpat® and differentiates from Keppra®. UCB expects peak sales of € 600 million by 2026.

€ million	2023 HY	2022 HY	Act	CER[1]
U.S.	53	520	-90%	-90%
Europe	73	155	-53%	-53%
Japan	40	32	27%	38%
International markets	38	36	5%	9%
Total Vimpat®	204	744	-73%	-72%

VIMPAT® (lacosamide) is available for people living with epilepsy. The expected generic erosion in the U.S. and the EU started in March and September 2022, respectively, negatively impacted the overall net sales. The other regions showed good, continued growth.

€ million	2023 HY	2022 HY	Act	CER[1]
U.S.	92	33	>100%	>100%
Europe	8	3	>100%	>100%
International markets	2	-	n/a	n/a
Total Fintepla®	102	35	>100%	>100%

FINTEPLA® (fenfluramine) was acquired via Zogenix in March 2022 and is approved for seizures associated with rare epileptic syndromes, Dravet syndrome and Lennox-Gastaut syndrome, providing new treatment options for patients and families living with these rare syndromes that are particularly challenging to treat.

BIMZELX® (bimekizumab) for people living with psoriasis is being launched throughout Europe, the UK, Japan, Canada and further countries. Total net sales were € 52 million (after € 10 million), thereof € 43 million in Europe (after € 9 million). UCB is serving more than 10 000 people living with psoriasis around the globe, where BIMZELX® is available for patients and it now captures more than one third of new prescriptions of IL17 products for psoriasis. For the U.S., the regulatory review is ongoing with an expected action by the U.S. authority in Q3 2023.

EVENITY® (romosozumab) for women living with severe postmenopausal osteoporosis at high risk of fracture saw its net sales in Europe increased to € 24 million after € 9 million. EVENITY® is being launched successfully globally by Amgen, Astellas and UCB since 2019, with net sales outside Europe reported by the partners.

NAYZILAM® (midazolam) Nasal Spray[CIV], a nasal rescue treatment for epilepsy seizure clusters reached net sales of € 42 million in the U.S., an increase of 17% (+16% CER).

2023 HY financial highlights

Due to rounding, some financial data may not add up in the tables.

For the six months ended 30 June	Actual		Variance	
€ million	2023	2022	Actual rates	CER
Revenue	**2 589**	**2 925**	**-11%**	**-13%**
Net sales	2 378	2 705	-12%	-14%
Royalty income and fees	42	45	-7%	-8%
Other revenue	169	175	-3%	-3%
Adjusted Gross Profit	**2 004**	**2 250**	**-11%**	**-13%**
Gross Profit	**1 787**	**2 080**	**-14%**	**-16%**
Marketing and selling expenses	- 753	- 730	3%	4%
Research and development expenses	- 759	- 798	-5%	-4%
General and administrative expenses	- 104	- 115	-9%	-9%
Other operating income/expenses (-)	315	114	>100%	>100%
Adjusted EBIT	**486**	**551**	**-12%**	**-21%**
Impairment, restructuring and other income/expenses (-)	- 6	- 61	-91%	-91%
EBIT (operating profit)	**480**	**490**	**-2%**	**-13%**
Net financial expenses (-)	- 79	- 9	>100%	>100%
Profit before income taxes	**401**	**481**	**-17%**	**-27%**
Income tax expenses (-)	- 90	- 82	10%	8%
Profit from continuing operations	**311**	**399**	**-22%**	**-33%**
Profit/loss (-) from discontinued operations	0	0	N/A	N/A
Profit	**311**	**399**	**-22%**	**-33%**
Attributable to UCB shareholders	311	399	-22%	-33%
Adjusted EBITDA	**801**	**814**	**-2%**	**-9%**
Capital expenditure (including intangible assets)	158	174	-9%	N/A
Net debt (-)[2]	-2 439	-2 000	22%	N/A
Operating cash flow from continuing operations	249	393	-37%	N/A
Weighted average number of shares – non diluted (million)	**189**	**190**	**0%**	**N/A**
EPS (€ per weighted average number of shares – non diluted)	**1.64**	**2.10**	**-22%**	**-23%**
Core EPS (€ per weighted average number of shares – non diluted)	**2.63**	**3.15**	**-16%**	**-27%**

[1] Due to rounding, some financial data may not add up in the tables included in this management report
[2] For the net financial debt, the reporting date for comparative period is 31 December 2022

"The statutory auditor has issued an unqualified report with no emphasis of matter paragraph dated 26 July 2023 on the company's consolidated accounts as of and for the first half of the year ended 30 June 2023 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."

Revenue in the first six months of 2023 reached € 2 589 million (-11%; -13% CER[1]) and **net sales** were € 2 378 million (-12%; -14% CER[1]). Net sales reflect the generic erosion of VIMPAT® in the U.S. and Europe and of E KEPPRA® in Japan – compensated by positive CIMZIA® growth and strong launches of FINTEPLA®, EVENITY® and BIMZELX®.

Royalty income and fees were € 42 million (-7%; -8% CER[1]) and other revenue was € 169 million (-3%; -3% CER[1]) due to milestones – including a one-time amount of € 70 million for VIMPAT® partnership activities in Japan – and other payments from R&D partners.

Adjusted gross profit before "amortization of intangible assets linked to sales" was € 2 004 million (-11%; -13% CER[1]) and in-line with the net sales performance. The adjusted gross margin is stable at 77%.
Gross profit after "amortization of intangible assets linked to sales" reached € 1 787 million – a gross margin of 69% after 71% in June 2022 and reflecting the addition of FINTEPLA® amortization.

Operating expenses decreased to € 1 302 million (-15%; -14 CER[1]) reflecting lower expenses and higher other operating income. Operating expenses are consisting of:

- higher marketing and selling expenses of € 753 million (+3%; +4% CER[1]) – reflecting investments behind the launches and pre-launch activities: Global FINTEPLA® launch activities, global BIMZELX® launch activities as well as preparation for the U.S., and global launch preparations for RYSTIGGO® (rozanolixizumab) and zilucoplan in generalized myasthenia gravis.
- lower research and development expenses of € 759 million (-5%; -4% CER[1]) reflecting the continued investments in UCB's progressing late-stage pipeline encompassing five phase 3 projects and four phase 2 projects as well as two projects in phase 1b as well as ongoing earlier stage research activities. The R&D ratio reached 29% after 27% due to the lower topline.
- lower general and administrative expenses of € 104 million (-9%; -9% CER[1]), thanks to improved value-focused allocation of resources and ceasing integration costs for Zogenix as planned.
- higher other operating income of € 315 million following € 114 million in the first six months of 2022 – driven by the net contribution from Amgen in connection with the commercialization of EVENITY® of € 156 million after € 108 million and by other operating income from the sale of a portfolio of established brands in Europe (€ 145 million).

Underlying operational profitability – adjusted EBITDA[2] **–** reached € 801 million (-2%; -9% CER[1]) driven by lower revenue and lower operating expenses. The adjusted EBITDA ratio (in % of revenue) reached 31%, after 28% in June 2022.

Total impairment, restructuring and other expenses decreased to € 6 million, after € 61 million. Last year this was mainly driven by fees and restructuring expenses related to the acquisition of Zogenix.

Net financial expenses went up to € 79 million from € 9 million, stemming from higher net debt after the acquisition of Zogenix in March 2022, higher interest rates and a positive currency impact in 2022, not reoccurring in 2023.

Income tax expenses were € 90 million (+10%; +8% CER[1]). The average effective tax rate was 22% compared to 17% in June 2022. The increase in tax rate is explained by two items: an expected drop in profit before tax compared to 2022 where the tax charge remains stable and a one-off reversal of a deferred tax liability in 2022 which does not occur in 2023.

Profit decreased to € 311 million (-22%; -33% CER[1]) driven by lower revenue, lower operating expenses and lower other expenses, higher financial expenses, and higher taxes. The full amount is attributable to UCB shareholders.

Core earnings per share, which reflect profit attributable to UCB shareholders, adjusted for the after-tax impact of to be adjusted items, the financial one-offs, the after-tax contribution from discontinued operations and the net amortization of intangibles linked to sales, reached € 2.63 after € 3.15 in June 2022, based on 189 million weighted average shares outstanding.

Financial guidance for 2023 confirmed: Revenue is expected to reach € 5.15 - 5.35 billion, adjusted EBITDA[2] 22.5 - 23.5% of revenue and core EPS[3] of € 3.40 - 3.80. The financial guidance for 2025 is unchanged.

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Today, UCB will host a conference call/video webcast at 08:00 (EDT) / 13:00 (BST) / 14:00 (CEST)

Register here: https://www.ucb.com/investors

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About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 8 700 people in approximately 40 countries, the company generated revenue of € 5.5 billion in 2022. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements
This press release contains forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: the global spread and impact of pandemics (such as COVID-19), wars on territories where UCB has businesses, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or

disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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