Inspired by patients.
Driven by science.

Key modelling data for UCB half-year results 2023 and reminders for second half 2023

As of June 30, 2023

The UCB IR Team has compiled the following items to assist capital market participants in preparation of the upcoming half-year results 2023 publication, scheduled for July 27, 2023.

This document 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 guaranteeing 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 be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars and pandemics, including COVID-19, 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's 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, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving war in Ukraine and COVID-19 pandemic, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of this pandemic to UCB.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

In the event of any differences between this document and the Integrated Annual Report or Half-Year Report, the information included in the Report shall prevail.

Full-Year 2022 results

Latest data here

Guidance 2023

Revenue: €5.15 - 5.35bn
Adjusted EBITDA: 22.5 - 23.5%
Core EPS: €3.40 - 3.80
R&D expenses flat in absolute terms
Tax rate expected around 20%

Main drivers for guidance 2023

Underlying performance of the existing product portfolio,
FINTEPLA® sales growth, VIMPAT® annualized loss of exclusivity effects
Continued investments into several launches, inflation impacts
Zogenix acquisition becoming earnings accretive

Guidance 2025

Revenue: at least €6bn
Adjusted EBITDA: low- to mid-thirties %
Improved ESG rating performance

VIMPAT®

US: Loss of exclusivity March 2022
Sales erosion approx. -80% over the first 12 months
EU: Loss of exclusivity September 2022
Sales erosion faster than expected

CIMZIA®

Peak sales guidance: >€2.0bn by 2024 – achieved in 2022
US: Loss of exclusivity February 2024[1]
EU: Loss of exclusivity October 2024[1]
Current assumption for first possible biosimilar market entry: Late 2026 (no listing on clinicaltrials.gov as of now)

EVENITY®

Evenity is being developed and commercialized in collaboration with Amgen globally, as well as with Astellas in Japan
UCB books the European sales and European opex, Amgen books US, Japan and RoW sales
Net Profit split booked in "Other operating income"
Amgen reported Q1/2023 net sales of $US 254mn (Slide 10 in Amgen's Q1 presentation)

bimekizumab/BIMZELX®

Approved by 10 regulatory authorities and in 39 countries worldwide, reaching over 9,000 patients at the end of May
EU: Launched for Psoriasis (PSO); Psoriatic Arthritis (PsA) and Axial Spondyloarthritis (axSpA) approved in June 2023
US: FDA review ongoing, FDA action now expected in Q3/2023
Japan: Launched for PSO; Filed for PsA, Ankylosing Spondylitis (AS) and non-radiographic axSpA (nr-axSpA)
52-week data for PsA in TNFi refractory patients presented in June
Hidradenitis suppurativa (HS) phase 3 data presented in March, submissions expected Q3/2023

FINTEPLA®

Achieved €116mn sales for the period March-December 2022 (since completion of the Zogenix acquisition)
Approved in EU for treatment of Lennox-Gastaut syndrome (LGS) in February 2023
Japan: Submission for LGS planned in Q3/2023

rozanolixizumab/RYSTIGGO®

EU: Filed, feedback expected in H1/2024
US: Approved for generalized Myasthenia Gravis (gMG) in June 2023 following priority review by FDA
Japan: Filed in Q1/2023

zilucoplan

Filed in EU and US, feedback expected in Q4/2023
Filed in Japan, feedback expected in Q3/2023

M&A and BD activities

Minor sale of non-core assets in Q1/2023 (in January 2023, UCB sold an established brands portfolio of 5 prescription medicines, in a variety of non-core therapeutic categories commercialized in Europe), included in guidance 2023

ESG

Commitment to Net Zero emissions in June 2023

Pipeline

Pipeline on our website
Update due July 27, 2023

[1] Loss of exclusivity dates are indicative.