



Takeda Information

FAQs regarding Q2 FY2020 earnings

Global Finance IR

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The following are responses to some frequently asked questions (FAQs) regarding Q2 FY2020 earnings of Takeda Pharmaceutical Company Limited (Takeda), announced on October 29, 2020.

Q1. What was the consensus estimate for Q2 FY2020 (July-September 2020) results?

A1. To our knowledge, analysts from nine financial institutions¹ prepared estimates on Takeda's Q2 FY2020 (July-September 2020) results. Based on the estimates of these nine analysts, who provided an estimate for Q2 results after the Q1 FY2020 earnings announcement:

- Average estimated revenue was 810.3 bn yen
- Average estimated Core Operating Profit was 263.5 bn yen
- Average estimated Core Earnings Per Share (EPS) was 116 yen
- Average estimated Reported Operating Profit was 103.0 bn yen

Takeda's actual revenue was 788.9 bn yen, actual Core Operating Profit was 226.7 bn yen, actual Core EPS was 99 yen, and actual Reported Operating Profit was 48.3 bn yen for Q2 FY2020.

Q2. What was the impact of the novel coronavirus infectious disease (COVID-19) on Takeda's Q2 FY2020 results?

A2. To date, Takeda has not experienced a material effect on its financial results as a result of the global spread of COVID-19, despite the various effects on its operations as detailed on pages 14-16 of the [Summary of Financial Statements](#) submitted to the Tokyo Stock Exchange.

Based on currently available information, Takeda believes that its financial results for FY2020 will not be materially affected by COVID-19 and, accordingly, our FY2020 forecast reflects this belief. However, the situation surrounding COVID-19 remains highly fluid, and future COVID-19-related developments in FY2020, including new or additional COVID-19 outbreaks and additional or extended lockdowns, shelter-in-place orders or other government action in major markets, could result in further or more serious disruptions to Takeda's business, such as slowdowns in demand for Takeda's products, supply chain related issues or significant delays in its clinical trial programs. These events, if they occur, could result in additional impacts on Takeda's business, results of operations or financial condition, as well result in significant deviations from

¹ BofA Securities Japan, Citigroup, Cowen, Credit Suisse, Goldman Sachs, Jefferies, Mizuho Securities, Morgan Stanley MUFG and Nomura Securities.

our FY2020 forecast.

Q3. What is the impact of the COVID-19 outbreak on Takeda's PDT business? Do you expect the pandemic to impact plasma volume targets/ plasma collection for FY2020 and beyond?

A3. Takeda acknowledges current concerns about how the decline in plasma donation during the pandemic may impact our industry's ability to supply plasma-derived therapies short and mid-term to patients who rely on them. We are committed to doing everything we can to enable continuity of care for patients around the world. In view of the significant investments Takeda has been making to increase our plasma collection and production capacity, and the efficiency gains we are making across the value chain, we expect to be able to maintain and support the planned growth in demand for Takeda's plasma-derived therapies through to the end of our fiscal year (March 2021). The continuing uncertainty regarding the progression of COVID-19 means that it is too early to gauge the extent of the impact to plasma collections longer term, particularly given that any decline could be offset by how well we manage to mitigate it over time through all the various actions we are taking. We are monitoring the situation closely, evaluating different scenarios and have implemented mitigation plans that cover a wide range of variables in order to meet our commitments to patients.

During the pandemic, plasma collection centers have been designated as critical infrastructure and our centers are operational across all four countries where we collect plasma (the U.S., Austria, Hungary, Czechia). Moreover, we continue to open new centers as part of our sustained investment in increasing our plasma collection capacity by 65%+ by 2024. We have opened 13 new centers so far this fiscal year, and expect to open 20+ centers by the end of this fiscal year and a further 20+ next fiscal year. We've also seen an uptick in new donors which typically results in a higher Immunoglobulin (IG) volume in each donation.

Within our BioLife network, we have expanded our efforts to encourage donations through a variety of different actions and awareness initiatives, while continuing to prioritize the safety of our employees and donors with additional screening measures, distancing policies, and protective equipment for our staff. We are engaging broadly across the blood and plasma industries, with peers, professional associations, patient organizations, regulators and governments to emphasize the critical importance of plasma sourcing towards ensuring uninterrupted supply of these therapies for patients with chronic and complex conditions.

It is our belief that the positive awareness of plasma as a contributing solution to the pandemic will help foster recognition and support for the broader patient need for plasma around the world, including the need to permanently revise outdated regulation in order to improve availability of plasma.

Q4. Why did Takeda's H1 FY2020 revenue and Core Operating Profit decline versus the same period of the prior year?

A4. Takeda's revenue growth rate in H1 FY2020 was -4.2%, mainly affected by foreign exchange rate (-3.1pp) and divestitures (-1.6pp). Core Operating Profit in H1 FY2020 was also affected by divestitures and foreign exchange. Please refer to page 22 in the [Q2 FY2020 presentation material](#).

Q5. Why did Takeda's H1 FY2020 Underlying Core Operating Profit margin decline from Q1 (Q1: 34.7%, H1: 31.6%)?

A5. Takeda's gross margin in H1 was negatively affected by product mix, mostly from lower revenue in Rare Hematology products and leuprorelin. In terms of OPEX, while COVID-19 related cost savings such as lower travel expenses benefitted the underlying Core Operating Profit in H1 FY2020, Takeda has also been making investments in IT to support remote/virtual working, long-term strategy to China growth, as well as R&D investments for the Wave 1 pipeline (with all studies that had been delayed by COVID-19 having now resumed), and COVID-19 related spending such as the PDT CoVig-19 program. As a result, our underlying Core Operating Profit margin in H1 FY2020 declined from Q1 FY2020. However, Takeda has confirmed and is on track towards its full-year management guidance of "low thirties" underlying Core Operating Profit margin.

Q6. Why did the underlying growth of 14 global brands decline from Q1 (Q1: +20%, H1: +15.4%)?

A6. Our 14 global brands had grown +20% in Q1 FY2020 but the growth rate slowed to +15.4% in H1 FY2020. This was impacted by COVID-19 related prescribing trends in Oncology, and phasing of shipments of IG in the prior year.

Q7. Why was the underlying revenue decline of the 'Other' therapeutic area better than Q1 (Q1: -21%, H1: -13%)?

A7. In Q1 FY2020 there was a significant decline of "Other" products due to the loss of exclusivity of ULORIC, the termination of ENBREL co-promotion in Japan. However, the decline was less pronounced in Q2, because the LOE of ULORIC occurred at the start of Q2 FY2019. Furthermore, Takeda booked better sales of influenza vaccine and a one-time payment from Neurocrine within "Other" in Q2 FY2020.

Q8. Why did you see the slowdown of Immunoglobulin (IG) sales from Q1 (underlying growth, Q1: +29.8%, H1: +14.2%)? What is your forecast of IG growth for FY2020?

A8. In Q1 FY2020, IG delivered growth of +29.8% led by U.S., partly explained by supply dynamics in FY2019 when a shipment was delayed from Q1 FY2019 into Q2 FY2019. As a result of this dynamic, IG grew only +0.9% in Q2 FY2020. Across the two quarters, the supply fluctuation balanced out to deliver strong FY2020 Q2 year-to-date (YTD) growth of +14%. Takeda expects IG to continue to grow, and is on track to deliver the full-year FY2020 forecast of +10%-+20% underlying growth.

Q9. Albumin sales in H1 FY2020 decreased -13% versus the same period of the prior year. Why does Takeda maintain the full-year growth forecast of Albumin sales (+10%-20% growth)? Are you confident to achieve the forecast?

A9. Albumin sales in H1 FY2020 decreased -13% versus previous year, primarily related to the timing of shipments in China. We continue to monitor the China Albumin market and see continued strong demand. We expect to deliver our full-year Albumin forecast of +10%-+20%.

Q10. When does Takeda expect NATPARA to be back in the U.S. market?

A10. Takeda is working closely with the FDA on a proposed plan to resupply NATPARA in the U.S., however, as previously noted, it is anticipated that the required device modifications and product testing will likely delay availability beyond 2020. As a result, Takeda continues to expect zero U.S. revenue for NATPARA to be recognized in FY2020.

Q11. Why is the approval of ENTYVIO subcutaneous formulation (SC) delayed in the U.S. ?

A11. Takeda received a Complete Response Letter regarding ENTYVIO SC from the U.S. FDA in December 2019. In August 2020, Takeda had a productive meeting with the FDA wherein we gained clarity on the data necessary for the device required to support approval. Continued testing of the device will take time, and as a result, Takeda expects to potentially launch in Ulcerative Colitis in CY2022, pending FDA approval.

Q12. Why did net debt/adjusted EBITDA remain at 3.7 times from Q1 FY2020?

A12. Overall, Takeda is comfortable with the progress of de-leveraging and it has improved from 3.8 times at the end of March 2020. In this quarter, Takeda didn't receive cash from divestitures and we saw negative FX impact on EBITDA during Q2 FY2020. As a result, net debt/adjusted EBITDA remains at 3.7 times.

Q13. What are the main factors for upgrading Reported Operating Profit and Free Cash Flow (FCF) in your FY2020 guidance?

A13. Takeda has upgraded its Reported Operating Profit from 395.0 bn yen to 434.0 bn yen, reflecting the underlying performance of the business and gains on divestitures, which more than offset the negative impact of foreign exchange rates (Please refer to page 37 in the [Q2 FY2020 presentation material](#)). The FCF forecast upgrade is driven by an assumption of anticipated proceeds from additional divestitures announced since the Q1 results, as well as anticipated sales of real estate and marketable securities. Please note that the upgraded forecasts of Reported Operating Profit and FCF do not include anticipated proceeds from the divestment of the Takeda Consumer Healthcare Company (TCHC). If the TCHC deal were to be closed by March 31, 2021, there would be approximately 140.0 bn yen upside to Reported Operating Profit and approximately 230.0 bn yen in additional pre-tax cash proceeds.

Q14. The progress of Core Operating Profit in H1 FY2020 was 51.6% against full-year forecast. Are you confident in achieving the Core Operating Profit forecast of 984.0 bn yen for FY2020?

A14. We are confident to achieve the full-year FY2020 Core Operating Profit forecast of 984.0 bn yen, driven by accelerated business momentum and disciplined OPEX management, subject to unforeseen further impacts from foreign exchange rates* and COVID-19.

*Assumption of FX rates for FY20 Revised Reported Forecasts: 1 USD=106 JPY, 1 Euro=122 JPY, 1 RUB=1.4 JPY, 1 BRL=19.4 JPY, 1 CNY=15.3 JPY. For the FX sensitivity, please refer to the P.13 of [Databook](#).

Q15. What R&D efforts is Takeda taking against COVID-19?

A15. Takeda is taking a comprehensive approach to treat and prevent COVID-19 through multiple activities and partnerships focused on advancing development of a variety of potential therapies and vaccines.

- Vaccines: Takeda has partnered with the Government of Japan, Novavax and Moderna, to help accelerate the availability of a COVID-19 vaccine in Japan. We are leveraging our extensive and well-established global manufacturing and supply capabilities regarding the Vaccines from Novavax and Moderna, and building upon our existing influenza pandemic preparedness efforts in Japan.
- Hyperimmune globulin: Takeda co-founded the CoVIg-19 Plasma Alliance and joined forces with other leading plasma companies to develop and manufacture investigational hyperimmune immunoglobulin medicine in the global fight against COVID-19. The Alliance is also participating in The Fight Is In Us campaign and related convalescent plasma donation campaign.
- Repositioning of internal therapies: The company is also assessing existing Takeda products (including FIRAZYR (icatibant) and TAKHZYRO (lanadelumab)) and those in development for activity against the COVID-19 virus, and has joined the COVID R&D Alliance, the IMI Care Alliance and the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership.

For more details, please refer to page 7 in the [Q2 FY2020 presentation material](#).

Q16. When does Takeda expect approval of CoVIg-19, an investigational treatment for COVID-19?

A16. The CoVIg-19 Plasma Alliance, an unprecedented collaboration of leading plasma companies supported by global organizations outside the plasma industry, has confirmed that patients have enrolled in the Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC) Phase 3 clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

Takeda expects it will take several months to complete dosing and evaluation for all patients. The timing will ultimately depend upon how quickly the study is enrolled. Once completed and assuming the results are positive, we will submit for regulatory authorizations. We are pleased with the remarkable progress we have made since initiating the CoVIg-19 Plasma Alliance in April 2020. If the trial proves successful, this therapy could greatly benefit those at risk of serious complications from COVID-19.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](#)) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries.

For more information, visit <https://www.takeda.com>.

Contacts

Investor Relations

Christopher O'Reilly, +81-(0)3-3278-2543
takeda.ir.contact@takeda.com

Media Relations

Kazumi Kobayashi, +81 (0)3-3278-2095
kazumi.kobayashi@takeda.com

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Further information on certain of Takeda's Non-IFRS measures is posted on Takeda's investor relations website at <https://www.takeda.com/investors/reports/quarterly-announcements/>

Reconciliation from reported revenue to underlying revenue growth presented in accordance with IFRS are included as an appendix to FY2020 Q2 presentation.

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