Better Health, Brighter Future

Takeda Information

Financial FAQs regarding FY2019 Q3 earnings

Global Finance IR

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The following are responses to some frequently asked questions (FAQs) regarding FY2019 Q3 earnings of Takeda Pharmaceutical Company Limited (Takeda), announced on February 4, 2020.

NOTE: From FY2019 Q1, the term "Core Earnings" has been renamed "Core Operating Profit". The definitions are identical, and only the terminology has changed.[1]

Q1. What was the consensus estimate for FY2019 Q3 (October-December) results?

A1. To our knowledge, analysts from nine financial institutions[2] prepared estimates on Takeda's Q3 (October-December) results. Based on the estimates of these nine analysts, who provided an estimate for Q3 results after the FY2019 Q2 earnings announcement:

- average estimated revenue was 841.1 bn yen
- average estimated Core Operating Profit was 248.4 bn yen
- average estimated Core Earnings Per Share (EPS) was 100 yen

Takeda's actual revenue was 859.3 bn yen, actual Core Operating Profit was 250.5 bn yen, and actual Core EPS was 115 yen for FY2019 Q3.

Q2. How did your products perform in FY2019 Q3 YTD[3]?

A2. As previously reported in the FY2019 Q3 earnings release[4] and presentation[5], on a pro-forma underlying basis[6], Takeda's FY2019 Q3 YTD (April-December) revenue declined by -1.2%. The decline was driven by intensified competition and increasing price pressure in Rare Hematology, as well as generic entry for Firazyr® and Uloric®, and the effect of inventory stocking for hereditary angioedema (HAE) products including Cinryze® and Firazyr® in FY2018. These headwinds were partially offset by the growth of Takeda's 14 global

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[1] For full definitions of Takeda's disclosure metrics and reconciliation tables, please refer to the appendix of the FY2019 Q3 earnings presentation

[2] Citigroup, Goldman Sachs, Credit Suisse, Mizuho Securities, Morgan Stanley, Bank of America, Jefferies, Nomura Securities, and Cowen.

[3] FY2019 Q3 YTD (year-to-date): April-December 2019

[4] https://www.takeda.com/newsroom/newsreleases/2020/takeda-demonstrates-business-momentum-accelerated-integration-synergies-and-raises-fy2019-guidance-including-positive-reported-operating-profit/

[5] https://www.takeda.com/siteassets/system/investors/report/quarterlyannouncements/fy2019/qr2019_q3_p01-en.pdf

[6] FY2018 Q3 YTD pro-forma baseline represents the sum of Takeda revenue for FY2018 Q3 YTD (Apr-Dec) plus Shire revenue for the same period, where Shire revenue was converted to JPY at the rate of $1 = 111 JPY (average FX rate for FY2018) and converted from US GAAP to IFRS with no material difference; Takeda revenue and Shire revenue was adjusted to remove the revenue from divested assets. Please refer to reconciliation on slide 38 in FY2019 Q3 earnings presentation.

brands, such as Entyvio® and Takhzyro®, which in aggregate posted a strong year-over-year underlying revenue growth of +20%. Please refer to pages 7 and 15 in the FY2019 Q3 earnings presentation[5] and pages 13-14 of the DATABOOK[7] for additional information.

Despite the FY2019 Q3 YTD pro-forma underlying revenue decline of -1.2%, underlying revenue is expected to recover in Q4, and we confirm our full-year FY2019 underlying revenue guidance of "flat to slightly increasing".

Q3. How much cost synergy did Takeda realize in FY2019 Q3 YTD?

A3. Takeda has not provided a specific number for cost synergies realized in FY2019 Q3 YTD. We continue to work towards our target of $2bn of annual recurring pre-tax cost synergies by the end of FY2021, and with synergies being realized faster than initially planned, we aim to be at a run rate of 80% of the target by end of FY2020 (initially we expected to be at run-rate of 70% by end of FY2020).

Synergy savings are embedded into Operating Expenses (OPEX) in our plan, and part of our Key Performance Indicators (KPIs) are measured against the achievement of Profit and Loss (P&L) and OPEX targets. We track OPEX every month for each Business Unit and Function.

Q4. Takeda's updated Core Operating Profit guidance for the full fiscal year is 950.0 bn yen, while in FY2019 Q3 YTD, Core Operating Profit was at ¥792.2 bn (achievement rate against full-year target of 83.4%, refer to page 25 in FY2019 Q3 earnings presentation[5]). What headwinds do you expect in FY2019 Q4?

A4. Revenue in FY2019 Q4 will be impacted by the lack of U.S. revenue for Natpara® as well as further revenue erosion of products that faced loss of exclusivity earlier in the year such as Firazyr® and Uloric®. We also expect OPEX seasonality, and investment in key business areas. Historically, Legacy Takeda's Q3 YTD Core Operating Profit achievement rate has been approximately 90% of the full year result in the past 5 years.

Q5. What is the P&L impact due to the completed Purchase Price Allocation (PPA) in FY2019, and in FY2020 onwards?

A5. We finalized the PPA for the acquisition of Shire and confirmed a positive P&L impact, resulting from a longer average amortization period compared to the preliminary PPA conducted after closing the deal. Moreover, there was minimal change to the fair value of the Shire intangible assets and goodwill.

For FY2019, we expect a positive P&L impact of 118.8 bn yen compared to the previous forecast.[8] Shire intangible amortization expenses are reduced from 423.0 bn yen to 325.2 bn yen (-97.8 bn yen), and expenses for the unwinding of inventory step-up are also reduced from 211.0 bn yen to 190.0 bn yen (-21.0 bn yen) for FY2019.

From FY2020 onwards, we expect the annual amortization expenses associated with Shire intangibles to be around 330 bn yen until FY2023, then declining to 210 bn yen in FY2027. These are based on an average weighted amortization period of 12 years, which is a revision from 10 years in the preliminary PPA. The unwind of inventory step-up expense is expected to be 86 bn yen in FY2020, declining to 33 bn yen in FY2021.

As a reminder, both amortization and unwind of inventory step-up are non-cash expenses, and do not affect Core Operating Profit or cash flow.

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[7] https://www.takeda.com/siteassets/system/investors/report/quarterlyannouncements/fy2019/qr2019_q3_d_en.pdf

[8] Previous forecast as of October 31, 2019

Q6. Why does Takeda still estimate 101.0bn yen impairment of intangible assets in its FY2019 guidance?

A6. We have estimated an impairment forecast based on the value of intangible assets on our balance sheet, and the historical rate of occurrence of impairment. As we have finished the PPA process, which resulted in decreasing the value of intangible assets, we've taken this opportunity to refine the impairment forecast. This change is not based on any specific potential impairment candidate.

Q7. Why did the net debt/adjusted EBITDA ratio increase from 3.9x in FY2019 Q2 to 4.1x in FY2019 Q3?

A7. As we mentioned at Q2 earnings, net debt increased by approximately 60 bn yen between FY2019 Q2 and FY2019 Q3 due to the payment in December 2019 of the half-year dividend, and also tax on the proceeds of the Xiidra® divestiture. Furthermore, adjusted EBITDA declined by approximately 50 bn yen from the Q2 last twelve months (LTM) period to the Q3 LTM period, due to timing of inventory harmonization in FY2018.

As a result, the net debt/adjusted EBITDA ratio as of the end of FY2019 Q3 was 4.1x. Takeda remains committed to rapid de-leveraging towards its target of 2x net debt/adjusted EBITDA within the fiscal years ending March 2022 – March 2024.

Q8. What has changed in your FY2019 reported Operating Profit forecast?

A8. The reported Operating Profit has been raised by 120.0 bn yen versus the previous forecast[8]. This change is primarily driven by the following factors:

- Core Operating Profit upgrade (+20.0 bn yen)
- Purchase Price allocation benefit (+118.8 bn yen, comprised of decrease in expenses for unwind of inventory step up (21bn yen) and decrease in amortization of intangible assets (97.8 bn yen))
- Reduction of impairment placeholder (+20 bn yen)
- Increase of integration costs (-8 bn yen)
- Other operating expenses (-38 bn yen), etc.

Q9. What factors should we keep in mind when considering FY2020 guidance?

A9. We will inform the market of our FY2020 guidance at the FY2019 Q4 earnings announcement, scheduled for May 13, 2020.

When considering our FY2020 guidance, notable factors that should be kept in mind include the momentum of Takeda's 14 global brands, the full-year impact of products that faced loss of exclusivity in FY2019 (Uloric®, Firazyr® etc.), the recall of Natpara® in the U.S., the Velcade® competitive situation, and the impact of deconsolidation of divested businesses including Xiidra®, OTC, and non-core assets (FY2019 revenue contribution from assets announced for divestiture[9]: approximately 60 bn yen).

[9] Assets announced for divestiture as of February 4, 2020.

Q10. Why does Takeda expect zero Natpara® revenue for FY2020 in the U.S. market?

A10. Takeda has been working closely with the FDA on a proposed plan to resupply Natpara®, but additional device modifications and product testing will likely cause more than a year's delay in bringing Natpara® back to patients in the U.S. As a result, we expect zero U.S. revenue for Natpara® to be recognized in FY2020.

We are committed to ensuring supply, through a Special Use Program, to patients previously prescribed Natpara® who are at extreme risk of life-threatening complications as a result of discontinuation of treatment.

Q11. How will Takeda manage the Complete Response Letter (CRL) regarding Entyvio® subcutaneous formulation in Ulcerative Colitis (UC)? Does Takeda plan to file Entyvio® SC formulation for Crohn's Disease (CD)?

A11. In December 2019, Takeda received a CRL from the U.S. Food and Drug Administration (FDA) in response to the submission of a Biologics License Application (BLA) for an investigational subcutaneous (SC) formulation of Entyvio® in UC. The FDA's communication is unrelated to the clinical safety and efficacy data and conclusions from the pivotal trial supporting the Biologics License Application. The communication from the FDA included queries related to the design and labelling of the SC product. We are assessing the details of the letter, gathering information needed to resolve the FDA's questions, and will work closely with the Agency on a path to approval. We aim to provide an update within H1 CY2020 regarding our approach for resolving the CRL. Filing of vedolizumab subcutaneous for maintenance therapy in adults with moderate to severe CD in the U.S. is also pending resolution of the CRL. Takeda remains confident in the growth outlook for Entyvio®, and its potential to realize four to five billion U.S. dollars in annual peak revenue.

Q12. Why did Takeda enter a settlement and license agreement with Roche relating to Entyvio®?

A12. F. Hoffmann-La Roche AG (Roche) filed patent infringement lawsuits against Takeda in Germany, Italy and Spain alleging that Entyvio® infringes a Roche patent issued in those countries. Additionally, Takeda filed a lawsuit in the U.K. seeking nullification of Roche's patent in the U.K. and Roche filed a counterclaim for infringement. In December 2019, Takeda entered into a settlement and license agreement with Roche to resolve all ongoing patent proceedings and disputes between the companies relating to Entyvio®, and Roche's European Patent number 2007809 relating to glycosylated antibodies. Anticipated payment obligations under the settlement and license agreement are not expected to be material to Takeda.

Q13. Why is Takeda's immunoglobulin (IG) revenue growth rate (FY2019 Q3 YTD underlying growth: +4%) lower than the market growth?

A13. In FY2019 Q1 (April-June), there was a temporary imbalance of supply and demand in the U.S. due to phasing of IVIG supply. Since then, the phasing of IG has righted itself, growing by 8% in Q2 (July-September) and 7% in Q3 (October-December). Takeda still expects to meet its target of high-single-digit growth of IG for the remainder of FY2019, driven by the ramp-up of production at our newly operational Covington facility, and focusing on our strategy to grow subcutaneous immunoglobulin (SCIG) products, HyQvia® and Cuvitru®.

We continue to invest significantly in increasing both total plasma volume and manufacturing capacity by >65% over the next five years.

Q14. What are the details of the TAK-007 license agreement with The University of Texas MD Anderson Cancer Center (MDACC)?

A14. Takeda established a license agreement and research agreement with the MDACC to develop cord blood-derived chimeric antigen receptor-directed natural killer (CAR-NK) cell therapies[10]. Under the agreement, Takeda will receive access to MDACC's CAR-NK platform and the exclusive rights to develop and commercialize up to four programs, including a CD19-targeted CAR-NK cell therapy and a B cell maturation antigen (BCMA)-targeted CAR-NK cell therapy. Takeda and MDACC will also conduct a research collaboration to further develop these CAR-NK programs. We are establishing the CD19 CAR-NK as the lead cell therapy candidate in oncology (development code: TAK-007), for which we intend to initiate a pivotal study in 2021. It is anticipated that the CD19 CAR-NK cell therapy could be administered in an outpatient setting. In an ongoing Phase 1/2a clinical study treating patients with relapsed and refractory B cell malignances, the CD19 CAR-NK cell therapy has not been associated with the severe cytokine release syndrome (CRS) or neurotoxicity observed with existing CAR-T therapies.

On February 5, 2020, the MD Anderson Cancer Center announced that results from the Phase 1/2a clinical study were published in the *New England Journal of Medicine*.[11]

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 Diseases, 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.

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[10] https://www.takeda.com/newsroom/newsreleases/2019/takeda-and-md-anderson-announce-collaboration-to-accelerate-the--development-of-clinical-stage-off-the-shelf-car-nk-cell-therapy-platform/

[11] https://www.mdanderson.org/newsroom/cd19-car-nk-cell-therapy-achieves-73-percent-response-rate-in-patients-with-leukemia-and-lymphoma.h00-159379578.html

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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/quarterly-announcements-2019/

Reconciliation from reported revenue to underlying revenue growth presented in accordance with IFRS are included as an appendix to FY2019 Q3 presentation.

Pro Forma Information

This document includes certain pro forma information giving effect to the Shire acquisition as if it had occurred on April 1, 2018. This pro forma information has not been prepared in accordance with Article 11 of Regulation S-X. This pro forma information is presented for illustrative purposes and is based on certain assumptions and judgments based on information available to us as of the date hereof, which may not necessarily have been applicable if the Shire acquisition had actually happened as of April 1, 2018. Moreover, this pro forma information gives effect to certain transactions and other events which are not directly attributable to the Shire acquisition and/or which happened subsequently to the Shire acquisition, such as divestitures and the effects of the purchase price allocation for the Shire acquisition, and therefore may not accurately reflect the effect on our financial condition and results of operations if the Shire acquisition had actually been completed on April 1, 2018. Therefore, undue reliance should not be placed on the pro forma information included herein.