Better Health, Brighter Future

Takeda Information

FAQs regarding FY2020 earnings

Global Finance IR

May 26, 2021

The following are responses to some frequently asked questions (FAQs) regarding the Q4 FY2020 earnings of Takeda Pharmaceutical Company Limited (Takeda), announced on May 11, 2021.

Q1. COVID-19: What impact did the novel coronavirus infectious disease (COVID-19) have on Takeda's FY2020 results?

A1. While the overall impact of the global spread of COVID-19 on Takeda's consolidated financial results for the fiscal year ended March 31, 2021 was not material, there were adverse effects on the revenue due to COVID-19 observed in certain therapeutic areas, especially Neuroscience in which stay-at-home restrictions reduced patient visits to medical care providers. This trend fluctuated throughout the fiscal year. These adverse impacts have been partially offset by benefits from prescribing trends during the pandemic, such as an expansion of certain products with a more convenient administration profile that was observed in the early phase of the outbreak. With regard to operating expenses, voluntary suspension of certain business activities such as business travel and events in response to COVID-19 led to lower spending. As a result of these factors, the impact of the global spread of COVID-19 on Takeda's profit was immaterial.

Please refer to pages 13-15 of the *Summary of Financial Statements* submitted to the Tokyo Stock Exchange for details on the impact on the spread of the COVID-19 and Takeda's initiatives in response.

Q2. COVID-19: What are Takeda's initiatives against COVID-19?

A2. Takeda has announced two partnerships to bring COVID-19 vaccines to Japan. The first partnership is with Novavax, for the development, manufacturing and commercialization of its COVID-19 vaccine candidate NVX-CoV2373 (development code in Japan: TAK-019) in Japan. The second partnership is with Moderna and the Government of Japan's Ministry of Health Labour & Welfare (MHLW) to import and distribute its COVID-19 vaccine candidate mRNA-1273 (development code in Japan: TAK-919) in Japan. In May 2021, Takeda announced positive interim results from the Phase 1/2 immunogenicity and safety clinical trial of TAK-919 in Japan have been submitted to the Japan Pharmaceuticals and Medical Devices Agency (PMDA) and Takeda obtained approval from the MHLW in May 2021. Additionally, Takeda has also announced a mutual agreement with IDT Biologika GmbH (IDT) to utilize capacity at IDT previously reserved for Takeda's dengue vaccine candidate to temporarily

manufacture the single-shot COVID-19 vaccine developed by Janssen Pharmaceutical Companies of Johnson & Johnson.

The CoVIg-19 Plasma Alliance is one example of Takeda's initiatives to develop potential therapies to combat COVID-19. In April 2020, Takeda and CSL Behring co-founded the Alliance with other leading global and regional manufacturers of plasma-derived therapies. Together, the Alliance members collaborated to develop and manufacture an investigational non-branded plasma-derived hyperimmune globulin (H-Ig) medicine, referred to as CoVIg-19 for adults hospitalized with COVID-19 at risk for serious complications. The H-Ig was evaluated in a multi-national Phase 3 clinical trial funded by the National Institute of Allergy and Infectious Disease (NIAID) of the U.S. National Institutes of Health (NIH) which was completed in March 2021. While the clinical trial did not meet its endpoints, the program contributed to a growing understanding of this challenging virus and strategies for patient care. Following the outcome of the trial, the CoVIg-19 Plasma Alliance's work was concluded.

In addition to the CoVIg-19 Plasma Alliance, Takeda has undertaken a number of efforts to help the world respond to COVID-19, including the evaluation of a number of our marketed products and pipeline compounds for efficacy against the COVID-19 virus and participation in global research collaborations. In terms of completing clinical study, I-SPY CONID-19 platform trial including icatibant has conducted, but the icatibant arm of the I-SPY trial has concluded since it reached the predefined futility criterion. And as for the COMMUNITY study, a Phase 2/3 adaptive design platform trial, new patient enrollment has been stopped in the investigational IV lanadelumab arm; participation will be completed/patients followed.

Q3. COVID-19: What is the development and regulatory status of the two COVID-19 vaccines Takeda is helping to bring to the market in Japan? How much revenue impact of these vaccines is included in you FY2021 forecast?

A3. Takeda filed a New Drug Application (NDA) of Moderna's vaccine in March 2021 in Japan, with positive data from the Phase 1/2 immunogenicity and safety clinical trial submitted in May 2021. After that, Takeda obtained approval from the MHLW in May 2021. For Novavax's vaccine, the clinical Phase 1/2 study in Japan started February 2021 and enrollment has been completed. Takeda aims to distribute the first doses in Japan in H2 FY2021, subject to regulatory approval. (Please also refer to *FY2020 Q4 presentation* slide #8)

Takeda plans to distribute 50 million doses of Moderna's COVID-19 vaccine in Japan and has included the expected revenue from this agreement in our FY2021 forecast. The FY2021 forecast does not include any contribution from the Novavax vaccine. Takeda is in ongoing discussions with all parties including the Government of Japan to potentially increase number of doses under contract for the Moderna vaccine. The current FY2021 forecast only includes the initial 50 million doses of the Moderna vaccine at this stage.

Q4. FY2021 Forecast/Management guidance: What do you anticipate the financial impact from COVID-19 and other assumptions used for the reported forecast and management guidance in FY2021?

A4. Takeda formulated its FY2021 forecast based on several assumptions, as follows. (Please also refer to *FY2020 Q4 presentation* slide #9, #36):

- To date, Takeda has not experienced a material effect on its financial results as a result of the global spread of the novel coronavirus infectious disease (COVID-19). Based on currently available information, Takeda believes that its financial results for FY2021 will not be materially affected by COVID-19 and, accordingly, Takeda's FY2021 forecast reflects this belief. However, the situation surrounding COVID-19 remains highly fluid, and future COVID-19-related developments in FY2021, 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 an additional impact on Takeda's business, results of operations or financial condition, as well as result in significant deviations from Takeda's FY2021 forecast.
- The gain on sale of a diabetes portfolio in Japan is booked as revenue (JPY 133.0B), and adjusted out of Core Operating Profit for FY2021
- Takeda expects at least one 505(b)2 competitor for subcutaneous VELCADE to launch in the U.S. around mid FY2021.
- Takeda does not expect to restart sales of NATPARA in the U.S. market in FY2021.
- The forecast and the guidance do not include the impact of any potential further divestitures beyond what has already been disclosed by Takeda.

Q5. Management guidance: How do you still achieve the low-to-mid 30% margin target by FY2021-2023 when you are increasing R&D investment?

A5. Takeda has accelerated the delivery of synergies, achieving the $2.3 billion target one year ahead of plan. We believe that these accelerated synergies will enable us to achieve FY2021 underlying core operating profit margin guidance of "Around 30%", despite the significant increase in R&D investment. Looking ahead towards FY2023, there are still a number of moving parts, hence we have now provided a target range of "low-to-mid 30s" underlying core operating profit margin. The key opportunities include revenue growth driven by our high-margin 14 Global Brands, the improvement of PDT business margins over time, and disciplined SG&A control. Takeda has provided a more nuanced range given that we are anticipating that this is an inflection year for the pipeline, with 5-6 NDA filings planned by the end of this fiscal year, our rollout of COVID-19 vaccine has just begun and there is still potential to expand our role with the vaccine distribution.

Q6. FY2021 Forecast/R&D: Where do you expect to use the incremental R&D expenses? What is the outlook for R&D investment in future?

A6. Takeda decided to increase R&D investment in FY2021 because we see significant potential in our pipeline, with 11 WAVE 1 pipeline NMEs expected to launch by fiscal 2024 with best-in-class / first-in-class potential in areas of high unmet need, and ~30 WAVE 2 programs with transformative or curative potential. In FY2021 we forecast an increase of R&D expenses of approximately 15%, but from FY2022 we expect the rate of increase to be lower. This incremental R&D investment is being driven by three main areas (Please also refer to *FY2020 Q4 presentation* slide #19):

- **Pipeline Momentum:** Orexin is a great example of building pipeline momentum. We saw the signals emerge for TAK-994 and TAK-925 and decided to increase our investment for additional indications, formulations, back up formulations and drug substance. Pre-investment is also ongoing for TAK-981. We are planning for success and investing broadly for TAK-981 and our oncology ambition.
- **Capability Building:** Select investment in clinical trial start capability so we can begin trials quickly, data/ digital sciences so we can analyze completed trials in a timely fashion, and cell therapy manufacturing to provide clinical trial material for oncology programs like TAK-007 (CAR-NK for CD-19+ cancer).
- **Partnerships:** Incremental business development completed recently such as Maverick Therapeutics (TAK-186), Ovid Therapeutics (soticlestat), and Arrowhead Pharmaceuticals (TAK-999).

Q7. FY2021 Forecast/SG&A: What is the SG&A in FY2021? With such a significant increase of R&D expense, are you going to reduce the SG&A aggressively to better control the total OPEX?

A7. We see opportunities to control SG&A and remain disciplined in controlling this. We also see the potential for operating leverage from our high-margin 14 global brands.

Q8. PDT business: How did the PDT business perform in FY2020? What are your expectations for the FY2021 outlook?

A8. Takeda continues to execute on our previously communicated goals of increasing both plasma collection and manufacturing capacity within the existing network by >65% by 2024 (versus 2018 baseline). Just under halfway through this five-year target timeframe, we are ahead of where we expected to be and very much on track to achieve our growth goal. Takeda also continues to build a robust pipeline and has signed a couple of development partnerships. Takeda ended the year strong and delivered full-year PDT Immunology year-on-year (YoY) underlying growth of +9.8%. Takeda's IG portfolio showed full-year underlying growth of +15.7% in line with guidance of double-digit growth and with sales increasing across all regions.

Takeda expects to continue to grow our total PDT business in FY2021. YoY growth of our PDT Immunology portfolio is expected to be +10-20%. Immunoglobulin is expected to grow +5-10%. For Albumin, we expect full recovery of sales in FY2021 and are projecting growth of over 30%. Finally, we expect over 30% plasma collection YoY growth in FY2021 with potentially fewer constraints related to collection as a result of the COVID-19 pandemic.

(Please also refer to *FY2020 Q4 presentation* slide #7)

Q9. PDT business/COVID-19: What was the impact of COVID-19 on plasma collection for FY2020? What is your assumption for FY2021?

A9. The pandemic impacted collections industry-wide, but Takeda's digital process improvements & operational excellence initiatives limited volume decline to -11% in FY2020 versus FY2019 globally, and only -5% at U.S. collection centers. Takeda expects over 30% plasma collection growth in FY2021; on track to the target of increasing collection volumes by >65% by 2024 (versus 2018 baseline). (Please also refer to *FY2020 Q4 presentation* slide #7)

Q10. Hikari plant: What's the most recent update on the situation of the Warning Letter?

A10. On Dec 22, 2020 Takeda submitted a request for guidance on changing the site status based on overall progress to date, and the U.S. FDA has committed to an on-site reinspection in July 2021.

Q11. Capital Allocation Policy: Given Takeda has no bond maturities in FY2021, how will you allocate your capital this fiscal year?

A11. Takeda has decided to increase R&D investment as FY2021 is anticipated to be an inflection year for our R&D pipeline. Our first priority is to invest in growth drivers such as strategic investment in R&D, new product launches including in China, and expanding our presence in plasma-derived therapies. Second priority is to reduce debt toward our target of 2x ("low-twos") net debt/adjusted EBITDA within fiscal years 2021 to 2023. And our third priority is to return cash to shareholders, maintaining our well-established dividend policy of 180 yen per share annually.

Despite having no more debt maturities in FY2021, we plan to continue pre-paying future debt efficiently even beyond the bonds and loans that have already been called for pre-payment in May/June 2021. Takeda is committed to our deleveraging target of 2x ("low-twos") net debt/adjusted EBITDA in the FY2021-2023 timeframe and we will continue to make our capital allocation decisions with this goal in mind. (Please also refer to *FY2020 Q4 presentation* slide #42)

Q12. R&D catalysts: What pipeline updates do you expect in FY2021?

A12. Takeda anticipates that FY2021 will be an inflection year for our R&D pipeline. First, with respect to potential submissions and approvals for the Wave 1 pipeline, Takeda anticipates 5 to 6 NDA regulatory submissions to the U.S. FDA and/or other major regulatory agency globally, with the potential for 4 NME approvals. Second, as for data readouts and proof-of-concept (POC), one of the highest potential projects in development is the orexin franchise, and Takeda expects a data readout of TAK-994 Phase 2b in narcolepsy type 1 and TAK-994 POC in narcolepsy type 2, and is also exploring potential indications for our early stage oral orexin agonist TAK-861, and intravenous formulation TAK-925. Takeda also plans to obtain the POC of TAK-755 (iTTP), TAK-981, TAK-573, TAK-906, and TAK-951 in FY2021. Lastly with respect to regional submissions and approvals, Takeda expects up to 13 submissions[1] and 8 approvals in Japan[2], up to 12 submissions[1] and 6 approvals in China[2], and potential for two COVID-19 vaccines (TAK-019, TAK-919) approvals in Japan. Since the earnings call, TAK-919 was approved by MHLW in May 2021.

1. Includes submissions under review
2. Global brands, regional brands, and NMEs

Q13. R&D Investment: How do you define internal and external spend? What is in the ~40% internal / ~60% external spend?

A13. External spend are direct pipeline expenses that mainly relate to CROs, labs, and clinical trial materials cost. Internal spend mostly relate to payroll of our employees and other fixed costs. Our internal spend (R&D employees) support our pipeline development through direct / indirect support of development, research efforts, business development, etc. (Please also refer to *FY2020 Q4 presentation* slide #18)

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 discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. 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**.

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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 Q4 presentation*.

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