



Better Health, Brighter Future



# Business Report

## The 146th (interim period)

April 1, 2022 - September 30, 2022

**Takeda Pharmaceutical Company Limited**

TSE : 4502 NYSE : TAK



## Dear Shareholders,

As we reach the end of the first half of FY2022 (April 1, 2022 to September 30, 2022), I want to thank you for your continued support. Our strong performance has led to accelerating our growth, advancing our pipeline and delivering on our commitments. We've reconfirmed our full-year FY2022 Management Guidance and the significant upside we are seeing from foreign exchange has led us to raise our reported and core forecasts<sup>(a)/(b)</sup> and free cash flow<sup>(a)/(c)</sup> outlook for the full year—all of which gives us further confidence in our ability to bring new therapies to patients and deliver long-term growth.

I'm personally enthusiastic about the recent milestone achievement of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency recommending approval of our dengue vaccine candidate in the EU and dengue-endemic countries for prevention of dengue disease. This marks an important global public health moment that has the potential to reduce the significant burden of dengue. It also comes just two months after the vaccine's first approval in Indonesia as QDENGAR<sup>®</sup>. This is the only dengue vaccine approved for use regardless of prior dengue exposure.

With several promising clinical study results in the first half of FY2022, we also had important regulatory updates, including a positive CHMP opinion for maribavir for the treatment of adults with post-transplant cytomegalovirus infection and/or disease that is refractory to prior therapies. Additionally, we had strong momentum across our Growth and Launch Products\* including ENTYVIO<sup>®</sup>, TAKHZYRO<sup>®</sup> and Immunoglobulin.

Guided by our commitment to patients, our people and the planet, Takeda's vision is to discover and deliver life-transforming treatments. We take a purpose-led approach to driving global growth and long-term value creation for our stakeholders. As we continue to deliver on our financial objectives, we look forward to contributing to a bright future ahead.

Thank you,

**Christophe Weber**

Representative Director, President & CEO

## FY2022 H1 RESULTS

Our first half results are driven by strong momentum from our Growth and Launch Products\*. Core revenue and core operating profit grew 5.5% and 14.5%, respectively, at constant exchange rate<sup>(d)</sup>, while reported operating profit growth was affected by a one-time gain from the sale of the diabetes portfolio in Japan in FY2021 Q1 and FX impact. We continue to deleverage rapidly, finishing the first half with net debt to adjusted EBITDA at 2.6x, with 98% of our debt at fixed interest rates with a weighted average of 2%.

## FINANCIAL HIGHLIGHTS Results for FY2022 H1 Ended September 30, 2022

(Billion yen, except percentages and per share amounts)	REPORTED		CORE <sup>(c)</sup> (Non-IFRS) <sup>(a)</sup>		
	FY2022 H1	vs. PRIOR YEAR (Actual % change)	FY2022 H1	vs. PRIOR YEAR (Actual % change)	vs. PRIOR YEAR (CER % change <sup>(d)</sup> )
Revenue	1,974.8	+10.1%	1,974.8	+18.9%	+5.5%
Operating Profit	255.0	-26.3%	625.2	+28.7%	+14.5%
Margin	12.9%	-6.4pp	31.7%	+2.4pp	+2.5pp
Net Profit	166.8	-9.2%	446.7	+33.0%	+14.4%
EPS (yen)	108	-8.1%	288	+34.6%	+15.8%
Operating Cash Flow	305.2	-23.7%			
Free Cash Flow (Non-IFRS) <sup>(a)(b)</sup>	296.9	-5.9%			

(a) Further information regarding certain of Takeda's Non-IFRS measures is posted on Takeda's investor relations website at <https://www.takeda.com/investors/financial-results/>.

(b) We define Free Cash Flow as cash flows from operating activities, subtracting acquisition of property, plant and equipment ("PP&E"), intangible assets and investments as well as removing any other cash that is not available to Takeda's immediate or general business use, and adding proceeds from sales of PP&E, as well as from sales of investments and businesses, net of cash and cash equivalents divested.

(c) Core results adjust our reported results calculated and presented pursuant to IFRS to exclude the effect of items unrelated to Takeda's core operations, such as, to the extent applicable for each line item, non-recurring items, purchase accounting effects and transaction related costs, as well as amortization and impairment of intangible assets and other operating income and expenses.

(d) CER (Constant Exchange Rate) change eliminates the effect of foreign exchange rates from year-over-year comparisons by translating Reported or Core results for the current period using corresponding exchange rates in the same period of the previous fiscal year.

## COMMERCIAL UPDATES ACROSS FIVE KEY BUSINESS AREAS

Growth in our key business areas in the first half of FY2022 was driven largely by Growth & Launch Products\*, which delivered revenue of 759.8 billion yen, marking a 19% increase on a CER basis.

\*Please refer to slide 19 of Takeda's FY2022 Q2 investor presentation (available at [takeda.com/investors/financial-results/](https://www.takeda.com/investors/financial-results/)) for the definition of Growth & Launch Products.



**Gastroenterology (GI)**, with 546.4 billion yen in reported revenue, grew +12% on a CER basis driven by 17% global sales growth for ENTYVIO for ulcerative colitis and Crohn's disease on a CER basis in the first half. Due to continued strong performance and updated loss of exclusivity assumptions, we are raising the peak sales outlook range for ENTYVIO to \$7.5-9.0 billion, from a previous estimate of \$5.5-6.5 billion.



**Rare Diseases**, with 362.2 billion yen in reported revenue, grew +8% on a CER basis driven by strong sales of hereditary angioedema treatment TAKHZYRO, which grew 31% year-over-year on a CER basis due to the expansion of the prophylactic market, continued geographic expansion and strong patient uptake. LIVTENCITY™, which launched in the U.S. in December 2021, continues to generate high interest and strong uptake with 75% of U.S. transplant centers having initiated therapy with at least one patient.



**Plasma-Derived Therapies (PDT) Immunology**, with 314.0 billion yen in reported revenue, delivered strong growth of +14% on a CER basis driven by strong demand for Immunoglobulin (+17% growth at CER), particularly in the U.S. amid increasing supply, as well as solid growth for Albumin (+8% at CER) tempered by the impact of lockdowns in China. The PDT business continues to innovate and deliver for patients with life-threatening conditions.



**Oncology**, with 225.3 billion yen in reported revenue, declined -12% on a CER basis as a result of expected entry of multiple VELCADE® generic entrants that began in the U.S. in May 2022. Besides VELCADE, all other revenue totaled 204.5 billion JPY, a year-over-year increase of 6% at CER, led by strong demand for ALUNBRIG® in Japan, Europe and Growth & Emerging Markets, and ADCETRIS®, which continues to gain from increased access and uptake in frontline indications, and ICLUSIG® in the U.S.



**Neuroscience**, with 302.3 billion yen in reported revenue, grew +11% on a CER basis, driven by an expanding Attention Deficit Hyperactivity Disorder (ADHD) adult market in the U.S. for VYVANSE®/ELVANSE. Sales of TRINTELLIX were 49.8 billion yen (+5% growth at CER), due to continued recovery of the Major Depressive Disorder (MDD) market in the U.S. and strong market share gains in Japan.

## FY2022 FORECAST AND MANAGEMENT GUIDANCE

Based on Takeda's first half results, and primarily reflecting expected favorable foreign exchange rates during the remaining second half of FY2022, Takeda's reported and core forecasts and free cash flow outlook have been upgraded from the original forecast. Takeda is also reconfirming full-year FY2022 Management Guidance.

(Billion yen)	FY2022 ORIGINAL FORECAST (May 2022)	FY2022 REVISED FORECAST (October 2022)	FY2022 MANAGEMENT GUIDANCE Core Growth at CER (Non-IFRS) (Unchanged from May 2022)
Revenue	3,690.0	3,930.0	
Core Revenue	3,690.0	3,930.0	Low-single-digit growth
Reported Operating Profit	520.0	530.0	
Core Operating Profit	1,100.0	1,180.0	High-single-digit growth
Reported Net Profit	292.0	307.0	
Reported EPS (Yen)	188	198	
Core EPS (Yen)	484	525	High-single-digit growth
Free Cash Flow	600.0 - 700.0	650.0 - 750.0	
Annual Dividend per Share (Yen)	180	180	

For more details on Takeda's first half FY2022 results and other financial information including key assumptions in FY2022 forecast and management guidance, please visit: <https://www.takeda.com/investors/financial-results/>.

### Important Notice

For the purposes of this notice, “report” means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited (“Takeda”) regarding this report. This report (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this report. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This report is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this report, “Takeda” is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words “we”, “us” and “our” are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

The product names appearing in this document are trademarks or registered trademarks owned by Takeda, or their respective owners.

### Forward-Looking Statements

This report and any materials distributed in connection with this report may contain forward-looking statements, beliefs or opinions regarding Takeda’s future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as “targets”, “plans”, “believes”, “hopes”, “continues”, “expects”, “aims”, “intends”, “ensures”, “will”, “may”, “should”, “would”, “could”, “anticipates”, “estimates”, “projects” or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda’s global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda’s operations and the timing of any such divestment(s); the extent to which our internal energy conservation measures and future advancements in renewable energy or low carbon energy technology will enable us to reduce our greenhouse gas emissions; and other factors identified in Takeda’s most recent Annual Report on Form 20-F and Takeda’s other reports filed with the U.S. Securities and Exchange Commission, available on Takeda’s website at: <https://www.takeda.com/investors/sec-filings/> or at [www.sec.gov](http://www.sec.gov). Takeda does not undertake to update any of the forward-looking statements contained in this report or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this report may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda’s future results.

### Financial information and Certain Non-IFRS Financial Measures

Takeda’s financial statements are prepared in accordance with International Financial Reporting Standards (“IFRS”). This report and materials distributed in connection with this report include certain financial measures not presented in accordance with IFRS, such as Core Revenue, Core Operating Profit, Core Net Profit, Core EPS, Constant Exchange Rate (“CER”) change, Net Debt, EBITDA, Adjusted EBITDA and Free Cash Flow. Takeda’s management evaluates results and makes operating and investment decisions using both IFRS and non-IFRS measures included in this presentation. These non-IFRS measures exclude certain income, cost and cash flow items which are included in, or are calculated differently from, the most closely comparable measures presented in accordance with IFRS. By including these non-IFRS measures, management intends to provide investors with additional information to further analyze Takeda’s performance and core results, including when controlling for the effect of fluctuations in exchange rates. Takeda’s non-IFRS measures are not prepared in accordance with IFRS and such non-IFRS measures should be considered a supplement to, and not a substitute for, measures prepared in accordance with IFRS (which we sometimes refer to as “reported” measures). Investors are encouraged to review the definitions and reconciliations of non-IFRS financial measures to their most directly comparable IFRS measures, which are in the financial appendix at the end of Takeda’s H1 FY2022 investor presentation (available at [takeda.com/investors/financial-results](http://takeda.com/investors/financial-results)).

### Medical information

This report contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.



See the detail of the quick report here



### Contributing to the improvement of global public health A big step forward on dengue vaccine development

Read related news release



#### Dengue: A threat to 390 million people worldwide annually

Dengue is a mosquito-borne viral disease and causes an estimated 390 million infections and 500,000 hospitalizations annually.<sup>1,2</sup> Major symptoms include fever, rash, headache, and osteoarthritis. It can develop into severe illness and potentially lead to death if not treated early and appropriately.<sup>3</sup> The incidence of dengue has grown dramatically in recent years, and can be attributed to factors such as urbanization and climate change.<sup>1</sup> Dengue is also the leading cause of serious illness and death among children and adults in Latin America and Asia,<sup>4,5</sup> and the second most diagnosed cause of fever among travelers returning to Europe from endemic countries.<sup>6</sup> Takeda's QDENG A (Dengue Tetravalent Vaccine [Live, Attenuated]) (TAK-003) was approved by the Indonesian National Agency for Drug and Food Control in August this year for use in the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age. Additionally in October, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of TAK-003 for the prevention of dengue disease caused by any serotype in individuals four years of age and older in Europe and in dengue-endemic countries participating in the parallel EU-M4all procedure.\* QDENG A is the only dengue vaccine approved in Indonesia for use in individuals regardless of previous dengue exposure and without the need for pre-vaccination testing.<sup>7</sup> It has not yet been approved anywhere else in the world and Takeda will continue to initiate and progress regulatory filings in other dengue-endemic and non-endemic countries.

#### The pivotal global clinical trial demonstrated overall vaccine efficacy

In the pivotal global Phase 3 TIDES trial, TAK-003 prevented 84% of hospitalized dengue cases and 61% of symptomatic dengue cases over a 4.5-year period after vaccination. TAK-003 has been generally well tolerated, with no evidence of disease enhancement in vaccine recipients, and no important safety risks have been identified in the TIDES trial, to date.<sup>8</sup>

Takeda has supplied vaccines in Japan for more than 70 years, consistent with its purpose of delivering better health for people and a brighter future for the world. Takeda's global vaccine business is now applying innovation to tackle the major global public health issue of dengue.



<sup>1</sup> World Health Organization Fact Sheet. Dengue and Severe Dengue. January 2022. Retrieved August 2022

<sup>2</sup> Guzman MG, Halstead SB, Artsob H, et al. Dengue: a continuing global threat. *Nat Rev Microbiol*. 2010;8(12 Suppl):S7-S16. doi:10.1038/nrmicro2460

<sup>3</sup> About dengue fever by Minister of Health, Labour and Welfare; <https://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/0000131793.pdf>

<sup>4</sup> Knowlton K, et al. Mosquito-Borne Dengue Fever Threat Spreading in the Americas. The Natural Resources Defense Council (NRDC). 2019. Retrieved April 2022.

<sup>5</sup> Centers for Disease Control and Prevention. Dengue For Healthcare Providers Clinical Presentation. September 2021. Retrieved October 2022.

<sup>6</sup> Bulugahapitiya, U., Siyambalapatiya, S., Seneviratne, S. L., & Fernando, D. J. (2007). Dengue fever in travellers: A challenge for European physicians. *European journal of internal medicine*, 18(3), 185–192. <https://doi.org/10.1016/j.ejim.2006.12.002>

<sup>7</sup> Takeda. QDENG A Summary of Product Characteristics. Retrieved August 2022

<sup>8</sup> Tricou V, et al. Efficacy and Safety of Takeda's Tetravalent Dengue Vaccine Candidate (TAK-003) After 4.5 Years of Follow-Up. Northern European Conference on Travel Medicine (NECTM)

\* For more information on EU-M4all, please refer to our press release published on March 25, 2021.

<https://www.takeda.com/newsroom/newsreleases/2021/takeda-begins-regulatory-submissions-for-dengue-vaccine-candidate-in-eu--and-dengue-endemic-countries/>  
Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

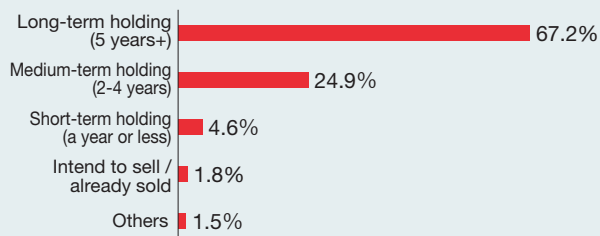
## Shareholder survey results

Visit the retail investor page

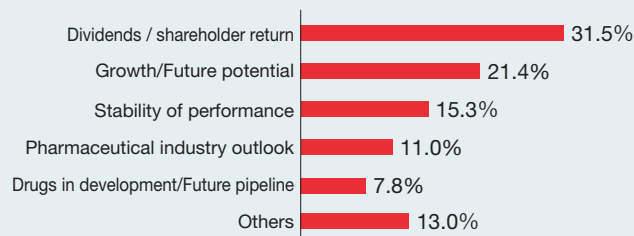


In March 2022, we invited 10,000 randomly selected Takeda shareholders to participate in an online survey. The responses we received provided valuable insight into the priorities, values and communication preferences of our shareholders. We would like to express our gratitude to everyone who participated.

### Future shareholding plans



### Reasons for investing / holding



### Selected responses

- I would like to receive information on the company's growth and future potential.
- I have expectations for Takeda to expand its new drug pipeline.
- I would like Takeda to contribute to Japan with medicines such as a COVID-19 vaccine.
- I would like to hear more about the benefits of the Shire acquisition.
- Takeda's dividends / shareholder returns

Survey period:  
March 1-22, 2022  
Methodology:  
Online survey,  
10,000 shareholders  
(randomly selected)

### Your voice matters

A new survey will be conducted online from December 1 to 26, 2022 and we encourage all our shareholders to participate. Your feedback and opinions are important to us and help us improve how we communicate with you. (The survey is currently only available in Japanese.)



**Access to the FY2022 shareholders survey questionnaire from the website or the QR code. > <https://www.net-research.jp/1152973/>**

Your eight-digit shareholder number is required to complete the survey. You can find your number on the interim dividend letter enclosed with this report.

## MEMO FOR SHAREHOLDERS

Fiscal year	April 1 to March 31 of the following year, each year
Ordinary general meeting of shareholders	June each year
Record dates	Ordinary General Meeting of Shareholders March 31 each year Term-end dividend March 31 each year Interim dividend September 30 each year
Number of shares per share unit	100 shares
Transfer agent and administrator of the special account inquiries	Mitsubishi UFJ Trust and Banking Corporation 4-5, Marunouchi 1-chome, Chiyoda-ku, Tokyo
Contact for the above	Osaka Corporate Agency Division 6-3, Fushimimachi 3-chome, Chuo-ku, Osaka 541-8502 0120-094-777 (toll-free number)
Methods used for public notices	Electronic public notice (Japanese only) Public notices are published on the website: <a href="https://www.takeda.com/jp/investors/public-notice/">https://www.takeda.com/jp/investors/public-notice/</a> However, if the Company is unable to make public notices by electronic means due to breakdown or other unavoidable reason, public notices will be published in the Nihon Keizai Shimbun.

### Webpage for Investors

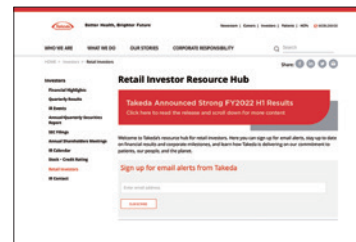
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Takeda Retail Investors

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Takeda Pharmaceutical Company Limited

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