BERNSTEIN
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Japan Biopharma

Japan Biopharma post-4QFY25/1QFY26 earnings wrap and our latest thoughts on our coverage

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Here are our latest thoughts on our coverage names based on the earnings and latest discussions with the companies.

DAIICHI SANKYO: OUTPERFORM, PT=JPY4,500: We continue to believe in positive readouts from Datroways' Avanzar, TL07 and TL15 later this year. Meanwhile FY25 earnings, FY26 guidance and the MTP exposed significant room for DS management to up their game, and we sense increasing frustration from investors. We think that the speed of their recently announced cost optimization initiatives is within management control.

CHUGAI: OUTPERFORM, PT=JPY9,800: We continue to believe that Foundayo should do as well as Wegovy Pill, if not better, and the stock should react positively as prescription/ sales numbers start backing the potential. However, we feel that Chugai does not have enough to bolster its stock momentum after Foundayo's growth prospect gets settled. We don't know the timing of the tide change yet and recommend investors to be vigilant.

TAKEDA: OUTPERFORM, PT=JPY6,900: We like their rich clinical catalyst path in FY26 and renewed cost cut efforts under the new CEO. If some of the anticipated readouts are positive, if not all, IBI363, zasocitinib and/or TAK-360 could significantly strengthen Takeda's growth trajectory in 2030s. Through the organization restructuring, Takeda aims to save annualized cost of >200Bn by FY28. The recently announced antitrust court ruling is a minor negative and does not impact our overall positive view for the stock.

EISAI: OUTPERFORM, PT=JPY6,100: We continue to think that Leqembi subcutaneous autoinjector IQLIK starting dose's launch expected in 2QFY2026 (PDUFA delayed to Aug 24th) should be a key catalyst for the stock. The new formulation will make the once-every-two-week 1.5-hr infusion plus monitoring at a medical facility to once-a-week 15-second injection at home. The convenience step-change should accelerate the drug's market adoption and reverse competitive dynamics vs. LLY's Kisunla.

OTSUKA: MARKET-PERFORM, PT=JPY11,600: Otsuka's current stock price reflects the company's future growth. Meanwhile, Voyxact's faster-than-expected market penetration and ulotatont's positive Ph3 for schizophrenia in later this year can be a positive surprise.

SHIONOGI: MARKET-PERFORM, PT=JPY3,000: We were unimpressed by Shionogi's slower-than-expected cost optimization plan and uncompelling investments in Radicava and Xocova launch in the US. Hope for Zatolmilast's fragile X syndrome opportunity has now dimmed. We don't see any potential upside risk for the next 12 months.

ASTELLAS: MARKET-PERFORM, PT=JPY2,200: We think Astellas can no longer excite the market with better-than-expected performance of mature products. While being positive about their cost optimization efforts, we are lukewarm about their growth drivers. Plus the pipeline assets face tough competition: Revolution Medicine's (not covered) daraxonrasib will likely set a high bar in PDAC before setidegrasib will get Ph3 readouts.

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BERNSTEIN TICKER TABLE

			20 May 2026		TTM	Reported EPS				Reported P/E (x)		
Ticker	Rating	Cur	Closing Price	Price Target	Rel. Perf.	Cur	2025A	2026E	2027E	2025A	2026E	2027E
4503.JP (Astellas)	M	JPY	2,295.00	2,200.00	26.7%	JPY	162.77	163.46	168.81	14.1	14.0	13.6
4519.JP (Chugai)	O	JPY	7,899.00	9,800.00	(30.4)%	JPY	263.73	316.80	373.10	30.0	24.9	21.2
4568.JP (Daiichi Sankyo)	O	JPY	2,605.50	4,500.00	(69.8)%	JPY	140.37	150.11	167.44	18.6	17.4	15.6
4523.JP (Eisai)	O	JPY	4,245.00	6,100.00	(32.8)%	JPY	163.76	168.31	211.50	25.9	25.2	20.1
4578.JP (Otsuka)	M	JPY	11,405	11,600	32.4%	JPY	685.06	563.74	634.04	16.6	20.2	18.0
4507.JP (Shionogi)	M	JPY	3,035.00	3,000.00	(8.8)%	JPY	241.11	247.57	264.99	12.6	12.3	11.5
4502.JP (Takeda)	O	JPY	5,255.00	6,900.00	(12.7)%	JPY	496.16	506.05	530.52	10.6	10.4	9.9
JPL			2,461.85									

O - Outperform, M - Market-Perform, U - Underperform, NR - Not Rated, CS - Coverage Suspended

4502.JP estimate is Adjusted EPS; 4502.JP valuation is Adjusted P/E (x); 4523.JP base year is 2024;

Source: Bloomberg, Bernstein estimates and analysis.

INVESTMENT IMPLICATIONS

Daiichi Sankyo: Outperform, PT=JPY4,500.

Chugai: Outperform, PT = JPY9,800.

Eisai: Outperform, PT = JPY6,100.

Takeda: Outperform, PT = JPY6,900.

Otsuka: Market-Perform, PT = JPY11,600.

Shionogi: Market-Perform, PT = JPY3,000.

Astellas: Market-Perform, PT = JPY2,200.

DETAILS

Our Japanese Biopharma coverage's 4Q FY2025/1QFY2026 earnings results were mix: Chugai, Takeda, Otsuka and Astellas beat the market expectation, while Daiichi Sankyo, Eisai and Shionogi's were miss. Plus FY2026 guidances of Daiichi Sankyo, Takeda, Eisai, Shionogi and Astellas were soft. As results, the market reacted negatively for Daiichi Sankyo, Eisai, Astellas and Shionogi.

Here are our latest thoughts on our coverage names based on the earnings and latest discussions with the companies.

DAIICHI SANKYO: OUTPERFORM, PT=JPY4,500

Daiichi Sankyo 4QFY25: FY26 earnings guidance is a miss. 2030 target has room for stretch through accelerating cost reduction

Daiichi Sankyo post 4QFY25 discussion: Management has to show they are up to the task of value maximization of their ADCs

OUR LATEST VIEW ON THE NAME

Our rating for the name is Outperform, and we continue to believe in positive readouts from Datroways' Ph3s Avanzar and/or Tropion Lung07 for 1L nonsquamous, Trop2+ NSCLC and TL15 for 2L+ EGFR mut NSCLC, and their positive impact to the stock price. However 4QFY2025 earnings, FY2026 guidance and 2026–2030 MTP exposed significant room for DS management to up their game. In particular, reported loss provisions for CMO compensation fee (JPY170Bn for FY2025 and JPY80Bn for FY2026) was not only a negative financial surprise but also a displeasing revelation that the supply plan overestimates only came to the management's attention at the very end of the mid-term planning exercise. Plus we cannot help but think that their newly announced cost optimization efforts through operation excellence initiative lacks sense of urgency. Our lower PT is mainly a reflection of lower FY26 Enhertu forecast; higher cost of sales due to the CMO compensation through FY2028; and lower financing income per company guidance.

KEY TAKEAWAYS FROM 4QFY2025 EARNINGS, FY2026 GUIDANCE AND 2025-2030 MTP

As mentioned above, the key insights from the company's communication from the earnings season is that the management has to show they are up to the task of value maximization of their ADCs. It is reassuring that Enhertu continues strong commercialization progress, so does Datroway's launch. Most recently, Enhertu has nabbed two more FDA approvals for early HER2+ breast cancer indications neoadjuvant and adjuvant (i.e., pre- and post-operative setting): now the drug has all the key indications on its label. Datroway's rapid penetration in 3L+ EGFR mut NSCLC in its launch phase should have lasting positive impact as this gives oncologists adequate experience with the drug before its bigger indications of 1L NSCLC IO combo Ph3s (AVANZAR, TROPION-Lung07, 08 and 10) and 2L EGFR mut NSCLC (TL15) come to the market.

KEY CONTROVERSIES

While the market's expectation for Datroway Avanzar and TL07's readout for 1L NSCLC remains low, DS's new R&D head articulated the confidence: within nonsquamous Trop2+ NSCLC "ORR was doubled and duration of response got extended".

Avanzar and TL07, Datroway + Imfinzi or Keytruda + platinum chemo in 1L nonsquamous, Trop2+ NSCLC, remains controversial but is no longer viewed as binary risk since trial value is not priced in. Both DS and AZ (covered by Smith) managements have been reticent about the probability of success of these Ph3s, yet John Tsai's, DS's new R&D head, comment during the earnings call was encouraging given that he should have more objective stance on the drug's data as someone coming from outside the organization. When asked whether his confidence came from clinical data that were not yet disclosed to the public, he said not. In addition to Tsai's comment, AZ reiterated during their earnings call that Datroway's peak sales projection should be USD5Bn+, implying the contribution from the 1L NSCLC indication. Meanwhile, DS confirmed that the Trop2 NMR biomarker based patient stratification is now included in TL08 as key secondary endpoints (PFS and OS) for 1L nonsquamous PD-L1 TPS >50% NSCLC with Datroway + Keytruda vs Keytruda alone. AZ explained that the difference in the trial design (Avanzar and TL07 include Trop2+ patients' PFS and OS as primary) is due to the good response of the PD-L1 high population to Keytruda alone, making the patient stratification less necessary for the combo trial.

We think that the company has room to accelerate cost optimization through the newly announced operation efficiency program.

The company's launch announcement of the operation excellence initiative is positive as the cost optimization was not their priority for the past years while driving development and commercialization of the ADC portfolio. It should not be one or the other—DS should be able to drive growth with ADCs and optimize cost in parallel. Yet their sense of urgency comes across rather muted as they emphasized that the significant impact from the efforts should come in FY2030. As its peers such as Takeda and Astellas have been delivering significant cost cut for the past years (both of them are continuing their efforts for the coming years), their timeline feels very slow. We see incentive and potential from management to accelerate cost optimization as they head to a profitability crunch in FY27.

NEAR-TERM CATALYSTS AND KEY EVENTS

EXHIBIT 1: **DS's 2026 catalysts and key events**

Catalyst
Non-catalyst key event

	Topic	Key event/catalyst	Timeline	Comment
Catalysts and key events in FY2026	Datroway	Avanzar TLR readout in 1L TROP2+ve nonsq. NSCLC	2HCY2026	Daiichi Sankyo stock's key catalyst of the year. Given the market's persistent skepticism, this opportunity is not priced in, making this event a huge upside if positive or an overhang lift if negati - either way positive for the stock trajectory. Yet, we believe that inclusion of Trop2-based patient selection should support high probability of success of the trial. PoS 75%
		TROPION-Lung07 TLR readout in 1L TROP2+ve nonsq NSCLC, PD-L1 TPS <50%	2HFY2026	Daiichi Sankyo has aligned with FDA to include Trop2-based patient stratification with NMR biomarker as in Avanzar. If the trial is positive, Datroway can be combined with Keytruda which is the SoC for 1L NSCLC. PoS 75%
		TROPION-Lung08 TLR readout in 1L nonsq NSCLC, PD-L1 TPS ≥50%	FY2027	Daiichi Sankyo is negotiating with FDA to include Trop2-based patient stratification with NMR biomarker as they did for TL07. If the biomarker is included, PoS 75%.
		TROPION-Lung15 TLR readout in 2L EGFR mut NSCLC	2HFY2026	Datroway is tested in combo w/wo Tagrisso for the setting. Datroway's previously observed efficacy in EGFR mut NSCLC in TL01 and 05 (the drug is approved for 3L+ for the cancer type) support high probability of success of the trial. PoS 90%
	I-Dxd	FDA accelerated approval for	3QFY2026	I-Dxd has secured a priority review for 2L+ ES-SCLC after platinum chemo based on Ph2 IDeate-Lung01 with support from Ph1/2 IDeate-PanTumor01. PDUFA date is Oct 10 2026. Given Imdelltra precedence, our PoC assumption is 84%.
	HER3 DXd, I-DXd, R-DXd	Ph2 pantumor trials' readout	2HFY2026 - FY2027	Ongoing Ph2 pantumor trials of HER3 DXd, IDXd and R DXd should start reporting clinical data for multiple cancer types. These data provide insights on for which cancer types these ADCs could be developed and what the scale of their commercial potential should be.

Source: Company reports, clinicaltrials.gov, Bernstein estimates and analysis

CHUGAI: OUTPERFORM, PT=JPY9,800

Chugai 1QFY26: Hemlibra drives the beat, but all eyes on Foundayo

Chugai post 1Q26 discussion: While Foundayo's launch progresses, Chugai chugs along on Nemluvio and pipeline assets

OUR LATEST VIEW ON THE NAME

The market has negatively reacted to early Foundayo's daily and wkly prescription data (we note that IQVIA data has inherent capturing challenge), which indicate significantly slower launch vs Wegovy Pill (Exhibit 2)—Chugai stock is down >20% vs its historic high at the end of Feb. We continue to believe that Foundayo should do as well as Wegovy Pill, if not better, and the stock should react positively as prescription/sales numbers start backing the potential. However, we feel that Chugai does not have enough to bolster its stock price after Foundayo's growth prospect gets settled. We don't know the timing of the tide change yet and recommend investors to be vigilant.

1QFY2026 EARNING KEY TAKEAWAYS

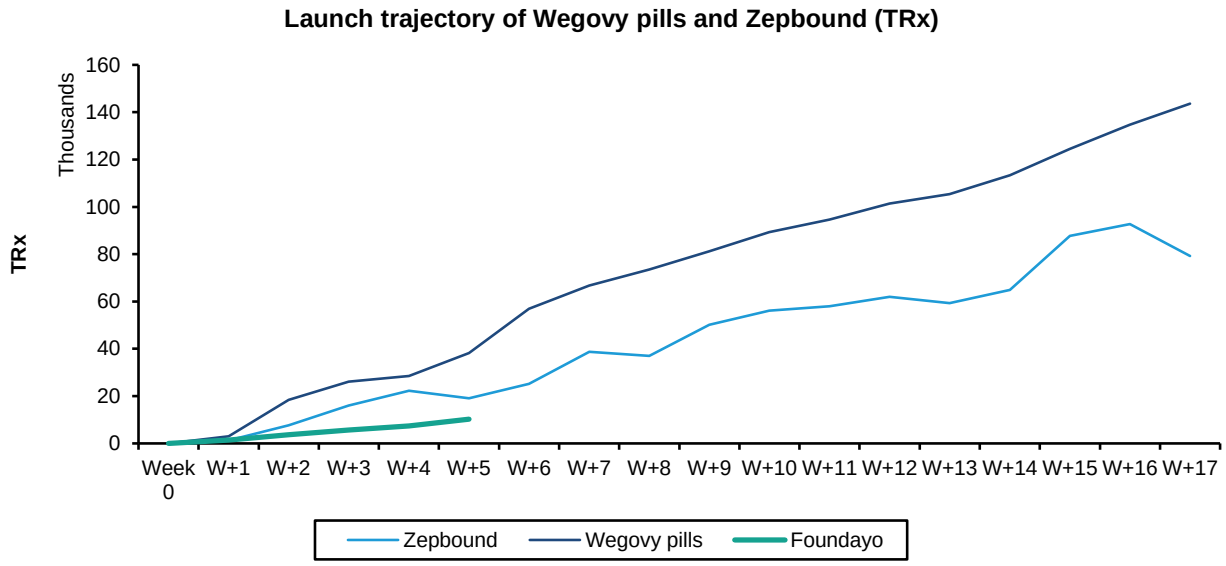
Chugai has delivered robust start of FY2026:1QFY26 top line and core operating profit beat consensus thanks to higher than expected oevrseas sales of Hemlibra and Actemra. Foundayo royalties will begin to be recognized in 2Q, concurrent with end-market sales recognition. In contrast to the strong 1Q performance, the company remains conservative about Hemlibra's overseas sales growth. This is due to that their forecast is bound to Roche's (covered by Smith) order, who remains conservative on their global sales with expectation of impact from Novo's (covered by Smith) Mim8 launch (PDUFA in June).

KEY CONTROVERSIES

We continue to believe that Foundayo should do as well as Wegovy Pill, if not better, and the stock should react positively as prescription/sales numbers start backing the potential.

It is too early to conclude the battle of the pills—please check out our key takeaways from our recent expert call on this topic where we spoke to three distinctive oral GLP-1 prescribers, LINK. We note that LLY (covered by Breen) has to educate prescribers first before launching DTC blast in 3Q because Foundayo is a new drug while Wegovy Pill has an advantage of a known molecule. This may partially explain the gap of the launch optics. At their earnings call, LLY assured that they had >20,000 patients treated with Foundayo at the end of Apr, much stronger number than the wkly TRx data had suggested. They also communicated that 80% of Foundayo patients are new to GLP-1 and a third of over 8,000 physicians who had prescribed Foundayo are new to oral GLP-1, robust signals for the drug's impact to the GLP-1 market expansion as expected.

EXHIBIT 2: **Foundayo launch has been significantly slower than Wegovy pills and Zepbound**



Data from Bernstein US Pharma (Breen) team see GLP-1 tracker
Source: IQVIA, Bernstein analysis

EXHIBIT 3: **It is not certain whether Scholar Rock's apitegromab-like efficacy in combination with tirzepatide is enough to make emugrobart a game changer in obesity**

Topline outcome of apitegromab's Ph2 EMBRAZE for obesity

	24 Weeks		
	apitegromab 10 mg/kg + tirzepatide (n=43)	placebo + tirzepatide (n=44)	Difference apitegromab vs. placebo
Change in Lean Mass (SE)	-1.6 (0.57) kg -3.4 (1.25) lbs	-3.5 (0.52) kg -7.6 (1.14) lbs	1.9 (0.58) kg 4.2 (1.27) lbs (p=0.001) 54.9% preservation
Total Mass Loss due to Lean Mass Loss (SE) in %	14.6 (3.19) %	30.2 (2.89) %	-15.6 (3.23) %
Change in Fat Mass (SE)	-8.5 (0.85) kg -18.8 (1.87) lbs	-8.0 (0.77) kg -17.7 (1.70) lbs	-0.5 (0.86) kg -1.1 (1.90) lbs
Total Mass Loss due to Fat Mass Loss (SE) in %	85.3 (3.22) %	69.5 (2.93) %	15.8 (3.27) %
Change in body weight (SE) (% change in body weight)	-11.2 (1.21) kg -24.6 (2.65) lbs (-12.3%)	-12.5 (1.09) kg -27.5 (2.41) lbs (-13.4%)	1.3 (1.22) kg 2.9 (2.69) lbs

Source: Company reporting

MIM8's launch impact to Hemlibra should be limited.

Chugai projects +3% growth for Hemlibra overseas sales in 2026 vs. +12% in 2025), reflecting Roche's conservative view on the drug's global sales growth prospect at low single digit this year vs. +11% in 2025. They are citing competitive impact from Novo's impending Mim8 launch (PDUFA June 30, 2026). Mim8 does have a convenience advantage as it offers prefilled syringe vs. Hemlibra's manual subcutaneous injection yet given undifferentiated safety and efficacy profile of the two drugs, physicians' familiarity with Hemlibra, and broad and rock-solid business from continuing patients, Mim8's meaningful inroad is unlikely particularly for the coming years. While Chugai/Roche have not disclosed any timeline, they have an autoinjector of Hemlibra in the pipe.

Chugai's OPM has room for further expansion.

Chugai achieved 49.5% operating margin in FY2025, the highest among Japanese biopharma companies, thanks to their unique business model of being Roche's subsidiary and disciplined cost management. We project further margin expansion driven by three factors: 1) as royalty contribution increases with orforglipron, Nemluvio and Hemlibra; 2) R&D spend remains stable at ~15% of revenue; and 3) SG&A cost should slightly decline thanks to aggressive digitalization of promotion activities and other areas of operation.

Post Foundayo may be a challenging period for Chugai to keep the stock momentum, despite that th should grow with further margin expansion.

Foundayo, Nemluvio and Hemlibra will be Chugai's key growth drivers through the end of the decade, which are in the model. Meanwhile, we think that Chugai's pipeline progress is not too assuring for the mid-term stock per NXT007 appears to be potentially a more efficacious drug than Hemlibra, yet its commercial impact may be incr

its predecessor's strong success in the current market. It remains highly uncertain whether Emugrobart (FKA GYM329) may not become a game changer in obesity. Chugai expects a similar efficacy level from the drug's combination with tirzepatide to Scholar Rock (not covered) apitegromab's Ph2 EMBRAZE (Exhibit 3), to which the market did not react. Other pipeline assets are still early.

NEAR-TERM CATALYSTS AND KEY EVENTS (EXHIBIT 4)

Catalyst
Non-catalyst key event

	Topic	Key event/catalyst	Timeline	Comment
Catalysts and key events in 2026	Emugrobart/ GYM329	Readout of Ph2 GYMINDA for obesity or overweight with weight-related comorbidity	Aug-26	The outcome of the trial should indicate potential positioning of the combination of emugrobart + tirzepatide: further weight loss, weight maintenance, fat mass loss, muscle loss prevention.

Source: Company reporting, ClinicalTrials.gov, Bernstein analysis

TAKEDA: OUTPERFORM, PT=JPY6,900

Takeda 4QFY25: 4Q bottomline beat and FY26 guidance in-line. New CEO sails in with continuing financial discipline

OUR LATEST VIEW ON THE NAME

We recently upgraded Takeda to Outperform for their rich clinical catalyst path in FY26 and renewed cost cut efforts through organization restructuring under the new CEO, Julie Kim, LINK. They are expecting multiple PoC/Ph2 data disclosures: IBI363's 1L and 2L NSCLC and 1L CRC (please see our note on the asset, LINK); zasocitinib's Ph2 for IBD; and TAK-360's Ph2s for narcolepsy type 2 (NT2)and idiopathic hypersomnia (IH). These readouts, if positive, could significantly strengthen Takeda's growth trajectory in 2030's. Through the organization restructuring, Takeda aims to save annualized cost of c. JPY100Bn in FY26 and >200Bn by FY28 (Exhibit 5). More recently, they announced an antitrust court ruling on their practice for Amitiza, a constipation drug (please see our note for the details of this case, LINK). While Takeda intends to appeal the case, they will revise the already reported FY25 earnings to reflect a loss provision of USD2.5Bn as part of other operating expense and expect cash-out of the amount in FY26. This is a minor negative and does not impact our view.

KEY TAKEAWAYS FROM 4QFY25 EARNINGS AND FY26 GUIDANCE

4QFY25 topline missed due to lower-than-expected Entyvio and PDT, but the profit beat thanks to lower OPEX derived from the efficiency program, annualized cost saving of ~JPY300Bn in FY25.

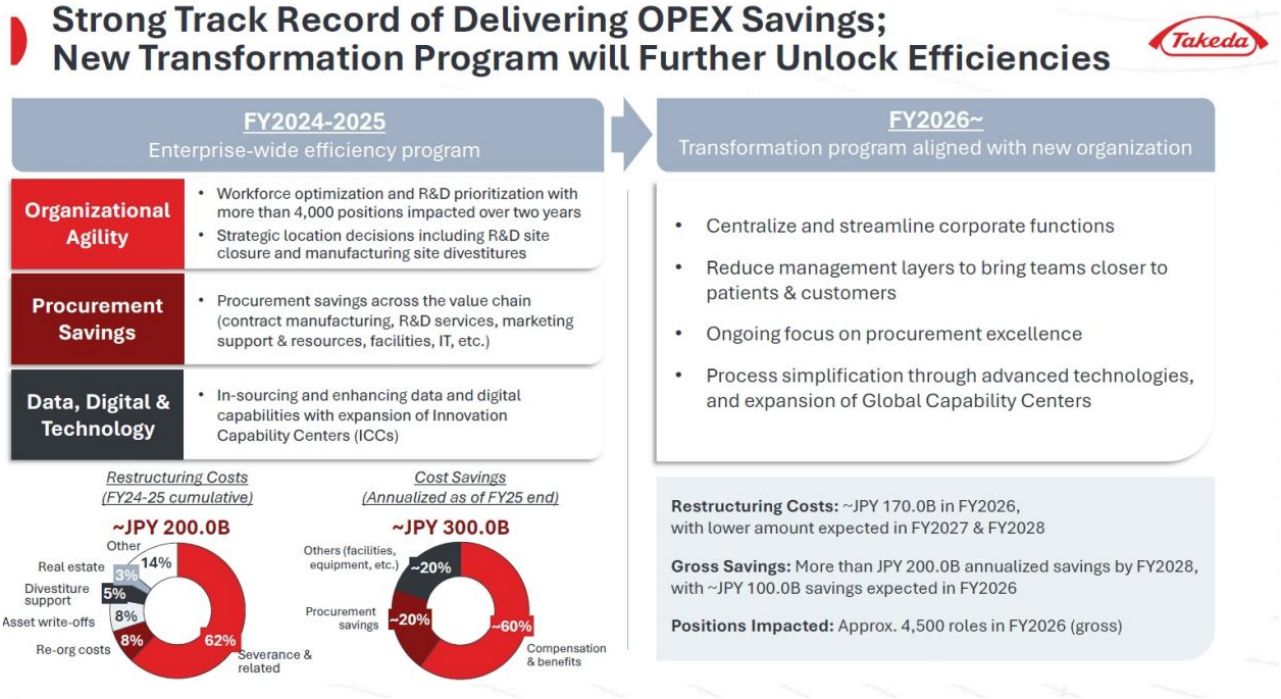
Takeda FY26 guidance was in-line, yet there may be some moving parts. Growth projections for Entyvio at 4% and PDT at low-to-mid single digit may be a stretch given the latest market situations. Yet these challenges may be off set by launches of oveporexton for narcolepsy type 1 and rusfertide for polycythemia vera, of which Takeda has not disclosed specific guidance.

KEY CONTROVERSIES

Anticipated multiple PoC/Ph2 readouts represent potential catalysts.

PoC data disclosure of IBI363 from the collaboration with Innovent (covered by Liang) is expected at this year's ESMO in late Oct for 1L and 2L NSCLC and 1L CRC (all China-only trial data). At ASCO at the end of May, Innovent will present preliminary data from the dose finding phase of the PoC trial for 1L NSCLC, response rate from a limited sample size over different doses, which should not trigger a stock move. Meanwhile, the primary completion estimates of TAK-360's Ph2s for NT2 and IH are in Jul–Aug, and zasocitinib's Ph2s for IBD's (Crohn's disease and ulcerative colitis) are Sep this year. Availability of prior clinical data for these products for the target indications is limited, thus the uncertainties of these clinical readouts are fairly high. Yet given the number of the readouts, we believe some should be positives while others may not.

EXHIBIT 5: **Under the new CEO, Takeda renews its cost saving efforts: aiming to save annualized cost of c. JPY100Bn in FY26 and >200Bn by FY28**



Source: Company reporting

NEAR-TERM CATALYSTS AND KEY EVENTS (EXHIBIT 6)

EXHIBIT 6: **Takeda's 2026 catalysts and key events**

Catalyst
Non-catalyst key event

Company	Product	Catalyst	Timeline	Bernstein view
Takeda	IBI363	PoC data disclosure for 1 and 2L NSCLC and 1L CRC at ASCO/ESMO	End May/ End Oct	These indications of IBI363 are not yet priced, thus posiotive PoC data disclosure should be positive catalysts. Some may be presented at ASCO while others at ESMO.
	TAK-360	Ph2 readout for NT2 and IH	Jul-Aug	Recent data disclosure of other orexin agonists, Alkermes's alixorexton and Centessa's ORX750 for NT2 and IH are encouraging for TAK360's potential in the conditions that are, unlike NT1, not directly linked with orexin deficiency.
	Oveporexton	FDA approval and launch for NT1	PDUFA Aug 10	Based on the robust Ph3 data, it is highly likely that the drug will be approved for NT1.
	Rusfertide	FDA approval and launch for PV	PDUFA Aug 29	Based on the robust Ph3 data, it is highly likely that the drug will be approved for PV.
	Zasocitinib	Ph2 readout for IBD (Crohn's disease and ulcerative colitis)	Sep	There is significant uncertainty as no TYK2 inhibiters have shown efficacy in IBD. Having said, this is the key opportunity, more so than psoriasis, and the Ph2 data is positive, this is positive for thestock.

Source: Company reports, ClinicalTrials.gov, Bernstein analysis

EISAI: OUTPERFORM, PT=JPY6,100

Eisai 4Q FY25: Launch success of Leqembi IQLIK starting dose is key to next leg of growth amid 4Q miss and soft FY26 guidance

OUR LATEST VIEW ON THE NAME

We continue to think that Leqembi subcutaneous autoinjector IQLIK starting dose's launch expected in 2QFY2026 (PDUFA delayed to Aug 24th) should be a key catalyst for the stock. The new formulation will make the once-every-two-week 1.5-hr infusion plus monitoring at a medical facility to once-a-week 15-second injection at home. The convenience step change should

accelerate the drug's market adoption and reverse competitive dynamics vs. LLY's Kisunla.

KEY TAKEAWAYS FROM 4QFY2025 EARNINGS AND FY26 GUIDANCE

4QFY2025 topline was beat, but the profit missed due to higher cost. R&D was lower than consensus, but SG&A was 18% higher than consensus due to higher than expected EU organization restructuring cost. Plus a previously hoped out-licensing deal did not materialize and could not offset the higher cost. Eisai now start to report "Core Operating Profit", which exclude one-time items. FY25 Core OP was JPY50Bn.

FY2026 topline guidance was slightly higher than consensus but the bottomline projection was lower due to higher OPEX. Leqembi (despite later PDUFA date) and Dayvigo guidance are both higher than cons while Lenvima guidance is in-line. SG&A was higher than consensus, partially due to higher Leqembi profit-share payment with its higher sales. As a result, FY26 operating profit guidance was 10% below consensus. Of note, Eisai's margin is low so slight change of sales and cost can make the bottomline beat or miss. Thus the bottomline view may change over the year. The company projects Leqembi should grow 63% YoY in FY26 thanks to IQLIK starting dose launch and increasing adoption of blood-based biomarker (BBM) as confirmatory Amyloid beta (Abeta) test.

KEY CONTROVERSIES

Leqembi QLIK starting dose's launch should trigger sales inflection in 2H FY2026

The new autoinjector's PDUFA is Aug 24th. Its launch timing aligns with the drug's robust growth phase as the overall anti-amyloid beta drug market is doubled in FY2025. The new formulation will make the once-every-two-week 1.5-hr infusion plus monitoring at a medical facility to once-a-week 15-second injection at home, a convenience game changer to patients, and their caretakers and hostpitals/clinics no longer have to worry about infusion bed capacity when starting the treatment for a new patient. As results, the launch of IQLIK starting dose should accelerate the drug's sales growth and reverse the competitive dynamics vs. Eli Lilly's (covered by Breen) Kisunla, which currently benefits from monthly dosing's lower infusion bed capacity requirement vs. Leqembi's bi-weekly IV. Lilly is not developing an subQ formulation for the drug.

NEAR-TERM CATALYSTS AND KEY EVENTS (EXHIBIT 7)

Catalyst
Non-catalyst key event

	Topic	Key event/catalyst	Timeline	Comment
Catalysts and key events in FY2026	Corporate strategy	Investor Day - Corporate Strategy	May-26	Eisai usually host an investor day at the end of March yet this year they moved the date to (likely) make it closer to the original PDUFA date for Leqembi IQLIK starting dose, which is now delayed to Aug 24th. After the earning, we do not expect stock-moving contents from the meeting.
	Leqembi	FDA's IQLIK starting dosing approval and its launch progression	Aug-26	After receiving approval for Leqembi's subQ autoinjector maintenance dose, Eisai has now filed the starting dose to FDA. The approval should significantly lower the treatment initiation barrier and clear differention from Lilly's Kisunla leading to the drug's sales inflection. PoS 80%
	Eli Lilly's Kisunla	Kisunla's TrailblazerAlz3 topline readout for preclinical AD	2HFY2026	Both Kisunla and Leqembi are being tested for precalinical AD in Ph3. Despite that Kisunla's Trailblazer-AlzA3 is expected to be read out ~2 yrs earlier than Leqembi's AHEAD, positive cross-read impact is expected if the trial is positive. Leqembi's Ph3 Clarity AD's subpop analysis has shown the drug's efficacy in early disease patients (low Tau) supporting solid success potential of the trial. PoS 60%

Source: Company reports, ClinicalTrials.gov, Bernstein analysis

OTSUKA: MARKET-PERFORM, PT=JPY11,600

Otsuka 1QFY26: Strong beat driven by Rexulti, Abilify Maintena and Jynarque. Voyxact's launch progress remains robust

Otsuka post 1Q2026 IR discussion: Positive 2026 business progress with likely guidance revision at 2Q in sight

OUR LATEST VIEW ON THE NAME

Otsuka's current stock price reflects the company's future growth. Meanwhile, Voyxact's faster-than-expected market penetration and ulotatont's positive Ph3 for schizophrenia in later this year can be a positive surprise.

KEY TAKEAWAYS FROM 1QFY2026 EARNINGS

Otsuka's 1Q26 was a strong beat driven by topline thanks to Jynarque, Rexulti and Abilify Maintena. Jynarque's Gx penetration has been slower than expected because only one Gx from Lupin (not covered) has been launched so far despite that two more products have been approved. Abilify Maintena also enjoys Gx launch delay in EU, while the company expect US Gx impact to

emerge in 2H this year. As for Voyxact, while too early for details to be disclosed, the company assured robust progress of the launch with little future. They don't see Vertex's (covered by Pickering) povetacicept Phase 3 data as serious threats to Voyxact and think that its first-mover advantage should remain a key asset. **There is good likelihood for upward revision of the 2026 guidance at 2Q.**

KEY CONTROVERSIES

Voyxact's overall 2-yr eGFR outcome should be positive. So far the drug's anti-drug antibody (ADA) has not come up as an issue. Given the robust 9-month uPCR data from the interim analysis, we expect that overall 2-year eGFR from Ph3 VISIONARY should be positive. According to Otsuka, they will announce the topline in Jun–Aug and have a full data presentation at ASN Kidney Week in Oct. Before the final data presentation, they also plan to present an interm eGFR data at ERA in Jun (the company did not specify but it should be 9- or 12-mon data). Unless it is extreme positive or negative, we believe it should not impact the stock price. It has been reported that Voyxact has led to generation of ADA: 88 of 256 (34%) patients treated with Voyxact developed ADA, of whom 21 patients (24%) developed ADA that had neutralizing activity. The 9-month uPCR reduction from baseline was reported to be numerically lower in those with ADA+ (42%) compared to those -ve (53%). According to the drug's label, "the clinical significance of the differences in uPCR reduction according to the presence or absence of ADA is not clear". ADA can have more impact for the longer-term efficacy if the level increases over time. However during our recent expert call, REPLAY, he downplayed the ADA impact. Otsuka has also said that they have not received any ADA related feedback from prescribers.

Ulotaront's fate remains uncertain–we need to wait for the Ph3 readout for schizophrenia in the fall. Ulotaront has failed in two Ph3 trials for schizophrenia. Yet Otsuka believes that the drug can be active, and they can run a better Ph3 than the previous ones because those trials were conducted during the COVID pandemic when patients with the psychiatric condition were particularly vulnerable, and Otsuka was running them with Sumitomo Pharma (not covered) as a partner thus did not have a full control. The ongoing Ph3 for schizophrenia will be read out in 2H (Oct, according to ClinicalTrials.gov). In addition, the company is starting ulotaront's Ph3 for generalized anxiety disorder this year based on Ph2/3 outcome they obtained last year (the data not yet disclosed). Meanwhile, Otsuka has decided not to pursue major depressive disorder in Ph3.

NEAR-TERM KEY EVENTS (EXHIBIT 8)

Catalyst
Non-catalyst key event

	Topic	Key event/catalyst	Timeline	Comment
Catalysts and key events in FY26	Voyxact	Disclosure of interim eGFR data from Ph3 VISIONARY at ERA 2026	Jun-26	Interim data may be 9- or 12-mon eGFR. We expect this data to be indicative of positive final 2-yr data yet this should not be considerd as definitive.
		Topline reporting of final 2-yr eGFR data from Ph3 VISIONARY via press release	Jun-Aug 2026	Given the robust 9-month uPCR data from the interim analysis, we expect that overall 2-year eGFR should be positive. Meanwhile the impact of Voyxact's anti-drug antibody remains uncertainty for the drug's long-term potential.
		Disclosure of final 2-yr eGFR data from Ph3 VISIONARY at ASN Kidney Week 2026	Oct-26	The details of the final 2-yr eGFR data presentation.
		Filing of the final Ph3 data with auto-injector for full approval	2H 2026	The timing should allow Otsuka to launch the auto-injector right around the time Vertex povetacicpet enters the market in 2027.
	Centanafadine	FDA approval for ADHD	Jul-26	Based on positive Ph3 data for across pediatric and adult patients, it is likely that the drug will be approved for ADHD. PDUFA Jul 24th. If the drug is considered stimulant (our and the company's base case is non-stimulant), max 3-mon DEA review would follow the regulator decision before the launch.
	Ulotaront	Topline readout of Ph3 for schizophrenia	Oct-26	After failing in two Ph3s for the indication, uncertainty for the ongoing Ph3's outcome is high. Yet Otsuka seems to believe in the potential of the drug and confident that they can develop it better on their own without Sumitomo
		Initiation of of Ph3 for generalized anxiety disorder	2026	Based on Ph2/3 (the data yet to be disclosed), Otsuka has decided to proceed with the Ph3 for GAD. Meanwhile, they decided not to pursue major depressive disorder with ulotaront
	Zipalertinib	Topline readout of Ph3 REZILIENT3 for 1L EGFR exon 20 insertion NSCLC	4Q 2026	The EGFR TKI is being tested in the setting in combination with platinum chemo vs the chemo alone. We assume PoS 70% based on the earlier data in pretreated EGFR exon 20 insertion NSCLC patients.
	Rexulty	IRA Medicare price negotiation	Sep-Nov 2026	Reculti is part of this year's IRA Medicare price negotiation. The negotiated Maximum Fair Price will be applied to the drug in Jan 2028

Source: Company reporting, ClinicalTrials.gov, Bernstein analysis

SHIONOGI: MARKET-PERFORM, PT=JPY3,000

Shionogi 4QFY25: The fruit from the three deals is not coming as soon as we had anticipated

Shionogi post 4QFY25: No post-merger upside yet as cost cut has to wait till FY27 and they invest in US Radicava and Xocova

OUR LATEST VIEW ON THE NAME

We were unimpressed by Shionogi's slower-than-expected cost optimization plan and uncompelling investments in Radicava and Xocova launch in the US. Hope for Zatolmilast's fragile X syndrome opportunity has now dimmed. We don't see any potential upside risk for the next 12 months and recommend it for funding short.

KEY TAKEAWAYS FROM 4QFY2025 EARNING AND FY2026 GUIDANCE

4QFY25 OP was a major miss, due to SG&A 30%+ higher than cons. The bottomline profit was salvaged by higher finance income, where most of the delta came from higher-than-expected ViiV dividend and increase of overseas investment gain including FX impact.

FY26 profit guidance was lower than expected due to higher SG&A cost, despite higher topline. The main gap came from SG&A expense, which reflects investment in the US Radicava business (JPY20Bn+) and the US launch of Xocova for COVID prevention (~JPY20Bn, PDUFA on June 16). The CEO explained that the SG&A cost guidance has "some buffer" as they want to make sure to deliver the OP guidance and plan to refine the US plans.

Hope for zatolmilast for fragile X syndrome has faded, and Shionogi is going back to a drawing board for a new regulatory strategy. The drug's two Ph3s, CNS-301 for adults and 204 for pediatric patients did not deliver positive readout despite that FDA had allowed them to change the latter's primary endpoint based on the former's outcome. Management thinks that realistic next steps should be a new Ph3 with revised trial design which will be determined based on the ongoing data analysis of CNS-301 and 204. While the drug's Ph2 for Jordan syndrome (an ultra-rare neurodevelopmental disorder caused by genetic mutations) is expected to read out in 2QFY26, this drug will likely won't reach the market for the foreseeable future. To utilize the rare disease commercial operation resources acquired through the Radicava deal, Shionogi is currently in discussion for a rare disease asset, according to the company.

KEY CONTROVERSIES

No post-merger upside in FY26 as cost cut has to wait till FY27 and they invest in US Radicava and Xocova

We thought Radicava would be a cash cow, but Shionogi thinks otherwise and intends to invest c. JPY20Bn for the ALS drug in FY26. They plan for disease awareness activities to drive earlier referral/diagnosis (e.g., DTC) and real-world evidence generation vs first-line generics so that Radicava becomes a first-line treatment of choice. US Radicava team argues for another leg of growth for the coming 2–3 years with proper funding. They are also investing in US Xocova launch for COVID prevention. The management probably knows that the drug's commercial potential should not be as high as Pfizer's Paxlovid which sold USD2.4Bn in 2025: Shionogi's drug is not for COVID treatment but rather for those who have had close contact with COVID patients to prevent infection and severe disease, and the pandemic feels a distant memory. Yet they likely see this launch as an important step for their global business expansion and justify the investment. The key is how timely they can determine the drug's viability and adjust their spending.

NEAR-TERM KEY EVENTS (EXHIBIT 9)

Catalyst
Non-catalyst key event

	Topic	Key event/catalyst	Timeline	Comment
Catalysts and key events in FY2026	Zatolmilast	Ph2 readout for Jordan's syndrome	2Q FY2026	The trial has reached last-patient-in and is expected to read out the topline in 2Q

Source: Company report, ClinicalTrials.gov, Bernstein analysis

ASTELLAS: MARKET-PERFORM, PT=JPY2,200

Astellas 4QFY2025: 4Q beat came from non-strategic brands. No surprise from FY26 guidance.

AMRAHPIOIB NAPAL

path

Astellas post 4QFY25 IR discussion: As Yoshii's "beginning of the end" approach, not enough drivers to chart a regrowth

OUR LATEST VIEW ON THE NAME

We think that Astellas can no longer excite the market with better-than-expected performance of mature products, i.e., Xtandi and Myrbetriq. While being positive about their continuing cost optimization efforts under CFO's leadership, we are lukewarm about their post-Xtandi growth drivers, Izervay in particular. Plus the pipeline hopefuls should face touch competition: Revolution Medicine's (not covered) daraxonrasib, a pan-RAS inhibitor, will likely set a high bar in PDAC before Astellas's setidegrasib, KRAS G12D targeted protein degrader will get Ph3 readouts towards the end of the decade. From now on, we expect little upside through the end of the decade unless the new MTP, which is due next Tue, May 26, significantly changes the trajectory view. We will host post-MTP discussion with the CEO, Mr Naoki Okamura on Thu, May 28 at 2pm HKT—please join us, LINK.

KEY TAKEAWAYS FROM 4QFY2025 EARNINGS AND FY2026 GUIDANCE

Astellas beat consensus, with a topline beat driven by Myrabetriq, to which the market no longer reacted positively. Myrbetriq's beat derived from the Gx settlement reached with Lupin and Zydus (not covered): there was a one-time royalty payment for the amount the Gx companies had sold in the market prior to the agreement.

Astellas's initial FY26 guidance was in-line with consensus for top-line and core OP. Astellas estimates JPY40Bn cost saving from ongoing Sustainable Margin Transformation in FY26. They explained that some of the saving is expected to come from items that they have invested in, e.g., operational productivity improvement from back office consolidation, in-house promotion material production.

Prior to the US LOE in 2027, the company braces for Xtandi's "beginning of the end" this year. While expecting the last stretch in EU and Japan, the company projects the drug's global sales should start declining (-JPY50Bn vs FY2026) due to US IRA Medicare price discount to be implemented in Jan 2027 (estimated impact of USD200Mn for 4Q) and LOEs in China Brazil, Turkey and South Korea.

KEY CONTROVERSIES

We will know next Tuesday whether Astellas present compelling paths for 30% OPM in 2027 and post Xtandi LOE regrowth in the new MTP.

Astellas will present their 2026–2030 mid-term plan next Tuesday, May 26. 30% OPM in 2027 and post-Xtandi LOE regrowth are two key points in the new plan, which are better than today's consensus. As for the 30% OPM in 2027, the company will have to show significant SG&A cut while ramping up R&D investment. This is of particular interest because of the close timeline. Given that Kitamura CFO's skillful expectation management so far (i.e., conservative guidance, multiple upward revisions), we expect that the plan should be meant to be delivered. Regarding the post-Xtandi LOE regrowth path, it should require higher-than-expected growth from Padcev and Izervay as their oncology pipeline assets (e.g., KRAS targeted protein degraders) should not start making meaningful contribution by the end of the decade. Yet for this, they have some time before hitting the timeline.

Revolution Medicines (not covered) is likely setting a high bar in PDAC against Astellas's KRAS targeted protein degrader.

Daraxonrasib, Revolution's pan-RAS inhibitor, has reported a strong Ph3 topline for 2L+ PDAC (60% OS risk reduction vs chemo) regardless of RAS mutation, and its ongoing Ph3 for 1L is expected to read out one year before Astellas setidegrasib's Ph3 interim analysis for KRAS G12D patients in 2029. Astellas thinks that setidegrasib's potential differentiation is safety/tolerability, not efficacy. Please check out our recent published primer of KRAS-targeted therapies, LINK.

NEAR-TERM KEY EVENTS (EXHIBIT 10)

Catalyst
Non-catalyst key event

	Topic	Key event/catalyst	Timeline	Comment
Catalysts and key events in FY2026	Mid-Term Plan	2026-2030 MTP disclosure	May-26	Astellas plans to disclose their 2026-2030 mid-term plan where the company intends to show paths for OPM 30% in 2027 and post-Xtandi LOE regrowth by 2030. These are above today's consensus.
	ASP3082/ setidegrasib	Data presentation of Revolution daraxonrasib's Ph3 for pre-treated PDAC at ASCO 2026	May-26	Abstract will be out on Thursday, May 21st in the US time. Revolution has already announced a positive topline readout from Phase 3 RASolute 302 for pretreated PDAC: a median OS of 13.2 months versus 6.7 months for chemotherapy, with a hazard ratio of 0.40 ($p < 0.0001$). Daraxonrasib's strong data should set a high bar for setidegrasib
		CRC PoC data	2026	The company plans to judge PoC of the drug's CRC indication in 4QFY2025, and the Ph1 data should be disclosed sometime later.
	Xtandi	Implementation of IRA Medicare Maximum Faire Price	Jan-26	The negotiated 2027 MFP is USD7,004, 48% discount vs 2024 30-day list price of USD13,480

Source: Company reports, ClinicalTrials.gov, ASCO 2026, Bernstein analysis

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