Otsuka Pharmaceutical / Otsuka Holdings

Deep Dive Research Report | March 11, 2026
Prepared by Ada Cockpit Research

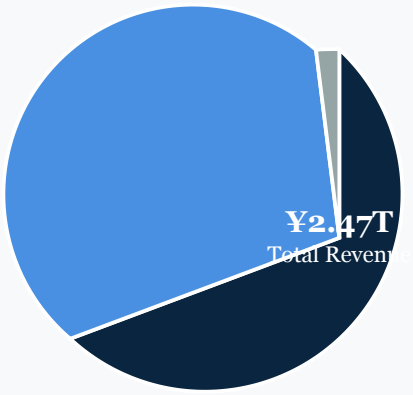
Executive Summary

FY2025 REVENUE	OPERATING PROFIT	NET INCOME
¥2.47T	**¥479.4B**	**¥363.2B**
+6.0% YoY	+48.2% YoY	+5.8% YoY

EMPLOYEES
35,338
Consolidated

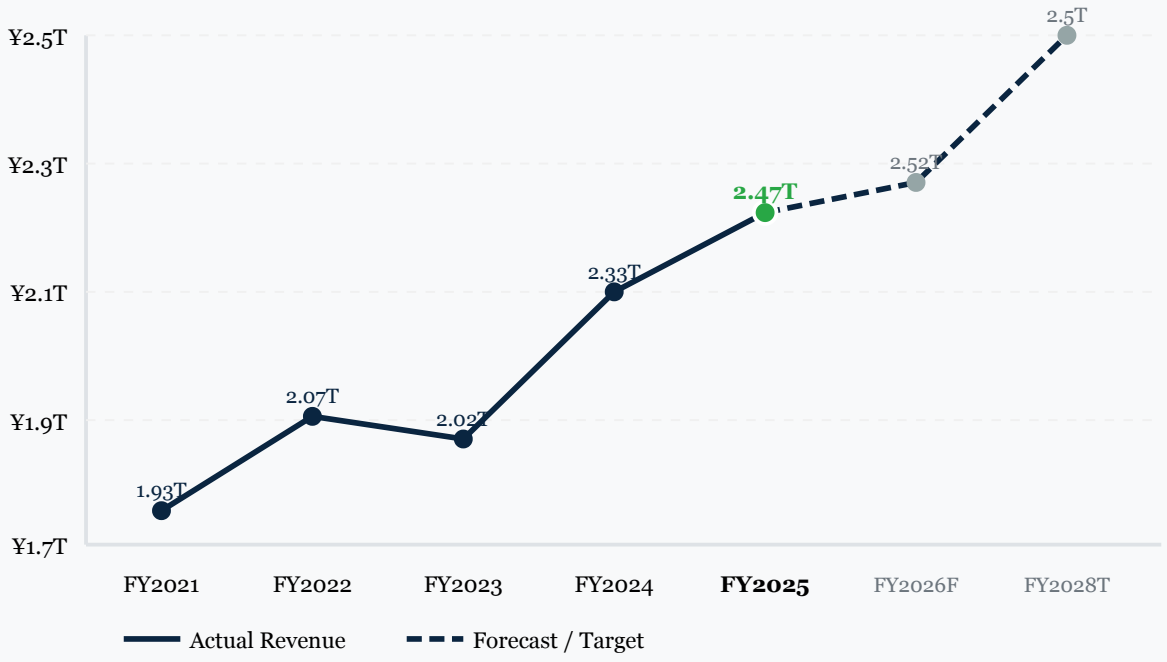
Company Overview: Otsuka Holdings (TSE: 4578) is a global pharmaceutical and nutraceutical company headquartered in Tokyo, Japan. Founded in 1921 by Busaburo Otsuka and formally established as Otsuka Pharmaceutical in 1964, the company operates across CNS/psychiatry, nephrology, oncology, rare diseases, and consumer health. Market cap: $34-36 billion USD as of March 2026.

Revenue Mix by Business Segment (FY2025)



- Pharmaceuticals (70.7% | ¥1,744B)
- Nutraceuticals (23.4% | ¥578B)
- Other (5.9% | ¥147B)

Revenue Growth Trajectory (FY2021-FY2028 Target)



Forward-Looking Statement: This report contains forward-looking statements based on current expectations and available data as of March 2026. Actual results may differ materially due to risks outlined in the Risks and Challenges section, including patent expiries, regulatory uncertainties, competitive dynamics, foreign exchange fluctuations, and pipeline execution risks.

Strategic Position

Otsuka faces a critical inflection point in 2026-2027 as three major products lose patent exclusivity:

- **Abilify Maintena** (aripiprazole LAI): Patent EXPIRED October 2024; generic competition active
- **Rexulti** (brexpiprazole): Patent expires March 2026; forecasted 70-80% revenue erosion by 2028
- **Jynarque** (tolvaptan): US patents expire September 2026; generic entry estimated April 2030

Company guidance indicates **¥310 billion revenue headwind** from loss of exclusivity (LOE) events, driving forecasted FY2026 operating profit decline of 24.9% to ¥360B and net income decline of 27% to ¥265B.

Growth Drivers

- **Sibeprenlimab (Voyxact)**: First-in-class anti-APRIL antibody for IgA nephropathy; FDA approved November 25, 2025; peak sales potential $500M-1B+
- **Centanafadine**: Novel NDSRI for ADHD; NDA under FDA priority review with PDUFA date July 24, 2026; peak potential $500M-1.5B
- **Ulotaront**: TAAR1 agonist for schizophrenia/MDD; Phase 3 ongoing via $890M Sunovion partnership; peak potential $1-3B if approved
- **Nutraceutical Expansion**: Pocari Sweat Asia-Pacific growth and Nature Made e-commerce targeting ¥620B by FY2028 (from ¥578B FY2025)

Medium-Term Plan (2024-2028)

The 4th Medium-Term Management Plan targets **¥2.5 trillion revenue by FY2028**, requiring ¥480B growth from FY2023 baseline (¥2.02T) to offset ¥310B LOE impact. Key financial targets include ROIC ≥9.5%, ROE ≥10%, and total investment of ¥3.2 trillion (¥1.5T R&D, ¥500B capex, ¥1.2T M&A).

Drug Portfolio: CNS/Psychiatry Products

Product	Indication(s)	FY2025/Latest Revenue	YoY Growth	Patent/Exclusivity Status	Peak Sales Potential
Rexulti (brexpiprazole)	Schizophrenia, MDD adjunctive, Alzheimer's agitation	DKK 4,695M (~$900M-1B) 9mo 2025	+26% (CER)	**US/EU patents expire Mar 2026**	$1.5-2.0B (pre-LOE)
Abilify Maintena (aripiprazole LAI)	Schizophrenia, Bipolar I	Est. $1.0-1.5B (2024)	-12% (est.)	**EXPIRED Oct 2024**	Declining to $459M by 2029
Abilify Asimtufii (aripiprazole 2-mo LAI)	Schizophrenia	<$100M (new launch)	New (approved 2023)	Patent protected through 2030s	$500M-1B
Ulotaront (SEP-363856)	Schizophrenia (Phase 3), MDD (Phase 3 initiating)	Pipeline; no revenue	N/A	Patent protected; first-in-class TAAR1	$1-3B (if approved)
Centanafadine	ADHD (NDA review)	Pipeline; PDUFA July 24, 2026	N/A	Patent protected; orphan designation	$500M-1.5B (est.)

P&L Ownership: Rexulti and Abilify Maintena are co-marketed with Lundbeck (US: 80/20 profit split Otsuka/Lundbeck; EU5+Nordics+Canada: 50/50). Ulotaront is co-developed with Sunovion (50/50 profit share). Centanafadine is 100% Otsuka-owned.

Drug Portfolio: Nephrology, Oncology, Rare Disease

Product	Indication(s)	FY2025/Latest Revenue	YoY Growth	Patent/Exclusivity Status	Peak Sales Potential
Jynarque/Samsca (tolvaptan)	ADPKD, hyponatremia	¥227.2B ($1.5B) FY2022	+18.1% (FY2022)	**US patents expire Sep 2026**	Declining post-2026 LOE
Sibeprenlimab (Voyxact)	IgA nephropathy	**FDA approved Nov 25, 2025**	Launch phase	Patent protected; first-in-class anti-APRIL	$500M-1B+ (TAM $6-10B)
Lonsurf (trifluridine/tipiracil)	mCRC, gastric cancer	¥62.5B ($420M) FY2023	+8.7% (FY2023)	Patent protected through late 2020s	$600M-800M
Repinatrabit (JNT-517)	Phenylketonuria (PKU)	Pipeline; Phase 3 initiated Dec 2025	N/A	Orphan drug designation; patent protected	$300M-500M (orphan market)
Pocari Sweat	Electrolyte beverage (nutraceutical)	Part of ¥578B nutraceutical segment	+1.6% (H1 FY2025)	N/A (consumer product)	¥150-200B annually

P&L Ownership: Lonsurf is owned and commercialized by Taiho Pharmaceutical (100% Otsuka subsidiary). Jynarque, Sibeprenlimab, and Repinatrabit are 100% Otsuka-owned with no co-marketing partnerships.

Ada Patient Finder Analysis: Top Opportunities

Methodology: Ada Patient Finder fit evaluated on 6 criteria: diagnostic delay, underdiagnosis prevalence (>20% target), per-patient net revenue (>$10K/year threshold), Ada symptom surfacing capability, addressable market size, and label breadth. Scores range 1-10.

Drug	Indication	Fit Score	Per-Patient Revenue (Net)	Diagnostic Delay	Underdiagnosis %	Addressable Pool (US)
Rexulti	Schizophrenia, MDD	8/10	$10K-12K/year	4 years (MDD) 11 months (schizophrenia)	29-30%	2-3M (MDD) 300K-500K (schizophrenia)
Ulotaront	Schizophrenia (pipeline)	7/10	$10K-13K/year (est.)	11 months median	29%	300K-500K undiagnosed
Jynarque	ADPKD	6/10	$110K-130K/year	5 months (from first sign) Late presentation in 30s-40s	30-40%	180K-540K undiagnosed
Sibeprenlimab	IgA nephropathy	5/10	$120K-150K/year (est.)	5 months median	20-30%	25K-40K undiagnosed

Priority Recommendations

URGENT: Rexulti (Pre-LOE Only)
Patent expires March 2026. Execute patient-finding campaigns immediately (Q1-Q2 2026) targeting MDD adjunctive therapy (larger pool, 4-year diagnostic delay). Focus on psychiatrists and primary care with depression screening. Post-March 2026, generic erosion reduces fit score to 2/10 (revenue falls below $10K threshold).

High Priority: Jynarque (Pre-Sep 2026)
Highest per-patient revenue in portfolio ($110K-130K/year). Target symptomatic undiagnosed patients presenting with flank pain + hematuria + hypertension + family history. Partner with nephrologists and primary care for urine testing campaigns. Early disease is asymptomatic, limiting Ada surfacing to symptomatic subset. US patent expiry September 2026 creates urgency.

Now: Sibeprenlimab (Voyxact)
FDA approved November 2025; no LOE concerns for decades. Very high revenue ($120K-150K/year estimated). Focus on patients with gross hematuria episodes (especially post-URI) or persistent foamy urine. Requires kidney biopsy for diagnosis, so Ada role is symptom-to-referral (not diagnosis). IgAN market crowding (Filspari, Tarpeyo, atacicept, povetacicept) requires differentiation messaging.

Pipeline Watch: Ulotaront (2027-2028)
If Phase 3 successful and FDA approved, strong fit similar to Rexulti (8/10 score potential). Novel TAAR1 mechanism differentiated from existing antipsychotics. Prepare launch strategy targeting same diagnostic delay stats (11-month schizophrenia delay, 29% underdiagnosis). 50/50 profit share with Sunovion reduces Otsuka upside vs. wholly owned assets.

Excluded from Patient Finder

- **Abilify Maintena:** Patent EXPIRED Oct 2024; generic competition reduces branded revenue to <$5K/year (below threshold)
- **Centanafadine (ADHD):** Strong diagnostic delays (10-15 years for adults, 55.9% diagnosed age 18+) BUT per-patient revenue $2.5K-3.5K/year << $10K threshold; economics don't justify premium patient-finding fees
- **Lonsurf (mCRC):** Later-line oncology; patients already diagnosed and in oncology care; no underdiagnosis at 3rd+ line therapy stage
- **Repinatrabit (PKU):** Universal newborn screening in developed countries = no underdiagnosis; diagnosed within days of birth

Key Risks and Challenges

Risk Category	Specific Risks	Impact Level	Timeframe
Patent Cliffs	Abilify Maintena (EXPIRED Oct 2024), Rexulti (Mar 2026), Jynarque (Sep 2026); ¥310B revenue headwind	**CRITICAL**	2024-2027
Regulatory Uncertainty	Centanafadine PDUFA July 2026 (approval risk); Ulotaront Phase 3 outcomes; Rexulti Alzheimer's CRL demonstrates approval unpredictability	**HIGH**	2026-2028
Competition	CNS: generic aripiprazole, Vraylar, Caplyta; IgAN: Filspari, Tarpeyo, atacicept, povetacicept; mCRC: Stivarga, checkpoint inhibitors	**HIGH**	Ongoing
Pricing Pressure	US IRA drug price negotiation (Jynarque exposed); Japan biennial price cuts; EU HTA scrutiny	**HIGH**	2026+
FX Volatility	70% revenue outside Japan; yen strength creates headwinds (recent yen weakness provided FY2025 tailwind)	**MODERATE**	Ongoing
Pipeline Execution	Limited R&D productivity (3 major approvals in 3 years despite ¥1.5T investment); acquisition integration risk (Jnana, Visterra)	**MODERATE**	2024-2028

Valuation and Peer Comparison

Company	Market Cap (USD)	FY Revenue (USD)	P/E Ratio	Primary Focus
Takeda Pharmaceutical	$40-45B	~$30B	12-14x	Oncology, GI, Rare Diseases, Vaccines
Daiichi Sankyo	$80-90B	~$10B	25-30x	Oncology (Enhertu ADC), Cardiovascular
Eisai	$25-30B	~$6B	15-20x	Alzheimer's (Leqembi), Oncology
Otsuka Holdings	**$34-36B**	**$16.16B**	**14-15x**	**CNS, Nephrology, Nutraceuticals**
Astellas Pharma	$20-25B	~$12B	10-12x	Urology, Oncology, Immunology

Valuation Analysis: Otsuka trades at 14-15x P/E, representing a **40-50% discount to Daiichi Sankyo** (25-30x) due to imminent LOE headwinds vs. Daiichi's Enhertu blockbuster growth trajectory. Conversely, Otsuka commands a **premium to Takeda** (12-14x) reflecting lower debt burden (Otsuka minimal debt vs. Takeda's Shire acquisition leverage) and stronger profitability margins (~18% business profit margin vs. Takeda ~15-16%). The multiple is in-line with Eisai (15-20x), reflecting comparable pipeline execution risk.

Investment Scenarios

Scenario	Key Assumptions	FY2028 Market Cap	P/E Multiple
Bull Case	Sibeprenlimab + centanafadine successful launches; ulotaront Phase 3 success; nutraceutical ¥620B achieved; LOE offset complete	$45-50B	18-20x
Base Case	Revenue ¥2.3-2.4T (short of ¥2.5T target); operating margin recovers to 17-18% by 2028; moderate pipeline success	$35-40B	13-15x
Bear Case	Generic erosion exceeds forecasts (-80%+ Rexulti/Abilify); pipeline failures (ulotaront, centanafadine CRLs); FX headwinds	$25-30B	10-12x

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