

Conference on Q2 FY2026 **(April 1, 2026 to September 30, 2026)** **Financial Results**

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Sumitomo Pharma Co., Ltd.

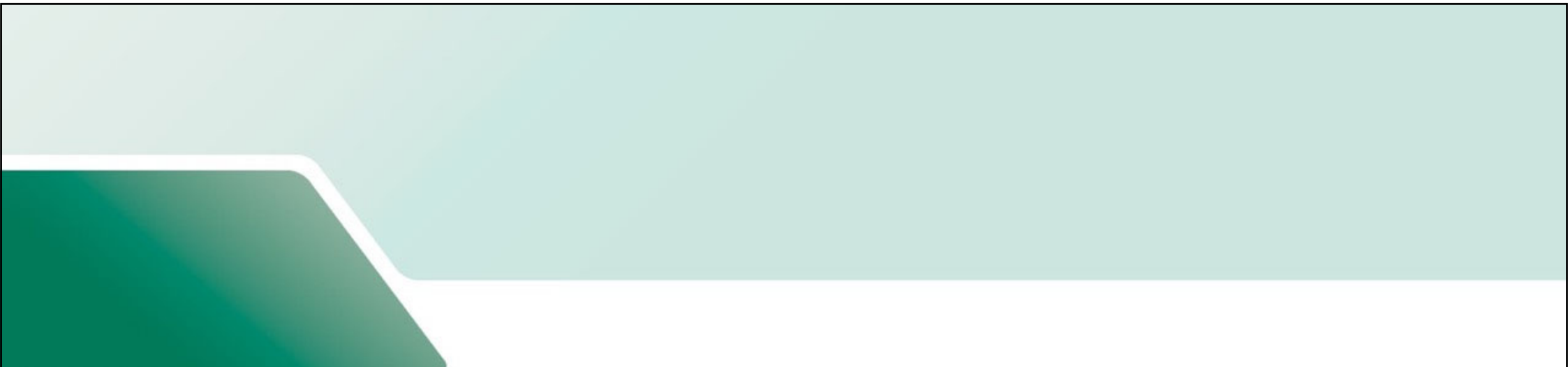
October 30, 2026

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This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties.

Accordingly, due to various subsequent factors, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals and other products (including those under development) contained herein is not intended as advertising or as medical advice.



Financial Results for Q2 FY2026

Financial Results for Q2 FY2026

Financial Results for Q2 FY2026 (Core Basis)

The forecasts for FY2026 were revised
(See P.8)

Billions of JPY

	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change			FY2026	
			Value	FX Impact	%	July 31 1H Forecasts	Progress %
Revenue	227.1	266.5	39.4	17.8	17.3	251.0	106.2
Cost of sales	89.7	123.5	33.8	8.1	37.7		
Gross profit	137.4	143.0	5.5	9.7	4.0		
SG&A expenses	74.0	78.3	4.4	3.9	5.9		
R&D expenses	17.5	23.8	6.3	1.4	35.9		
Others (core basis)	50.1	1.2	(48.9)				
Core operating profit	96.1	42.1	(54.0)	4.3	(56.2)	30.0	140.4
Adjustment items (negative number indicates net expense)	0.1	0.2	0.1				
Operating profit	96.2	42.3	(53.9)		(56.0)	30.0	140.9
Finance income/costs	(3.4)	(2.9)	0.5				
Profit before taxes	92.8	39.4	(53.4)		(57.6)		
Income tax expenses	(6.1)	1.1	7.2				
Net profit attributable to owners of the parent	98.9	38.2	(60.6)		(61.3)	26.0	147.1

Average rates:

Q2 FY2025 Results : 1US\$ = ¥146.03

Q2 FY2026 Results : 1US\$ = ¥159.49

FY2026 forecasts : 1US\$ = ¥155.00

Period end rates:

As of the end of March 2026 : 1US\$ = ¥159.90

As of the end of September 2026 : 1US\$ = ¥157.31

Year-on-year

- **Revenue**
Revenue increased primarily due to growth in the U.S., which more than offset the decline resulting from the partial transfer of the Asian business
- **Gross profit**
Gross profit margin decreased mainly due to the partial transfer of the Asian business
- **R&D expenses**
R&D expenses increased due to accelerated clinical development in oncology and advancement of programs in CNS

Vs. 1H Forecast

- **Core operating profit exceeded the forecast due to higher-than-expected sales revenue**

Financial Results for Q2 FY2026

Revenue of Major Products in the U.S.

	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change			FY2026		
						Value	FX Impact	%	May 13 Forecasts		JPY-basis Progress %
U.S.	Millions of USD			Billions of JPY					Millions of USD	Billions of JPY	
ORGOVYX®	473	681	207	69.1	108.6	39.4	9.2	57.0	1,354	209.9	51.7
GEMTESA®	297	407	110	43.4	64.9	21.5	5.5	49.6	686	106.3	61.0
MYFEMBREE®	43	58	15	6.3	9.3	3.0	0.8	46.8	100	15.4	60.5
RETHYMIC®	22	20	(3)	3.3	3.1	(0.2)	0.3	(5.5)	35	5.4	57.8
APTiom®	73	16	(57)	10.7	2.5	(8.1)	0.2	(76.2)	35	5.4	47.1
Others*	163	59	(105)	24.2	9.4	(14.8)	0.8	(61.3)	412	63.9	14.6
Total	1,073	1,240	167	157.0	197.8	40.8	16.7	26.0	2,622	406.4	48.7

Average rates:

Q2 FY2025 Results : 1US\$ = ¥146.03

Q2 FY2026 Results : 1US\$ = ¥159.49

- ORGOVYX® and GEMTESA® revenue increased significantly year-on-year
- APTiom® revenue decreased due to loss of exclusivity
- The prior-year for "Others" includes sales milestone revenue related to ORGOVYX®

* Major items included in Others

Q2YTD FY 2025 Results	Deferred revenue from the collaboration with Pfizer Sales milestone revenue related to ORGOVYX® (sales exceeding \$0.5B)	\$44M \$100M	Q2YTD FY 2026 Results	Deferred revenue from the collaboration with Pfizer	\$44M
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FY2026 May 13 Forecasts	Deferred revenue from the collaboration with Pfizer Sales milestone revenue related to ORGOVYX® (sales exceeding \$1.0B)	\$65M \$325M
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Financial Results for Q2 FY2026

Revenue of Major Products in Japan

Billions of JPY

	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change		FY2026	
			Value	%	May 13 Forecasts	Progress %
Japan						
XEPLION®/XEPLION TRI®	—	8.2	8.2	—	17.1	48.0
LATUDA®	6.9	7.3	0.4	5.2	13.6	53.3
TWYMEEG®	5.0	6.6	1.6	31.4	11.9	55.1
METGLUCO®	3.7	3.8	0.1	2.8	7.6	49.9
Equa®/EquMet®	7.5	—	(7.5)	—	—	—
AG products	6.1	5.9	(0.1)	(1.9)	11.2	53.1
Others	13.7	12.9	(0.8)	(6.0)	26.2	49.2
Total	42.8	44.6	1.8	4.2	87.6	51.0

- Commencement of sales of XEPLION®/XEPLION TRI®
- Continued sales growth of TWYMEEG®
- Termination of sales partnership for Equa®/EquMet®

Note: Sales of each product are shown by invoice price

Financial Results for Q2 FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
Q2YTD FY2026 Results	Revenue	44.6	197.8	24.1	266.5
	Cost of sales	25.0	78.1	20.4	123.5
	Gross profit	19.6	119.7	3.6	143.0

Q2YTD FY2025 Results	Revenue	42.8	157.0	27.3	227.1
	Cost of sales	21.9	56.9	10.9	89.7
	Gross profit	21.0	100.1	16.3	137.4

Change	Revenue	1.8	40.8	(3.2)	39.4
	Cost of sales	3.1	21.2	9.5	33.8
	Gross profit	(1.3)	19.5	(12.7)	5.5

Japan

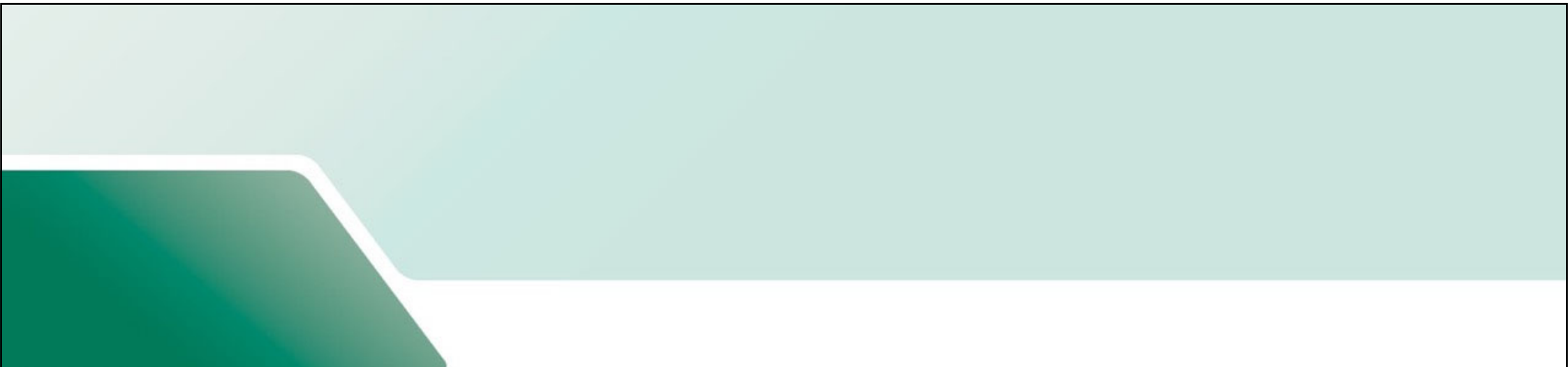
- Gross profit decreased due to the change in product mix

U.S.

- Gross profit increased due to higher revenue

Other

- Gross profit decreased due to the partial transfer of the Asian business



Financial Forecasts for FY2026

Financial Forecasts for FY2026

Financial Forecasts for FY2026 (Core Basis)

Billions of JPY

	FY2026 May 13 Forecasts	FY2026 Revised Forecasts	Change from Previous Forecasts		
			Value	FX Impact	%
Revenue	540.0	565.0	25.0	6.1	4.6
Cost of sales	245.0	246.0	1.0	3.1	0.4
Gross profit	295.0	319.0	24.0	3.0	8.1
SG&A expenses	155.0	164.0	9.0	1.5	5.8
R&D expenses	51.0	52.0	1.0	0.4	2.0
Others (core basis)	2.0	2.0	—		
Core operating profit	91.0	105.0	14.0	1.1	15.4
Adjustment items (negative number indicates loss)	(1.0)	(1.0)	—		
Operating profit	90.0	104.0	14.0		15.6
Finance income/costs	(6.5)	(5.0)	1.5		
Income tax expenses	6.5	5.0	(1.5)		
Net profit	77.0	94.0	17.0		22.1
Net profit attributable to owners of the parent	77.0	94.0	17.0		22.1
R O E	20.3%	24.1%			
R O I C	15.1%	17.6%			

FX rates:

FY2026

Previous Forecasts : 1US\$ = ¥155.00

Revised Forecasts : 1US\$ = ¥157.00

- **Revenue:** Revised upward by ¥25.0B
U.S. +¥18.7B :
Higher sales forecast for GEMTESA®
Others +¥5.4B :
Higher forecast for sales to the EU
- **SG&A:**
Higher promotional spending and
licensing expenses in the U.S.

Dividend Reinstatement Planned for FY2026 Year-End
Year-end dividend forecast : ¥15 per share

Financial Forecasts for FY2026

Revenue of Major Products in the U.S.

	FY2026 May 13 Forecasts	FY2026 Revised Forecasts	Change	FY2026 May 13 Forecasts	FY2026 Revised Forecasts	Change		
						Value	FX Impact	%
U.S.	Millions of USD			Billions of JPY				
ORGOVYX®	1,354	1,359	5	209.9	213.4	3.5	2.7	1.7
GEMTESA®	686	752	66	106.3	118.0	11.7	1.5	11.0
MYFEMBREE®	100	109	10	15.4	17.1	1.7	0.2	11.0
RETHYMIC®	35	38	3	5.4	6.1	0.7	0.1	13.0
APTiom®	35	33	(2)	5.4	5.2	(0.2)	0.1	(3.7)
Others*	412	415	3	64.0	65.3	1.3	1.0	2.0
Total	2,622	2,708	86	406.4	425.1	18.7	5.6	4.6

* Major items included in Others

FY2026 May 13 Forecasts	Deferred revenue from the collaboration with Pfizer	\$65M	FY2026 Revised Forecasts	Deferred revenue from the collaboration with Pfizer	\$65M
	Sales milestone revenue related to ORGOVYX® (sales exceeding \$1.0B)	\$325M		Sales milestone revenue related to ORGOVYX® (sales exceeding \$1.0B)	\$325M

FX rates:

FY2026

Previous Forecasts : 1US\$ = ¥155.00

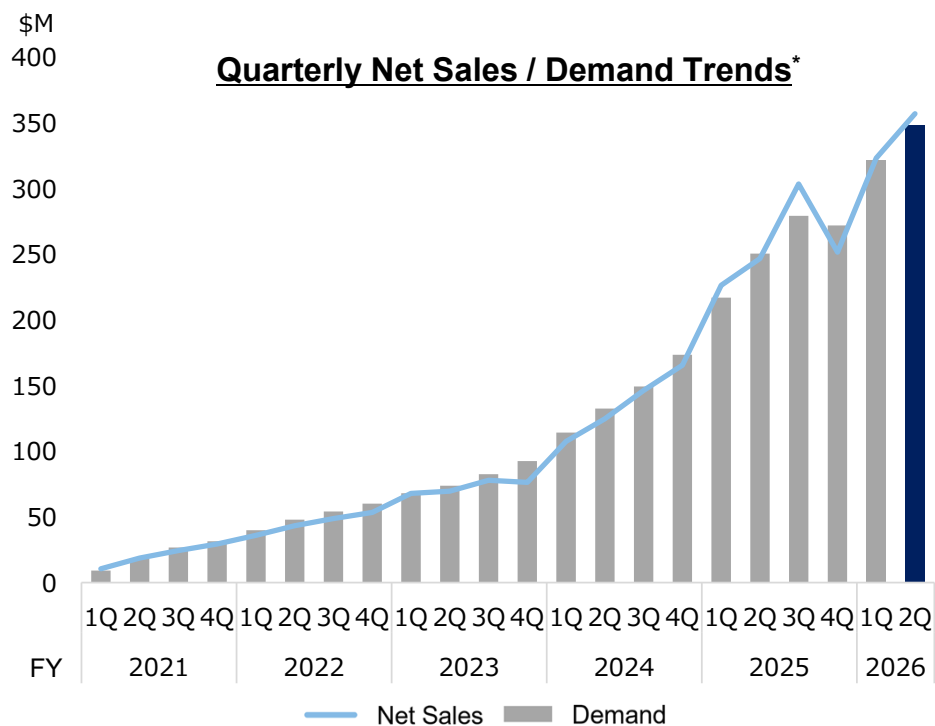
Revised Forecasts : 1US\$ = ¥157.00

■ GEMTESA® sales forecast revised upward to reflect favorable pricing in 1H

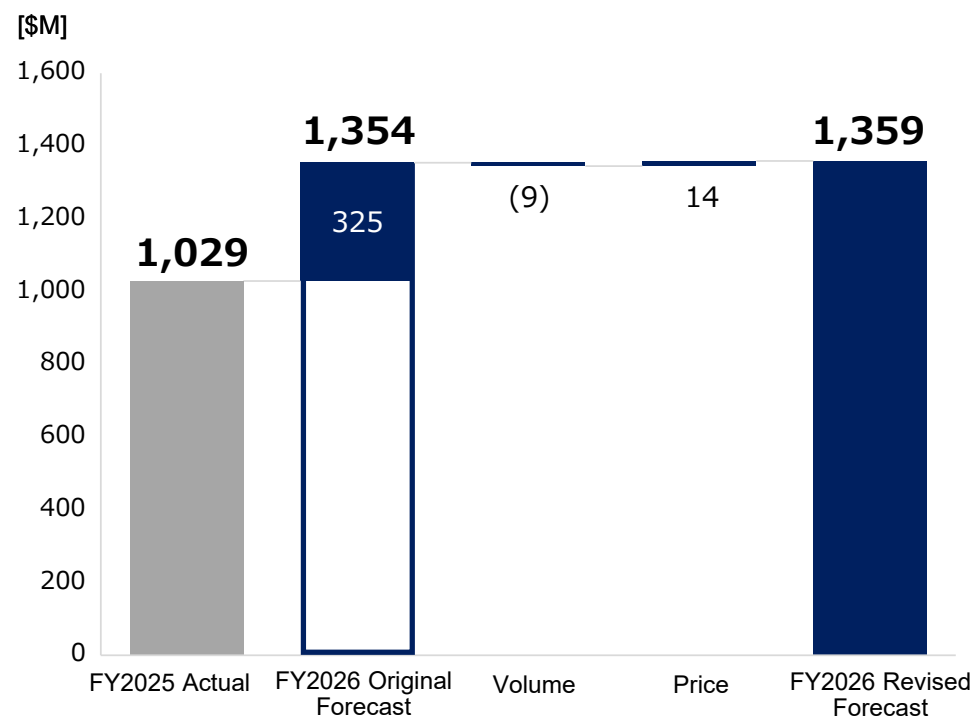
Financial Forecasts for FY2026

- Q2 YTD: Performed as planned and achieved 102% of net sales versus original forecast
Annual sales forecast revised upward to **\$1,359M (+\$5M)**

Plan for Q2 YTD FY2026	Actual for Q2 YTD FY2026	Year-over-year comparison
\$664M	\$681M (Achievement: 102%)	144%



Variance Analysis Between Original and Revised FY2026 Forecasts



Reference: YoY Growth: \$331M (+32%) — FY2026 (\$1,359M) vs. FY2025

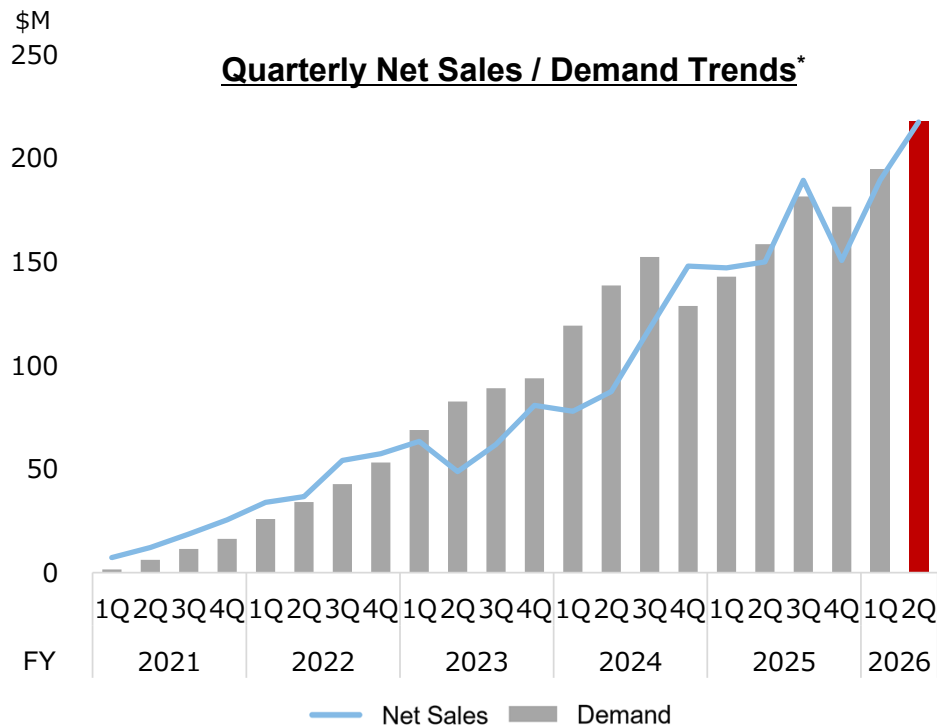
*Number of bottles (Internal calculation)

Financial Forecasts for FY2026

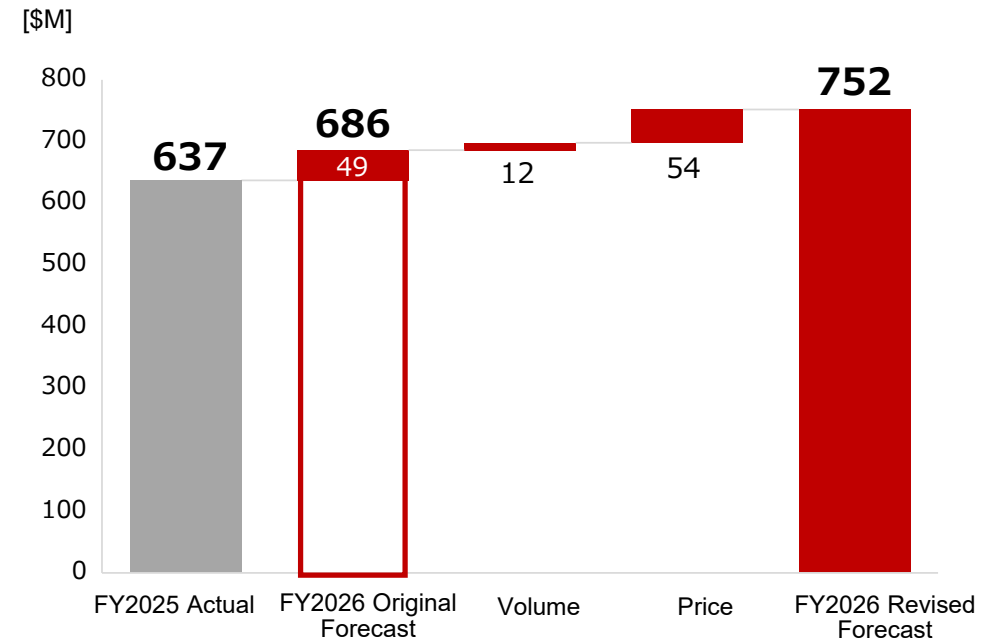


- Q2 YTD: Achieved 117% of net sales versus original forecast primarily driven by temporary pricing impacts
Annual sales forecast revised upward to **\$752M (+\$66M)**

Plan for Q2 YTD FY2026	Actual for Q2 YTD FY2026	Year-over-year comparison
\$347M	\$407M (Achievement: 117%)	137%



Variance Analysis Between Original and Revised FY2026 Forecasts



Reference: YoY Growth: \$115M (+18%) — FY2026 (\$752M) vs. FY2025

Financial Forecasts for FY2026

Gross Profit by Region (Core Basis)

Billions of JPY

		Japan	U.S.	Other	Total
FY2026 Revised Forecasts	Revenue	88.5	425.1	51.4	565.0
	Cost of sales	50.7	152.3	43.0	246.0
	Gross profit	37.8	272.8	8.4	319.0

FY2026 May 13 Forecasts	Revenue	87.6	406.4	46.0	540.0
	Cost of sales	52.1	152.7	40.2	245.0
	Gross profit	35.5	253.7	5.8	295.0

Change	Revenue	0.9	18.7	5.4	25.0
	Cost of sales	(1.4)	(0.4)	2.8	1.0
	Gross profit	2.3	19.1	2.6	24.0

Japan

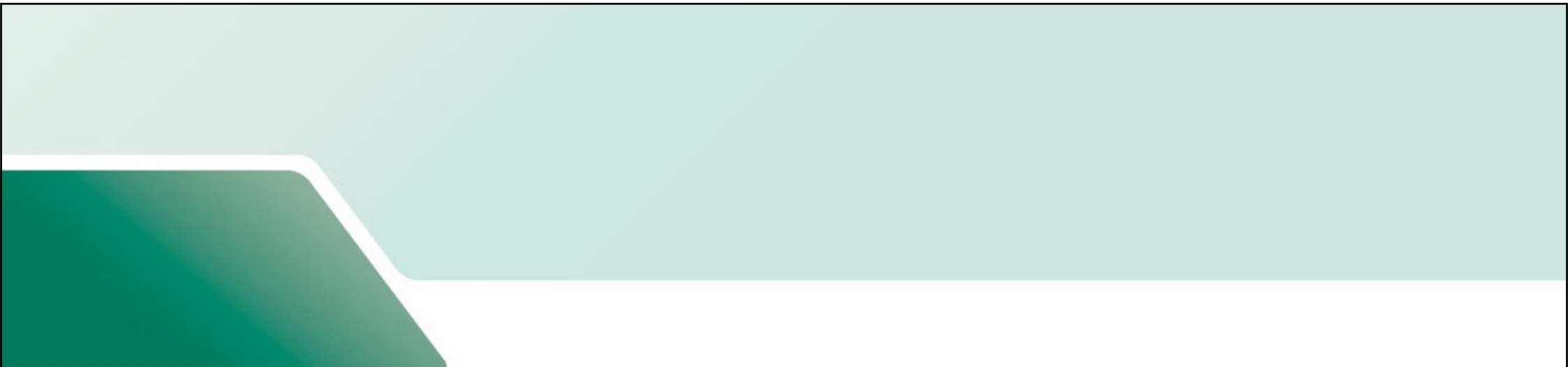
- Higher gross profit driven by upward revisions to TWYMEEG® sales forecast, with a limited increase in cost of sales

U.S.

- Higher gross profit mainly driven by pricing-driven revenue upside in 1H

Other

- Higher gross profit reflecting stronger sales to Europe



Research and Development

Research and Development

Development Pipeline (As of October 30, 2026)

Revisions since the announcement in July 2026 are shown in red

Area	Generic Name/Product Code	Mechanism of Action, etc.	Planned Indication(s)	Development Stage
Psychiatry & Neurology	DSP-0038	Serotonin 5-HT _{2A} receptor antagonist and serotonin 5-HT _{1A} receptor agonist	Alzheimer's disease psychosis	Phase 1
	DSP-0187	Selective orexin-2 receptor agonist	Narcolepsy	Phase 1
	DSP-3456	Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)	Treatment-resistant depression	Phase 1
	DSP-0378	Gamma-aminobutyric acid (GABA) _A receptor positive allosteric modulator	Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy	Phase 1
	DSP-2342	Serotonin 5-HT _{2A} and 5-HT ₇ receptor antagonist	To be determined	Phase 1
	DSP-0551	Multi-ion channel modulator	Tremor associated with Parkinson's disease	Phase 1
	CT1-DAP001/DSP-1083 (Japan)	Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells	Parkinson's disease	Post-marketing clinical study ongoing
	CT1-DAP001/DSP-1083 (U.S.)	Allogeneic iPS cell-derived dopaminergic neural progenitor cells	Parkinson's disease/Investigator-initiated clinical study, Company-sponsored clinical study	Phase 1/2
	HLCR011(Japan)	Allogeneic iPS cell-derived retinal pigment epithelial cells	Retinal pigment epithelium tear	Phase 1/2
	DSP-3077(U.S.)	Allogeneic iPS cell-derived retinal sheet	Retinitis pigmentosa	Phase 1/2
Oncology	Enzomenib	Selective menin inhibitor	Acute leukemia	Phase 2
	Nuvisertib	PIM1 kinase inhibitor	Myelofibrosis	Phase 1/2
	SMP-3124	CHK1 inhibitor	Solid tumors	Phase 1/2
	DSP-0390	EBP inhibitor	Glioblastoma	Phase 1
Others	KSP-1007	β-lactamase inhibitor	Complicated urinary tract and intra-abdominal infections, Hospital-acquired bacterial pneumonia	Phase 1
	fH1/DSP-0546LP	Split, Adjuvanted vaccine	Influenza virus prophylaxis	Phase 1

Major Topics in Clinical Development (August 1 – October 30, 2026)

● Psychiatry & Neurology

■ AMCHEPRY® / raguneprocel / CT1-DAP001 / DSP-1083

Parkinson's disease

Japan:

- First patient transplantation completed in the post-marketing clinical study (Phase 4 study) of allogeneic iPS cell-derived dopaminergic neural progenitor cells (See page 16 for details)

U.S. (CT1-DAP001/DSP-1083):

- Transplantations continued in the investigator-initiated study, and the first patient transplantation was completed in the company-sponsored study (both Phase 1/2 studies of allogeneic iPS cell-derived dopaminergic neural progenitor cells)

■ DSP-3077 (U.S.)

Retinitis pigmentosa

- Retinal sheet transplantation was performed in multiple patients in the Phase 1/2 study (see page 17 for details)

● Oncology

■ Enzomenib (U.S., Japan)

- Granted Breakthrough Therapy Designation in the U.S. for relapsed/refractory KMT2A-rearranged acute leukemia (October 21)

● Others

■ fH1/DSP-0546LP

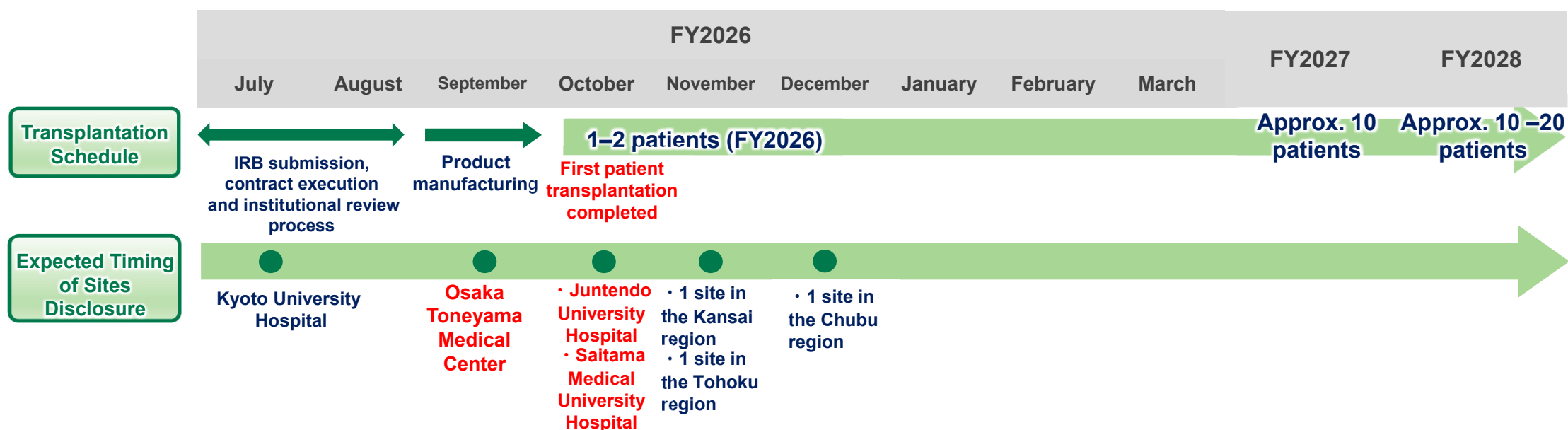
Universal influenza vaccine

- Final results from the Phase 1 study, including one-year follow-up, announced (see page 18 for details)

Research and Development

AMCHEPRY® Post-Marketing Clinical Study (Phase 4 Study) Schedule

- Advancing site activation and patient enrollment readiness for the Phase 4 study
- The first patient transplantation was completed at Kyoto University Hospital in October 2026
- Approximately 1–2 patients are planned in FY2026, approximately 10 in FY2027, and approximately 10–20 in FY2028
- Priority will be given to patients enrolled in the Phase 4 study. After study completion, treatment will expand to additional sites and a broader patient population



Please note that inquiries regarding the AMCHEPRY® post-marketing clinical study (Phase 4 study) are not accepted by participating medical institutions. Please contact us via our [corporate inquiry form](#)

Research and Development

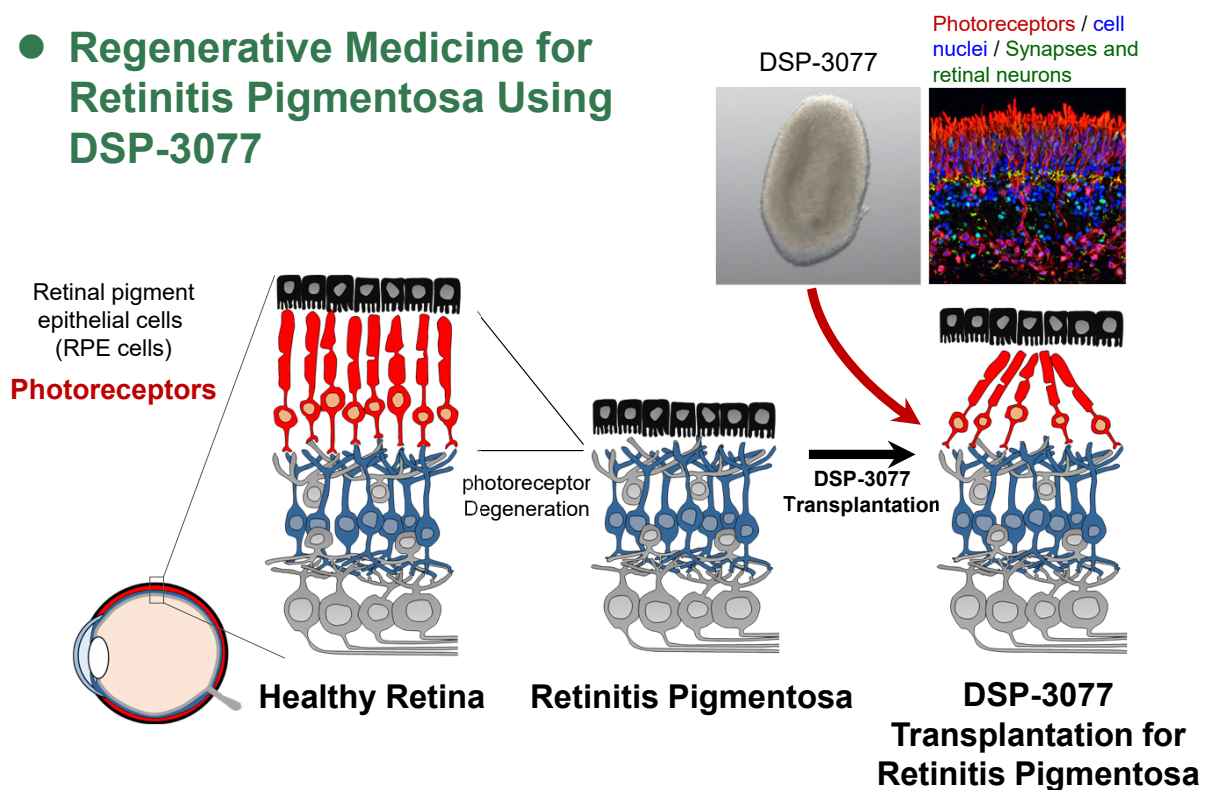
Psychiatry & Neurology: Allogeneic iPS Cell-Derived Retinal Sheet (DSP-3077) for Retinitis Pigmentosa

- ✓ Retinal sheet transplantation was performed in multiple patients in the U.S. Phase 1/2 study
- ✓ The Q2 FY2026 milestone was achieved, and the clinical study is progressing as planned

● About DSP-3077

- ✓ A retinal sheet derived from allogeneic iPS cells **containing abundant photoreceptor precursor cells**
- ✓ Single subretinal transplantation into the eye with poorer visual acuity

● Regenerative Medicine for Retinitis Pigmentosa Using DSP-3077



● Overview of U.S. Phase 1/2 Study (NCT06891885)

Target disease	Retinitis pigmentosa
Study design (target enrollment)	Open-label, single-arm, dose-escalation study; untreated fellow eye as control (12 patients)
Primary endpoint	Safety and tolerability
Secondary endpoints	Engraftment, efficacy, and others

Cohort	Patients	Visual acuity**	Dose***
Cohort 1	4 patients	HM* to approx. 0.05	Low dose
Cohort 2	4 patients	HM* to approx. 0.05	High dose
Cohort 3	4 patients	Approx. 0.05 – 0.1	High dose

* HM(hand motion) : visual acuity sufficient to distinguish the direction of hand movement.

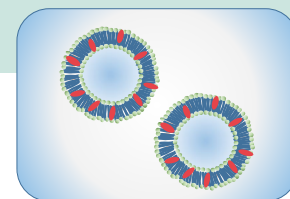
** Visual acuity: best-corrected visual acuity assessed using the ETDRS chart. Study-eye eligibility thresholds are hand motion, ETDRS 20 letters (approx. 0.05), and ETDRS 35 letters (approx. 0.1).

*** Low dose: 0.8–2.4 mm²; high dose: 2.4–6.4 mm²

Research and Development

Others: fH1/DSP-0546LP Universal Influenza Vaccine

- ✓ Favorable safety and tolerability were observed through one year after administration, and anti-LAH antibody titers remained elevated
- ✓ A controlled human infection study is planned to begin by the end of FY2026



DSP-0546LP Adjuvant
(Liposomal formulation)

Overview of the Phase 1 Study in Europe

Subjects	144 healthy adults (ages 18–40)
Design	Randomized, placebo-controlled, double-blind
Administration	Two intramuscular doses at three-week intervals

Safety and tolerability

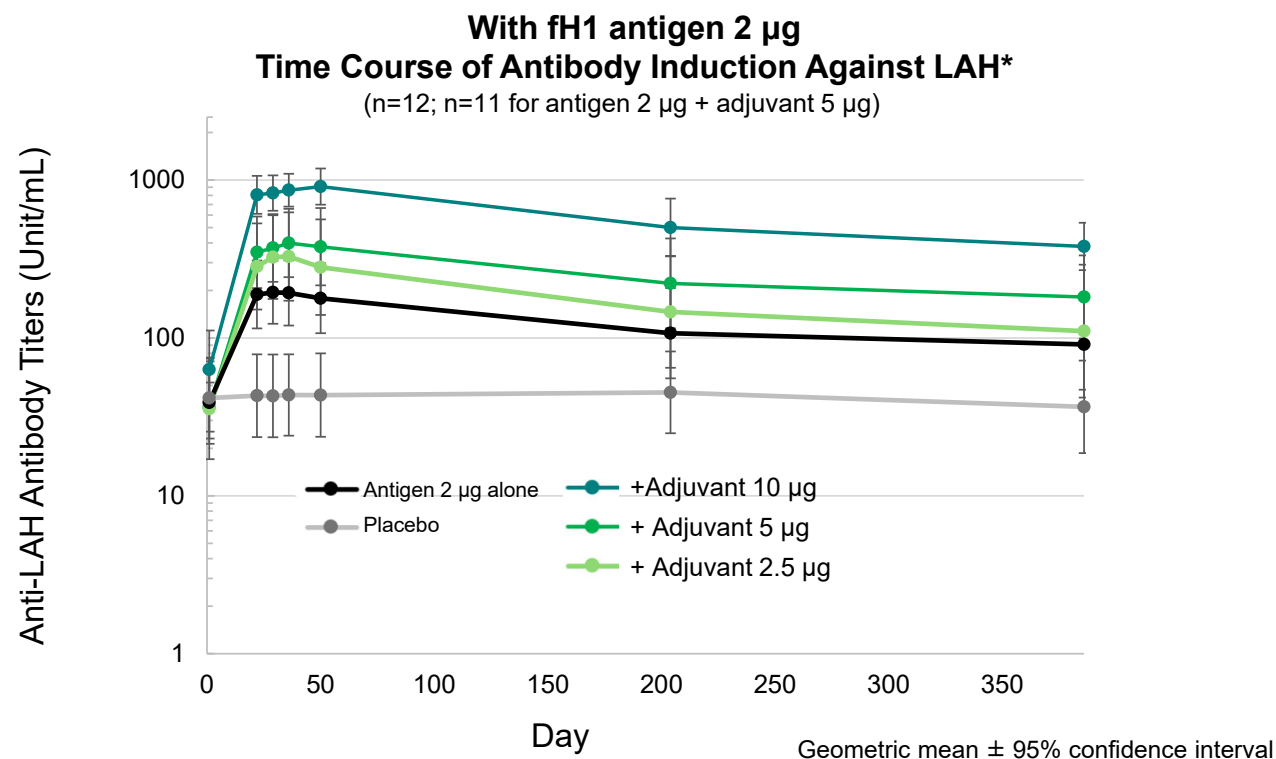
Four weeks after completion of dosing No serious adverse reactions

Through one year after administration No new major safety concerns; generally favorable tolerability

Exploratory Analyses Related to Protection Against Infection

Increased anti-LAH IgG1 subclass antibody titers

Increased neutralizing activity against the H1N1 strain



*LAH (Long Alpha Helix): A conserved antigenic region shared across a broad range of influenza viruses

Joint research under the AMED CiCLE program with the National Institutes of Biomedical Innovation, Health and Nutrition (NIBN).
See our [September 30, 2026](#) press release for details.

Research and Development

Revisions since the announcement in July 2026 are shown in red

Key Development Products: Major Milestones Scheduled in FY2026 (as of October 30, 2026)

Area	Program	Q1	Q2	Q3	Q4	Remarks
Psychiatry & Neurology	DSP-0378 (Progressive Myoclonic Epilepsy Developmental Epileptic Encephalopathy)				Initial PoC* acquisition	
	CT1-DAP001 / DSP-1083 (Parkinson's disease)			☑ (Japan) First transplantation ¹		¹ Post-marketing clinical study
	DSP-3077 (Retinitis pigmentosa)		☑ (U.S.) First transplantation ²			² Phase 1/2
Oncology	Enzomenib (Monotherapy, relapsed or refractory KMT2A-rearranged Acute Leukemia)	☑ Phase 2 Completion of enrollment for interim analysis		Phase 2 Interim analysis Top-line results		NDA filing (Q1 FY2027)
	Enzomenib (Monotherapy, relapsed or refractory NPM1-mutated Acute Myeloid Leukemia)	☑ Phase 2 Enrollment initiation			Phase 2 Completion of enrollment for interim analysis	
	Nuvisertib (Combination with momelotinib, newly diagnosed and relapsed or refractory Myelofibrosis)			Phase 3 Decision on recommended dose ³		³ To be determined in consultation with the FDA
	SMP-3124 (Monotherapy, solid tumors)				Phase 2 Decision on recommended dose ³	
Others	fH1/DSP-0546LP (Universal Influenza Vaccine)		☑ Final analysis of 1-year follow-up ⁴		CHIS** study Initiation	⁴ One-year follow-up safety data, antibody persistence, and subtype specific immune response analyses (e.g., IgG2, IgG4)

* Initial PoC (Proof of Concept): Preliminary confirmation of efficacy in patients based on a limited number of cases ** Controlled Human Infection Studies: Human challenge studies

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Financial Results for Q2 FY2026 (Full Basis)
Financial Position and Cash Flow
Prescription Trends of GEMTESA®
Revenue of Major Products in Japan
Product Launch Target
Regenerative Medicine/Cell Therapy
Launched Product and Development Pipeline (RACTHERA Co., Ltd.)

Appendix (Financial Results for Q2 FY2026)

Financial Results for Q2 FY2026 (Full Basis)

Billions of JPY

	Q2YTD FY2025 Results	Q2YTD FY2026 Results	Change	
			Value	%
Revenue	227.1	266.5	39.4	17.3
Cost of sales	89.7	123.5	33.8	37.7
Gross profit	137.4	143.0	5.5	4.0
SG&A expenses	76.6	78.7	2.2	2.8
R&D expenses	17.5	23.8	6.2	35.6
Other operating income and expenses	52.8	1.8	(51.0)	
Operating profit	96.2	42.3	(53.9)	(56.0)
Finance income and costs	(3.4)	(2.9)	0.5	
Profit before taxes	92.8	39.4	(53.4)	(57.6)
Income tax expenses	(6.1)	1.1	7.2	
Net profit attributable to owners of the parent	98.9	38.2	(60.6)	(61.3)

Appendix (Financial Results for Q2 FY2026)

Financial Position and Cash Flow

Billions of JPY

B / S	As of March 2026	As of Sep. 2026	Change
Assets	804.6	851.1	46.5
Goodwill / Intangible assets	371.6	361.7	(9.9)
Trade and other receivables	131.4	152.0	20.6
Cash and deposit / Short-term loan receivable	44.3	77.8	33.4
Liabilities	512.1	419.9	(92.2)
Bonds and borrowings	217.2	139.7	(77.5)
Other non-current liabilities	23.5	15.2	(8.3)
Other current liabilities	50.8	32.6	(18.2)
Equity	292.5	431.1	138.6
Share capital	22.4	71.3	48.9
Capital surplus	0.0	48.3	48.3
(Ratio of equity attributable to owners of the parent to total assets)	36.4%	50.7%	

Repayment of borrowings

Increase due to issuance of new shares

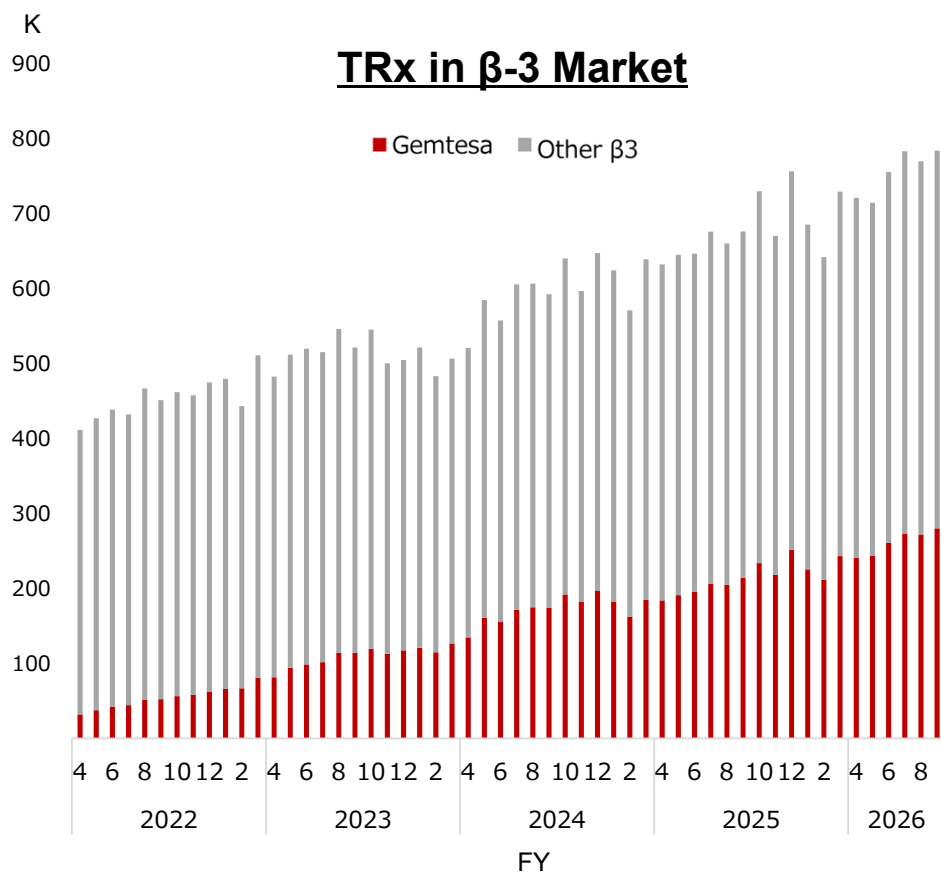
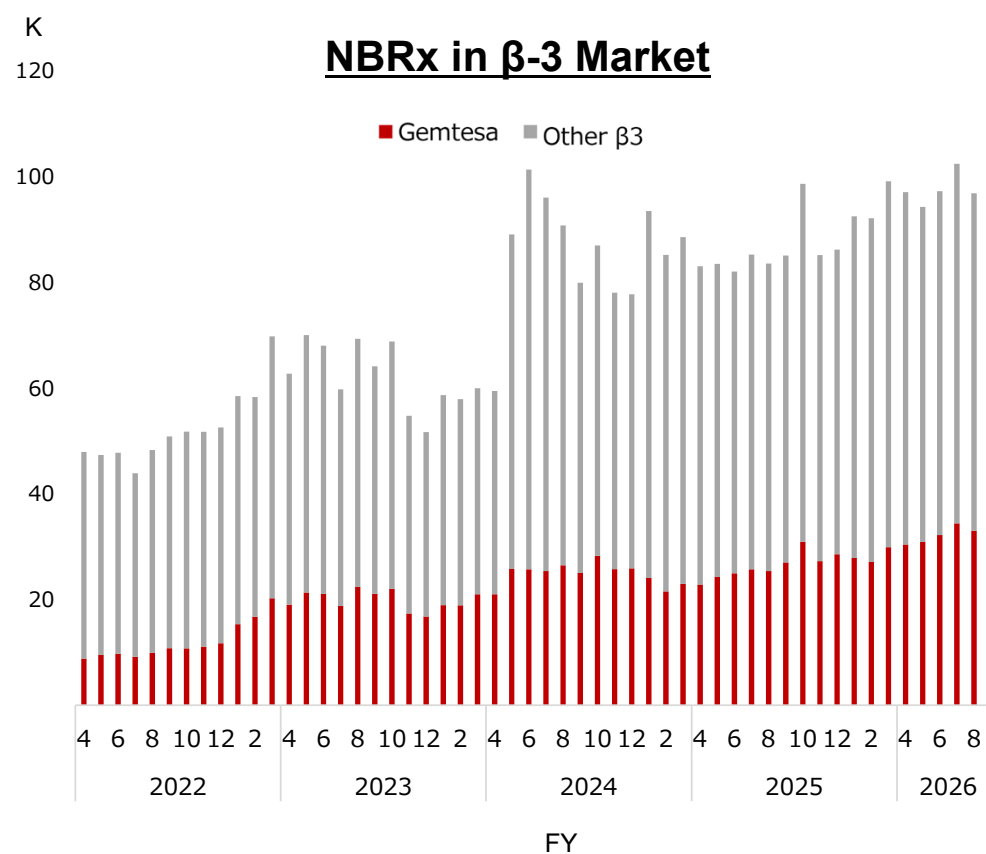
C / F	Q2 FY2025	Q2 FY2026	Change
Operating CF	18.0	16.7	(1.4)
Investing CF	27.6	0.5	(27.1)
Financing CF	(44.0)	17.6	61.5
Cash and cash equivalents at beginning of year	23.1	44.3	21.2
Cash and cash equivalents at end of period	38.5	77.8	39.3

FY25: Proceeds from loss of control of subsidiaries

FY25: Repayment of borrowings
FY26: Proceeds from issuance of new shares, repayment of borrowings

Prescription Trends of GEMTESA®

- GEMTESA® prescriptions, including total and new prescriptions, continued to increase despite the launch of Mirabegron generics in Apr. 2024



Appendix (Financial Forecasts for FY2026)

Revenue of Major Products in Japan

Billions of JPY

	FY2026 May 13 Forecasts	FY2026 Revised Forecasts	Change	
			Value	%
Japan				
XEPLION®/XEPLION TRI®	17.1	17.1	—	—
LATUDA®	13.6	13.9	0.3	2.2
TWYMEEG®	11.9	13.2	1.3	10.9
METGLUCO®	7.6	7.6	—	—
AG products	11.2	11.8	0.6	5.4
Others	26.2	24.9	(1.3)	(5.0)
Total	87.6	88.5	0.9	1.0

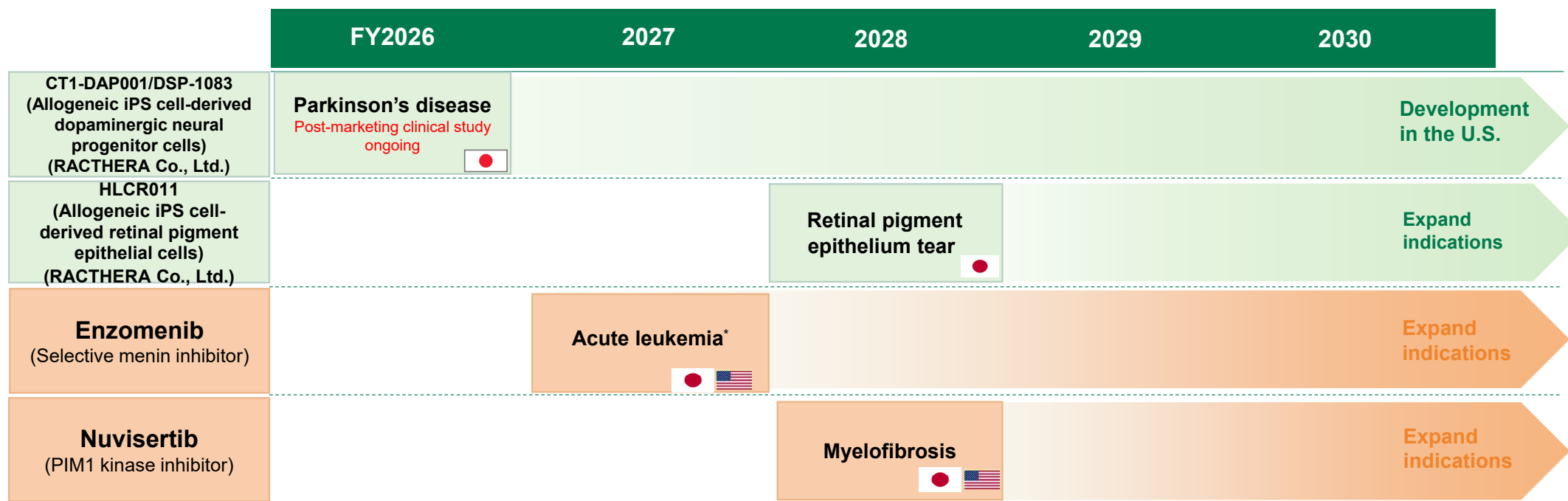
■ TWYMEEG[®] sales forecast revised upward to reflect strong sales

Appendix (Research and Development)

Revisions since the announcement in July 2026 are shown in red

Product Launch Target (as of October 30, 2026)

Psychiatry & Neurology Oncology



* Relapsed or refractory acute leukemia with KMT2A rearrangement or acute myeloid leukemia with NPM1 mutation

Appendix (Research and Development)

Revisions since the announcement in July 2026 are shown in red

Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (RACTHERA Co., Ltd.) (as of October 30, 2026)

Brand name/Cell type Product code	Indications	JP/ US	Pre-clinical	Clinical research	Phase 1/2	Phase 3	Approval application	Approval→ Launch
RETHYMIC®	Congenital athymia	US						
Dopaminergic neural progenitor cells (Allo iPS cell-derived) CT1-DAP001/DSP-1083	Parkinson's disease	JP US			4 5			1 6 Conditional and time-limited approval obtained in Japan (Mar. 2026)
Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011	Retinal pigment epithelium tear	JP			5			
Retinal sheet (3D retinal tissue) (Allo iPS cell-derived) DSP-3077	Retinitis pigmentosa	JP US		2	5			
Neural progenitor cells (Allo iPS cell-derived)	Spinal cord injury	JP US		3 7				
Nephron progenitor cells (organ) (Auto/ Allo iPS cell-based induced)	Kidney failure	JP/ US						

1. Kyoto University Hospital 2. Kobe City Eye Hospital 3. Keio University Hospital 4. University of California San Diego 5. Company-sponsored clinical study

6. Post-marketing clinical study (Phase 4 study) ongoing in Japan 7. For subacute spinal cord injury

