FY2026Q1 Financial Results

July 31, 2026

ONO PHARMA

Forward-Looking Statements

Forecasts and other forward-looking statements included in this document are based on information currently available and certain assumptions that the Company deems reasonable.
Actual performance and other results may differ significantly due to various factors. Such factors include, but are not limited to:

Forward-looking statements:	This presentation contains forward-looking statements regarding the Company's future plans, strategies, and performance.
Current assumptions:	These statements are based on current expectations, assumptions, and information available to management at this time.
Risks and uncertainties:	Forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially.
No guarantee of outcomes:	Forecasts, targets, and projections are not guarantees of future performance or achievement of stated goals.
Official guidance:	Official financial guidance should be referred to in accordance with relevant regulatory requirements and disclosures.
Product/market risks:	Risks include, but are not limited to, product development challenges, regulatory approvals, market acceptance, and competition.
Economic/industry risks:	Additional risks may arise from changes in economic conditions, currency fluctuations, and healthcare policy reforms.
No obligation to update:	The Company undertakes no obligation to update or revise any forward-looking statements as a result of new information or future events.
Prevailing language:	In the event of any inconsistency between language versions, the original Japanese language version shall prevail.

Information about pharmaceutical products (including products currently in development) included in this document is not intended to constitute an advertisement of medical advice.

Today's Attendees

Masaki Itoh	Corporate Executive Officer / Chief Officer of Finance & Accounting Division
Tatsuya Okamoto	Corporate Officer / Executive Vice President, Clinical Development
Hirokazu Kitada	Corporate Officer / Executive Vice President, Sales and Marketing
Kunihiko Ito	Corporate Officer / Executive Vice President, Global Business

Agenda

FY2026Q1 Financial Results (14:00-14:15)

Masaki Itoh — Corporate Executive Officer / Chief Officer of Finance & Accounting Division

Development Pipeline Progress Status (14:15-14:30)

Tatsuya Okamoto — Corporate Officer / Executive Vice President, Clinical Development

Q&A Session (14:30-15:00)

FY2026Q1 Financial Results

Main Points of the Financial Results (Core Basis)

FY2026Q1 results showed lower revenue but higher profit.

FY2026Q1 Sales Revenue	Revenue decreased by 11.4 JPY billion (8.9%) YoY to 116.2 JPY billion Japan: Revenue declined due to the termination of the FORXIGA co-promotion agreement. Overseas: Qinlock sales increased by 2.8 JPY bn YoY to 11.7 JPY bn, and Romvimza sales rose by 3.1 JPY bn YoY to 4.1 JPY bn. Overseas royalty income from Opdivo and other products also continued to grow steadily.
FY2026Q1 Core Profit for the Period	Core operating profit increased by 7.1 JPY billion (+22.5%) YoY to 38.7 JPY billion, and core profit for the period rose by 5.4 JPY billion (+21.9%) YoY to 30.2 JPY billion. Profit increased due to the absence of FORXIGA-related cost of sales and co-promotion expenses, as well as lower R&D expenses reflecting the reversal of one-time costs incurred in the prior-year period.
FY2026 Financial Forecast	No Update from the recent forecast. Revenue and Profit are expected to decline YoY. Revenue is expected to be 455.0 JPY bn (-11.8% YoY), mainly due to the termination of the co-promotion agreement with AstraZeneca for FORXIGA. The Company plans to continue investing in research and development at approximately 30% of net sales for future growth. Core operating profit is expected to be 124.0 JPY bn (-9.6% YoY) due to proactive investments and declining revenue

FY2026Q1 : Sales Revenue

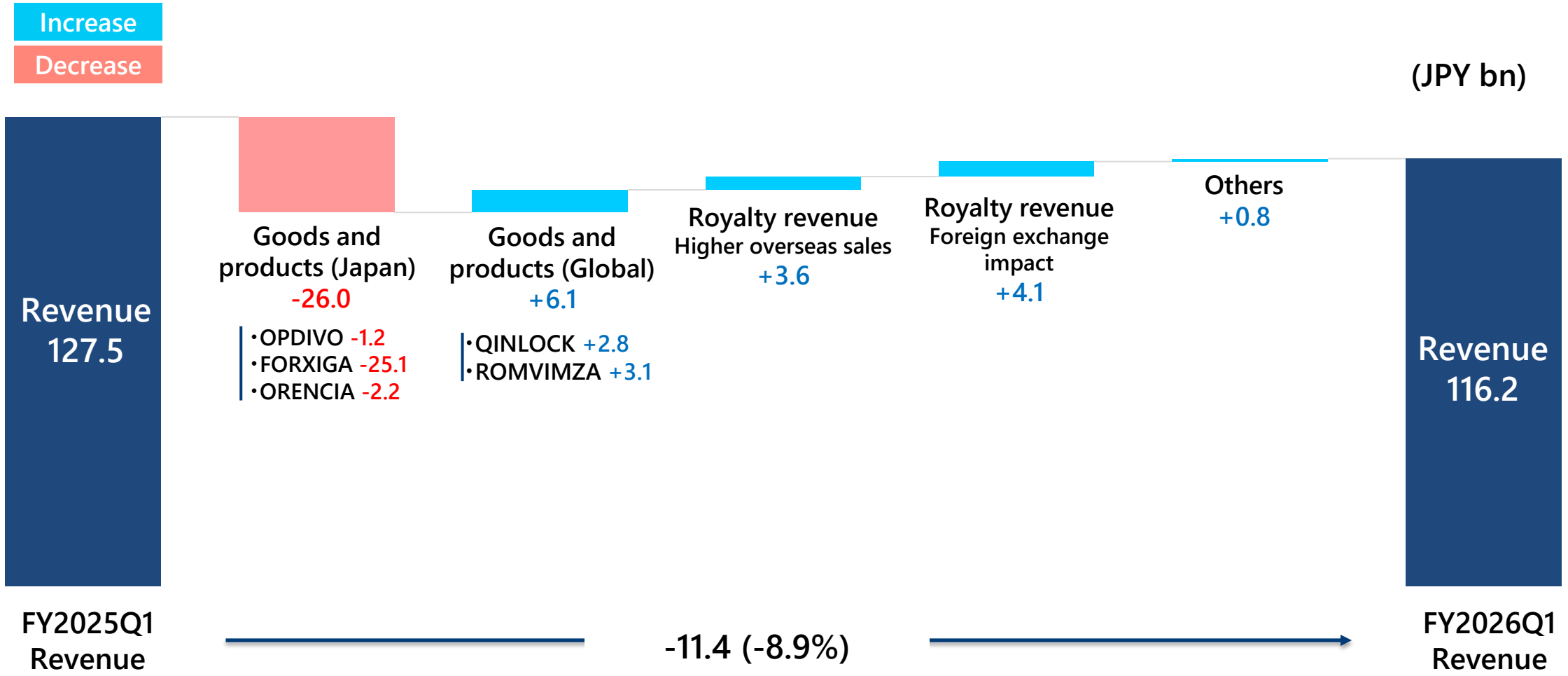
Revenue
116.2 JPY bn
YoY -11.4 JPY bn
(-8.9%)

Goods and Products Sales
67.9 JPY bn
YoY -19.8 JPY bn (-22.6%)

Royalty and Others
48.2 JPY bn
YoY +8.5 JPY bn (+21.2%)

FY2026Q1 : Sales Revenue (Breakdown)

Revenue declined by 11.4 JPY billion to 116.2 JPY billion YoY, primarily due to the loss of FORXIGA sales after the co-promotion agreement terminated, despite growth in Opdivo royalties and Deciphera-related revenue.



FY2026Q1 : Sales Revenue by Product / Japan

JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	116.2	-11.4	-8.9%	455.0
Goods and products	87.8	67.9	-19.8	-22.6%	270.0
Royalty and others	39.8	48.2	8.5	21.2%	185.0

Goods and Products (Japan)	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
OPDIVO Intravenous Infusion	29.4	28.2	-1.2	-4.1%	120.0
ORENCIA for Subcutaneous Injection	7.0	4.8	-2.2	-31.6%	19.0
VELEXBRU Tablets	3.0	3.2	0.1	4.6%	12.0
PARSABIV Intravenous Injection	2.2	2.4	0.2	10.0%	10.0
ONGENTYS Tablets	2.3	2.6	0.4	16.9%	10.0
GLACTIV Tablets	3.6	3.1	-0.4	-11.8%	9.5
BRAFTOVI Capsules	1.3	2.0	0.7	51.1%	8.5
KYPROLIS for Intravenous Infusion	2.0	1.8	-0.2	-12.0%	7.0

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.
・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

FY2026Q1 : Sales Revenue by Product / Overseas / Royalty

JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	116.2	-11.4	-8.9%	455.0
Goods and products	87.8	67.9	-19.8	-22.6%	270.0
Royalty and others	39.8	48.2	8.5	21.2%	185.0

Goods and Products (Overseas)	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
OPDIVO®	3.3	3.5	0.2	7.3%	13.0
QINLOCK®	8.9	11.7	2.8	31.5%	43.0
ROMVIMZA®	1.1	4.1	3.1	289.3%	19.0

Royalty and others	FY2025Q1	FY2026Q1	YoY		
			Change	Change(%)	
OPDIVO®	29.2	34.7	5.5	18.9%	
KEYTRUDA®	6.5	7.9	1.3	20.5%	

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

・Sales revenue of domestic products is shown in a gross sales basis (shipment price), and sales revenue of overseas products is shown in a net sales basis.

FY2026Q1 : Core Operating Profit

Core Operating Profit
38.7 JPY bn

YoY +7.1 JPY bn
(+22.5%)

Revenue 116.2 JPY bn

YoY -11.4 JPY bn (-8.9%)

Cost of Sales 20.6 JPY bn

YoY -7.5 JPY bn (-26.5%)

R&D Expense 32.4 JPY bn

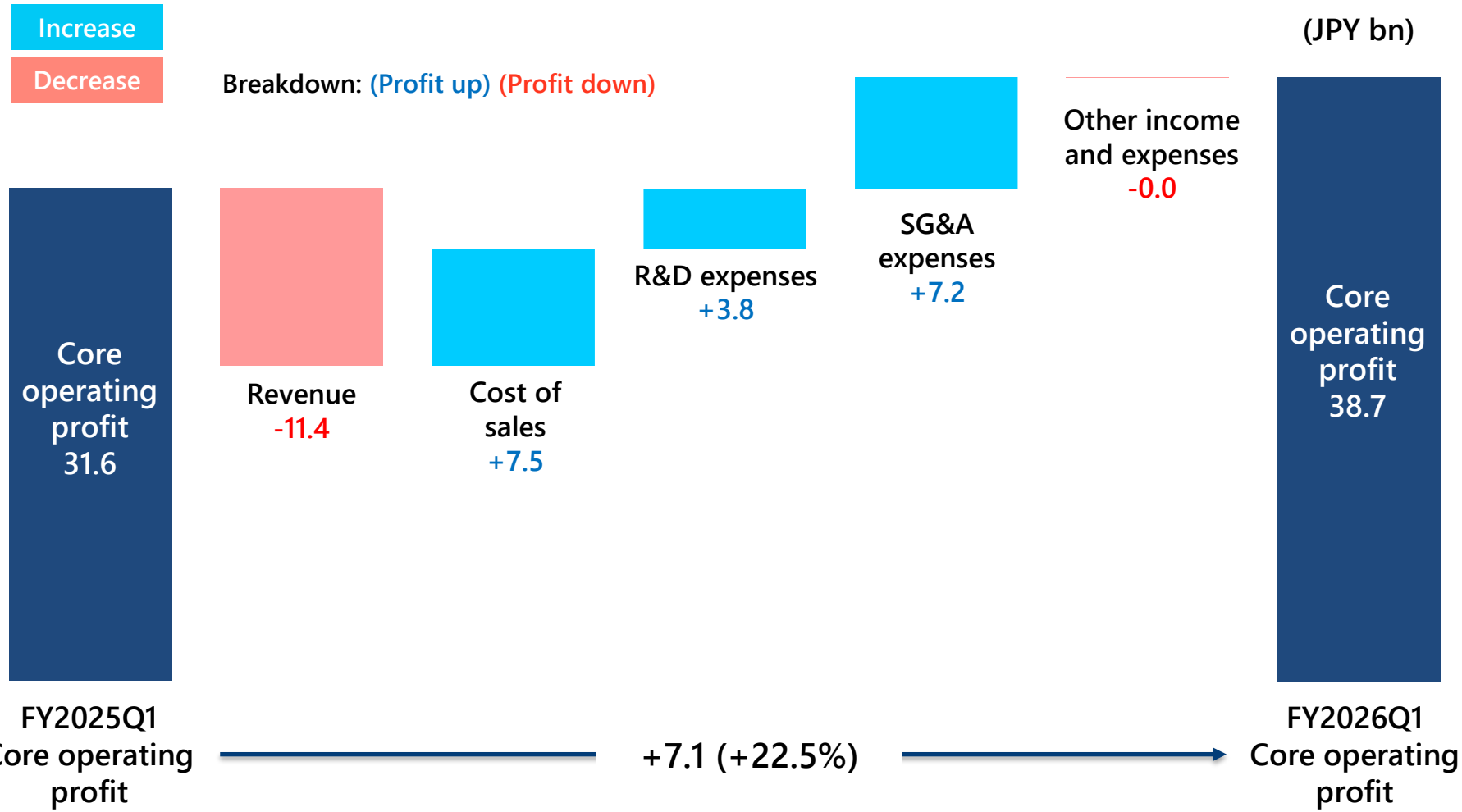
YoY -3.8 JPY bn (-10.6%)

SG&A Expense 23.9 JPY bn

YoY -7.2 JPY bn (-23.1%)

FY2026Q1 : Core Operating Profit (Breakdown)

Core operating profit increased by 7.1 JPY billion YoY to 38.7 JPY billion, driven by the absence of FORXIGA sales-related expenses following the termination of the co-promotion agreement and ongoing cost-efficiency initiatives.



YoY Breakdown

Sales revenue

Main reason
- Goods and products : -19.8
- Royalty and others : +8.5

Cost of sales

Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses

Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses

Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

FY2026Q1 : Financial Overview (Core)

JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	116.2	-11.4	-8.9%	455.0
Cost of sales	28.1	20.6	-7.5	-26.5%	84.0
R&D expenses	36.3	32.4	-3.8	-10.6%	143.0
SG&A expenses	31.1	23.9	-7.2	-23.1%	101.0
Core operating profit	31.6	38.7	7.1	22.5%	124.0
Core profit before tax	32.2	39.3	7.1	21.9%	124.0
Core profit for the period (attributable to owners of the Company)	24.8	30.2	5.4	21.9%	93.0

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

YoY Breakdown

Cost of sales -7.5 JPY bn (-26.5%)

COGS ratio : 17.8%
Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses -3.8 JPY bn (-10.6%)

R&D ratio：27.9%
Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses -7.2 JPY bn (-23.1%)

SG&A ratio : 20.6%
Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

Core operating profit ratio : 33.3%

(Ref) FY2026Q1 : Financial Overview (Full Basis)

JPY bn	FY2025Q1	FY2026Q1	YoY		FY2026 Forecast*
			Change	Change(%)	
Revenue	127.5	116.2	-11.4	-8.9%	455.0
Cost of sales	37.0	28.7	-8.3	-22.5%	114.0
R&D expenses	36.3	32.4	-3.8	-10.6%	143.0
SG&A expenses	31.1	23.9	-7.2	-23.1%	101.0
Operating profit	22.0	30.7	8.7	39.4%	94.0
Profit before tax	22.6	31.3	8.6	38.0%	94.0
Profit for the period (attributable to owners of the Company)	17.7	24.2	6.5	36.7%	71.0

* The consolidated financial forecast for the fiscal year ending March 2027, announced on May 8, 2026, is provided.

YoY Breakdown

Cost of sales -8.3JPY bn (-22.5%)

COGS ratio : 24.7%
Main reason
- Decrease due to the termination of FORXIGA co-promotion agreement

R&D expenses -3.8 JPY bn (-10.6%)

R&D ratio : 27.9%
Main reason
- Absence of one-time costs to Bristol-Myers Squibb recorded in the previous year
- Absence of expenses related to the drug discovery collaboration agreement with LigaChem recorded in the previous year

SG&A expenses -7.2 JPY bn (-23.1%)

SG&A ratio : 20.6%
Main reason
- Decrease in co-promotion fees due to the termination of FORXIGA co-promotion agreement

Operating profit ratio : 26.4%

(Ref) FY2026Q1 : Reconciliation from Full to Core Basis

JPY bn	IFRS (Full) basis	Adjustment				Core basis
		Amortization	Impairment loss	Others	Total	
Revenue	116.2					116.2
Cost of sales	28.7	-6.0		-2.0	-8.0	20.6
Gross profit	87.5	+6.0	–	+2.0	+8.0	95.5
R&D expenses	32.4				–	32.4
SG&A expenses	23.9				–	23.9
Other income /expenses (- Exp)	-0.5				–	-0.5
Operating profit	30.7	+6.0	–	+2.0	+8.0	38.7
Operating profit ratio	26.4%				–	33.3%
Finance income / Finance cost (- Exp)	0.6				–	0.6
Profit before tax	31.3	+6.0	–	+2.0	+8.0	39.3
Income tax expense	7.1	+1.5		+0.5	+2.0	9.0
Profit for the period	24.2	+4.5	–	+1.5	+6.1	30.2

Breakdown

Cost of sales

Main reason

- Amortization expenses related to intangible assets acquired through acquisitions or in-licensing
- Amortization expenses related to inventories from *PPA

R&D expenses

Main reason

- None

SG&A expenses and Other income&expense

Main reason

- None

*PPA : Purchase Price Allocation

FY2026 Financial Forecasts

FY2026 : Financial Forecast (Core/Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on May 8th, 2026.

JPY bn	FY2025 Actual	FY2026 Forecast	Change	Change (%)
Revenue	515.8	455.0	-60.8	-11.8%
Cost of sales	107.0	84.0	-23.0	-21.5%
R&D expenses	145.1	143.0	-2.1	-1.5%
SG&A expenses	123.6	101.0	-22.6	-18.3%
Core operating profit	137.1	124.0	-13.1	-9.6%
Core profit before tax	138.3	124.0	-14.3	-10.3%
Income tax expense	34.6	31.0	-3.6	-10.5%
Core profit for the year (attributable to owners of the Company)	103.5	93.0	-10.5	-10.1%

* The exchange rate assumed in the financial forecast is ¥155 per US dollar.

Breakdown

Cost of sales -23.0 JPY bn (-21.5%)

COGS ratio : 18.5%
Main reason

- Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement

R&D expenses -2.1 JPY bn (-1.5%)

R&D ratio: 31.4%
Main reason

- A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses
- Increase in global clinical trial costs

SG&A expenses -22.6 JPY bn (-18.3%)

SG&A ratio : 22.2%
Main reason

- The termination of co-promotion agreement for FORXIGA Tablets

Core operating profit ratio : 27.3%

(Ref) FY2026 : Financial Forecast (Full / Compared to the Previous Year)

There is no change from the consolidated financial forecasts, announced on May 8th, 2026.

JPY bn	FY2025 Actual	FY2026 Forecast	Change	Change (%)
Revenue	515.8	455.0	-60.8	-11.8%
Cost of sales	141.7	114.0	-27.7	-19.6%
R&D expenses	147.0	143.0	-4.0	-2.7%
SG&A expenses	123.7	101.0	-22.7	-18.3%
Operating profit	92.2	94.0	1.8	1.9%
Profit before tax	92.7	94.0	1.3	1.5%
Income tax expense	22.7	23.0	0.3	1.1%
Profit for the year (attributable to owners of the Company)	69.8	71.0	1.2	1.8%

Breakdown

Cost of sales -27.7 JPY bn (-19.6%)

COGS ratio : 25.1%
Main reason

- Decrease in sales related to FORXIGA tablets due to the termination of the co-promotion agreement

R&D expenses -4.0 JPY bn (-2.7%)

R&D ratio: 31.4%
Main reason

- A reclassification of certain expenses previously recorded as R&D expenses to SG&A expenses
- Increase in global clinical trial costs

SG&A expenses -22.7 JPY bn (-18.3%)

SG&A ratio : 22.2%
Main reason

- The termination of co-promotion agreement for FORXIGA Tablets

Operating profit ratio : 20.7%

* The exchange rate assumed in the financial forecast is ¥155 per US dollar.
The sensitivity to exchange rates is assumed to be an increase of ¥1.5 billion in revenue and an increase of ¥0.5 billion in operating profit for every ¥1 depreciation of the yen.

Development Pipeline Progress Status

Launch Projections - POC Pipeline-

As of July 31, 2026

Approved　Filed and preparing for filing

	FY2025	FY2026	FY2027	FY2028	FY2029 -	
US		ONO-4059 (VELEXBRU) PCNSL	QINLOCK GIST 2L		ONO-0530 sapablursen PV	ONO-4578 GC 1L ONO-2808 MSA
EU	ROMVIMZA TGCT		QINLOCK GIST 2L		ONO-0530 sapablursen PV	ONO-4578 GC 1L ONO-2808 MSA
JP	OPDIVO HCC 1L OPDIVO MSI-H CRC 1L BRAFTOVI CRC 1L FOLFOX	ONO-2017 cenobamate Partial-onset seizures QINLOCK GIST 4L VELEXBRU R/R SCNSL	OPDIVO Unresectable anaplastic Thyroid Cancer 1L OPDIVO HCC Adjuvant ONO-2017 cenobamate Primary generalized tonic-clonic seizures	ripretinib (QINLOCK) GIST 2L VELEXBRU Pemphigus 2L ONO-8531 povetacicept IgAN	ONO-5532 Gel-One Osteoarthritis ONO-2017 cenobamate Partial-onset seizures pediatric vimseltinib (ROMVIMZA) TGCT OPDIVO sc	ONO-0530 sapablursen PV ONO-8531 povetacicept pMN ONO-4578 GC 1L ONO-2808 MSA

PCNSL: Primary Central Nervous System Lymphoma, GIST: Gastrointestinal Stromal Tumor, PV: Polycythemia Vera, GC: Gastric Cancer, MSA: Multiple System Atrophy, TGCT: Tenosynovial Giant Cell Tumor, HCC: Hepatocellular Carcinoma, CRC: Colorectal Cancer, IgAN: IgA Nephropathy, pMN: Primary Membranous Nephropathy

New additions to this earnings call

Development pipeline (Oncology) ①

As of July 31, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ONO-4059 (tirabrutinib) BTK inhibitor	PCNSL 1L, ≥2L	■	■	■	■	■		2026.2 US : Filed (Part A)	US	NCT04947319
	SCNSL	■	■	■	■	■		2026.6 JP : Filed	JP	jRCT2031220529
	PCNSL ≥2L	■	■	■	■			FY2027 Primary Completion	US	NCT07104032
QINLOCK DCC-2618 (ripretinib) KIT inhibitor	GIST 2L KIT Exon 11+17/18	■	■	■	■			FY2027 Primary Completion	US, EU, KR, TW and others	NCT05734105
	GIST 4L	■						FY2027 Primary Completion	JP	NCT07618377
ONO-0530 (sapablursen) Antisense oligonucleotide targeting TMPRSS6	Polycythemia vera (PV)	■	■	■	■			FY2028 Primary Completion	JP, US, EU, KR, TW and others	NCT07429266
ONO-4578 PG receptor (EP4) antagonist	Gastric cancer*	■	■	■				FY2025 Primary Completion (Actual)	JP, KR, TW	NCT06256328
	Colorectal cancer*	■	■	■				FY2027 Primary Completion	JP, US, EU and others	NCT06948448
	Non-small cell lung cancer*	■						FY2026 Primary Completion	JP	NCT06542731
ONO-4482 (relatlimab) Anti-LAG-3 antibody	Melanoma*	■	■					FY2024 Primary Completion (Actual)	JP, US, EU and others	NCT01968109
ONO-7427 Anti-CCR8 antibody	Solid tumor*	■	■					FY2031 Primary Completion	JP, US, EU and others★1	NCT04895709
DCC-3116 (inlexisertib) ULK inhibitor	Advanced malignancies (with ripretinib)	■	■					FY2026 Primary Completion	US, EU	NCT05957367

PCNSL: Primary central nervous system lymphoma
SCNSL: Relapsed or refractory secondary central nervous system lymphoma
GIST: Gastrointestinal Stromal Tumor

MOA : Mode of Action
* : Combination with OPDIVO

★1 : Development right country: JP
Estimated study completion date shown in jRCT or ClinicaiTrials.gov

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2025 financial result in May 2026

Development pipeline (Oncology) ②

As of July 31, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
DCC-3009 Pan-KIT inhibitor	GIST							FY2028 Primary Completion	US	NCT06630234
ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody	T-cell lymphoma							FY2027 Primary Completion	US	NCT05079282
								FY2028 Primary Completion	JP	NCT06547528
ONO-8250 iPSC-derived HER2 CAR T-cell therapy	HER2-expressing solid tumor							FY2029 Primary Completion	US	NCT06241456
ONO-7428 Anti-ONCOKINE-1 antibody	Solid tumor							FY2029 Primary Completion	JP	NCT06816108
DCC-2812 GCN2 activator	Renal cell carcinoma, urothelial cancer, castration-resistant Prostate cancer							FY2028 Primary Completion	US	NCT06966024
ONO-7429 Anti-L1CAM ADC	Solid tumor							FY2028 Primary Completion	JP	Under registration

GIST: Gastrointestinal Stromal Tumor

MOA : Mode of Action

＊： Combination with OPDIVO

Estimated study completion date shown in jRCT or ClinicaiTrials.gov

F : Filed, A : Approval

※Red: Update after announcement of FY 2025 financial result in May 2026

Development pipeline (Non-oncology) ①

As of July 31, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ONO-2017 (cenobamate) Inhibition of voltage-gated sodium currents/positive allosteric modulator of $GABA_A$ ion channel	Partial-onset seizures							FY2025 JP : Filed	JP, KR and others★1	NCT04557085
	Partial-onset seizures (pediatric)							FY2028 Primary Completion	JP	NCT07594158
	Primary generalized tonic-clonic seizures							FY2026 Primary Completion	JP	NCT06579573
VELEXBRU Tablet (ONO-4059: tirabrutinib) BTK inhibitor	Pemphigus							FY2027 Primary Completion	JP	NCT06696716
ONO-8531 (povetacicept) BAFF/APRIL dual antagonist	IgA nephropathy							FY2027 Primary Completion	JP, US, EU, KR, TW and others★2	NCT06564142
	Primary membranous nephropathy				★3			FY2028 Primary Completion	US, EU, KR and others★2	NCT07204275
ONO-5532 (Gel-One) Cross-linked hyaluronate	Knee osteoarthritis							FY2027 Completion	JP	jRCT2031240621
	Hip osteoarthritis							FY2027 Completion	JP	jRCT2061240110
ROMVIMZA DCC-3014 (vimseltinib) CSF-1R inhibitor	Tenosynovial giant cell tumor (TGCT)							–	JP	Under registration
	Chronic graft versus host disease (cGVHD)							FY2029 Primary Completion	US	NCT06619561
ONO-2808 S1P5 receptor agonist	Multiple system atrophy (MSA)							FY2025 Primary Completion (Actual)	JP, US	NCT05923866

★1 : Development right country: JP, ★2 : Development rights countries: JP, KR, ★3 : P II b/III
MOA : Mode of Action Estimated study completion date shown in jRCT or ClinicaiTrials.gov

F : Filed, A : Approval
EU : European countries ※Red: Update after announcement of FY 2025 financial result in May 2026

Development pipeline (Non-oncology) ②

As of July 31, 2026

Code (Generic name) MOA, Modality	Target Indication	PI	PI/II	PII	PIII	F	A	Status	Area	ID
ONO-1110 Endocannabinoid regulation	Postherpetic neuralgia	■	■	■				FY2026 Primary Completion	JP	NCT06708416
	Fibromyalgia	■	■	■				FY2026 Primary Completion	JP	NCT06752590
	Hunner type interstitial cystitis	■	■	■				FY2026 Primary Completion	JP	NCT06752603
	Major depressive disorder	■	■	■				FY2026 Primary Completion	JP	NCT06792136
	Social anxiety disorder	■	■	■				FY2026 Primary Completion	JP	NCT06805565
ONO-2020 Epigenetic Regulation	Alzheimer's disease	■	■	■				FY2026 Primary Completion	JP, US	NCT06881836
	Agitation associated with dementia due to Alzheimer's disease	■	■	■				FY2026 Primary Completion	JP	NCT06803823
ONO-4685 (besufetamig) PD-1 x CD3 bispecific antibody	Autoimmune disease	▒						FY2024 Completion	JP	jRCT2071220081
		■						FY2024 Primary Completion (Actual)	EU	NCT05332704
ONO-4915 PD-1 x CD19 bispecific antibody	Autoimmune disease	▒						FY2026 Completion	JP	jRCT2071240056
ONO-2416	Psychiatric disease	▒						FY2027 Completion	JP	jRCT2071250147
ONO-3310	Kidney disease	▒						FY2027 Completion	JP	jRCT2071260026
ONO-6414	Autoimmune disease	▒						FY2027 Primary Completion	US	Under registration
ONO-3401	Neurological disease	▒						FY2027 Completion	JP	jRCT2071260067

MOA : Mode of Action

Estimated study completion date shown in jRCT or ClinicaiTrials.gov
Shaded boxes indicate studies on healthy volunteers.

F : Filed, A : Approval
EU : European countries

※Red: Update after announcement of FY 2025 financial result in May 2026

Appendix

Development status of OPDIVO

As of July 31, 2026

・Approval or filed/awaiting approval in the past year
・Ongoing key clinical trials for approval

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Non-small cell lung cancer	Neo-adjuvant・Adjuvant	With Chemo	III	III	III	Approved	Approved
Hepatocellular carcinoma	Adjuvant	Monotherapy	III	III	III	III	III
Rhabdoid tumor	2nd	Monotherapy	II	–	–	–	–
Richter transformation	2nd	Monotherapy	II	–	–	–	–
Unresectable anaplastic Thyroid Cancer	1st	With Lenvatinib	Filed	–	–	–	–
Solid tumor	–	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I	–	–	Approved	Approved
Pediatric malignant solid tumor Epithelioid sarcoma	–	ONO-4538HSC (Combination with vorhyaluronidase alfa)	I / II	–	–	–	–

※Red: Update after announcement of FY 2025 financial result in May 2026

OPDIVO Approval Track Record(1)

As of July 31, 2026

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Melanoma	Adjuvant・1st・2nd	Monotherapy, with Ipi (1st only)	Approved	Approved	Approved	Approved	Approved
	1st	Combination drug† (relatlimab)	–	–	–	Approved	Approved
Non-small cell lung cancer	Neo-adjuvant	With Chemo	Approved	Approved	Approved	Approved	Approved
	1st	With Ipi	Approved	Approved	Approved	Approved	–
		With Ipi / Chemo	Approved	Approved	Approved	Approved	Approved
		With Chemo	Approved	–	–	–	–
		With Chemo (NSQ)	Revision of labeling	Approved	Approved	–	–
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Hodgkin's lymphoma	Relapsed / Refractory	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	With AVD	–	–	–	Approved	Approved
Head and neck cancer	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Malignant pleural mesothelioma	1st	With Ipi	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	–	–	–	–
Malignant mesothelioma (Excluding Pleura)	1st	Monotherapy	Approved	–	–	–	–

†Combination drug (Relatlimab) : ONO-7121(Opdivo+Relatlimab (ONO-4482))

※Red: Update after announcement of FY 2025 financial result in May 2026

OPDIVO Approval Track Record(2)

As of July 31, 2026

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Gastric cancer	1st	With Chemo	Approved	Approved	Approved	Approved	Approved
	3rd	Monotherapy	Approved	Approved	Approved	–	–
Esophageal cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	With Ipi, with Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Colorectal cancer	MSI-H / dMMR (1st)	With Ipi	Approved	Approved	Approved	Approved	Approved
	MSI-H / dMMR (3rd)	Monotherapy	Approved	–	Approved	Approved	–
		With Ipi	Approved	Approved	Approved	Approved	Approved★★
Hepatocellular carcinoma	1st	With Ipi	Approved	Approved	Approved	Approved	Approved
	2nd	With Ipi	–	–	Approved	Approved	–

★★2nd Line

※Red: Update after announcement of FY 2025 financial result in May 2026

OPDIVO Approval Track Record(3)

As of July 31, 2026

Target disease	Treatment Line	Treatment	Phase				
			Japan	Korea	Taiwan	US	EU
Renal cell carcinoma	1st	With Ipi	Approved	Approved	Approved	Approved	Approved
		With TKI	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	Approved	Approved	Approved	Approved	Approved
Urothelial cancer / Bladder cancer	Adjuvant	Monotherapy	Approved	Approved	Approved	Approved	Approved
	1st	With Chemo	Approved	Approved	Approved	Approved	Approved
	2nd	Monotherapy	–	Approved	Approved	Approved	Approved
Cancer of unknown primary	1st	Monotherapy	Approved	–	–	–	–
Epithelial skin malignancies	1st	Monotherapy	Approved	–	–	–	–
Flat dose	240 mg (every 2 weeks)		Approved	Approved	Approved	Approved	Approved
	360 mg (every 3 weeks)		Approved	Approved	Approved	Approved	Approved
	480 mg (every 4 weeks)		Approved	Approved	Approved	Approved	Approved

※Red: Update after announcement of FY 2025 financial result in May 2026

Key milestones in FY2026 Q1 (FY ending March 2027)

As of July 31, 2026

(Development pipeline)

	Product/ Code(Generic name)	Target indication/Study name	Progress
Product to be approved	OPDIVO	Unresectable anaplastic thyroid cancer	Filed in JP (Jun.2026)
	VELEXBRU / ONO-4059 (tirabrutinib)	Relapsed or refractory secondary central nervous system lymphoma (SCNSL)	Filed in JP (Jun.2026)
P2	ROMVIMZA / DCC-3014 (vimseltinib)	TGCT	Started in JP (Jul.2026)
P1/2	ONO-4538HSC	Pediatric malignant solid tumor Epithelioid sarcoma	Started in JP (May.2026)
P1	ONO-3401	Neurological disease	Started in JP (Jul.2026)

(Drug discovery partnerships & Research collaborations / Licensing & Co-promotion)

Title	Progress
Ono Enters into a Collaboration Agreement with Sibylla Biotech to Generate Novel Drug Candidates for Neurological Disorders (Mar.2024-)	Discontinued

Events from April 2026 to July 31, 2026

ONO PHARMA

Dedicated to the Fight against Disease and Pain