Third Quarter (April 1 – December 31, 2017) Flash Report (unaudited)
Nine months ended December 31, 2017

ONO PHARMACEUTICAL CO., LTD.

February 2, 2018

Ono Pharmaceutical Co., Ltd. ("The Company") has announced its consolidated financial results for nine months ended December 31, 2017.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRSs”).

This Third Quarter Flash Report 2018 (unaudited) is summary information extracted from the financial statements announced, and the financial statements and the figures contained herein are prepared for reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan using the rate of 113 to $1, the approximate rate of exchange at December 29, 2017.

Amounts of less than one million yen and one thousand U.S. dollars have been rounded to the nearest million yen and one thousand U.S. dollars in the presentation of the accompanying consolidated financial statements.

Financial Highlights

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen			Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2016	Annual 12 months ended Mar. 31, 2017	**3rd Quarter 9 months ended Dec. 31, 2017**	**3rd Quarter 9 months ended Dec. 31, 2017**
Revenue	¥ 188,845	¥ 244,797	**¥ 200,570**	**$ 1,774,960**
Profit (Owners of the parent company)	42,472	55,793	**41,439**	**366,716**
Total equity	509,342	524,211	**527,750**	**4,670,356**
Total assets	583,405	617,461	**596,208**	**5,276,174**
		Yen		US$
Basic earnings per share	¥ 80.13	¥ 105.27	**¥ 79.74**	**$ 0.71**
Diluted earnings per share	¥ 80.13	¥ 105.26	**¥ 79.74**	**$ 0.71**

Third Quarter (April 1 – December 31, 2017) Flash Report (unaudited)
Nine months ended December 31, 2017

Revisions of Consolidated Financial Forecasts

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(1) Revisions to the full-year Consolidated Financial Forecasts Ending March 31, 2018 (April 1, 2017 ~ March 31, 2018)

(Unit: Millions of yen, except basic earnings per share)

	Revenue	Operating Profit	Profit before Tax	Profit	Profit (Owners of the Parent Company)	Basic earnings per share (Owners of the Parent Company)
Previous Forecast (A) *	254,000	50,000	53,000	39,700	39,500	75.66
Revised Forecast (B)	260,000	54,000	57,500	43,200	43,000	82.74
Change (B – A)	6,000	4,500	4,500	3,500	3,500	—
Change (%)	2.4	9.0	8.5	8.8	8.9	—
(Reference) Results of the previous fiscal year ended March 31, 2017	244,797	72,284	74,540	56,036	55,793	105.27

* The previous forecast was announced on November 6, 2017

(2) Reasons for the revisions

Regarding revenue, sales of our key product Opdivo increased steadily due to expansion of use for renal cell carcinoma, head and neck cancer approved in the previous fiscal year and gastric cancer approved in September 2017. In addition, we recognized a part of received upfront payment from Bristol- Myers Squibb along with the out-licensing of ONO-4578 as revenue in the third quarter. As the result, revenue forecast was upwardly revised to be ¥260.0 billion, an increase of ¥6.0 billion from the previous forecast ¥254.0 billion.

With regards to expenses, although cost of sales is increased due to an increase in sales, research and development costs and selling, general, and administrative expenses have been no changes from the previous forecast.

Consequently, operating profit is forecasted to be ¥54.0 billion (an increase by ¥4.5 billion from the previous forecast), profit before tax to be ¥57.5 billion (an increase by ¥4.5 billion from the previous forecast), profit for the year attributable to owners of the parent company to be ¥43.0 billion (an increase by ¥3.5 billion from the previous forecast).

(Note) The financial forecasts and statements contained in this announcement are made based on information that are available as of the date the announcement is made. Actual results may differ materially from those set forth in the announcements due to various uncertain factors.

Consolidated Statement of Financial Position

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

ASSETS	Millions of yen		Thousands of US$
	As of March 31, 2017	**As of December 31, 2017**	**As of December 31, 2017**
Current assets			
Cash and cash equivalents	¥ 146,323	¥ **39,708**	$ **351,402**
Trade and other receivables	73,255	**92,936**	**822,445**
Marketable securities	17,560	**12,624**	**111,721**
Other financial assets	819	**10,809**	**95,655**
Inventories	25,334	**30,448**	**269,451**
Other current assets	7,742	**10,595**	**93,761**
Total current assets	271,033	**197,121**	**1,744,435**
Non-current assets			
Property, plant, and equipment	83,659	**93,156**	**824,393**
Intangible assets	45,237	**55,132**	**487,894**
Investment securities	176,573	**198,577**	**1,757,322**
Investments in associates	114	**127**	**1,120**
Other financial assets	26,836	**46,553**	**411,972**
Deferred tax assets	10,739	**1,074**	**9,507**
Retirement benefit assets	–	**604**	**5,346**
Other non-current assets	3,271	**3,863**	**34,185**
Total non-current assets	346,428	**399,086**	**3,531,739**
Total assets	¥ 617,461	¥ **596,208**	$ **5,276,174**

LIABILITIES AND EQUITY	Millions of yen		Thousands of US$
	As of March 31, 2017	**As of December 31, 2017**	**As of December 31, 2017**
Current liabilities			
Trade and other payables	¥ 30,905	¥ **30,631**	$ **271,070**
Borrowings	423	**349**	**3,090**
Other financial liabilities	5,814	**7,781**	**68,856**
Income taxes payable	24,777	**2,743**	**24,274**
Provisions	6,086	**10,106**	**89,438**
Other current liabilities	14,928	**6,982**	**61,785**
Total current liabilities	82,933	**58,592**	**518,514**
Non-current liabilities			
Borrowings	542	**363**	**3,208**
Other financial liabilities	11	**11**	**99**
Retirement benefit liabilities	2,805	**2,720**	**24,073**
Provisions	30	**30**	**265**
Deferred tax liabilities	881	**913**	**8,078**
Long-term advances received	5,276	**5,039**	**44,593**
Other non-current liabilities	772	**790**	**6,987**
Total non-current liabilities	10,316	**9,865**	**87,304**
Total liabilities	93,250	**68,457**	**605,818**
Equity			
Share capital	17,358	**17,358**	**153,613**
Capital reserves	17,144	**17,168**	**151,931**
Treasury shares	(59,382)	**(38,147)**	**(337,585)**
Other components of equity	51,752	**73,855**	**653,582**
Retained earnings	492,237	**452,294**	**4,002,600**
Equity attributable to owners of the parent company	519,110	**522,528**	**4,624,141**
Non-controlling interests	5,101	**5,222**	**46,215**
Total equity	524,211	**527,750**	**4,670,356**
Total liabilities and equity	¥ 617,461	¥ **596,208**	$ **5,276,174**

Consolidated Statement of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2016	**3rd Quarter 9 months ended Dec. 31, 2017**	**3rd Quarter 9 months ended Dec. 31, 2017**
Revenue	¥ 188,845	**¥ 200,570**	**$ 1,774,960**
Cost of sales	(50,268)	**(50,235)**	**(444,554)**
Gross profit	138,577	**150,336**	**1,330,406**
Selling, general, and administrative expenses	(45,159)	**(49,477)**	**(437,853)**
Research and development costs	(38,980)	**(48,366)**	**(428,020)**
Other income	261	**390**	**3,451**
Other expenses	(1,396)	**(691)**	**(6,112)**
Operating profit	53,303	**52,191**	**461,871**
Finance income	2,937	**3,158**	**27,944**
Finance costs	(75)	**(26)**	**(229)**
Share of profit (loss) from investments in associates	27	**9**	**82**
Profit before tax	56,193	**55,333**	**489,669**
Income tax expense	(13,611)	**(13,793)**	**(122,065)**
Profit for the period	42,581	**41,539**	**367,603**
Profit for the period attributable to:			
Owners of the parent company	42,472	**41,439**	**366,716**
Non-controlling interests	109	**100**	**887**
Profit for the period	42,581	**41,539**	**367,603**
Earnings per share:	Yen		US$
Basic earnings per share	80.13	**79.74**	**0.71**
Diluted earnings per share	80.13	**79.74**	**0.71**

Consolidated Statement of Comprehensive Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2016	**3rd Quarter 9 months ended Dec. 31, 2017**	**3rd Quarter 9 months ended Dec. 31, 2017**
Profit for the period	¥ 42,581	**¥ 41,539**	**$ 367,603**
Other comprehensive income:			
Items that will not be reclassified to profit or loss:			
Net gain (loss) on financial assets measured at fair value through other comprehensive income	10,246	**23,363**	**206,749**
Remeasurement of defined benefit plans	373	**675**	**5,976**
Share of net gain (loss) on financial assets measured at fair value through other comprehensive income of investments in associates	1	**3**	**28**
Total of items that will not be reclassified to profit or loss	10,620	**24,041**	**212,753**
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	23	**158**	**1,400**
Net fair value gain (loss) on derivatives under hedge accounting	–	**6**	**49**
Total of items that may be reclassified subsequently to profit or loss	23	**164**	**1,449**
Total other comprehensive income (loss)	10,643	**24,205**	**214,202**
Total comprehensive income for the period	53,225	**65,744**	**581,805**
Comprehensive income for the period attributable to:			
Owners of the parent company	53,112	**65,620**	**580,705**
Non-controlling interests	113	**124**	**1,100**
Total comprehensive income for the period	53,225	**65,744**	**581,805**

Consolidated Statement of Changes in Equity

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2016	¥17,358	¥17,103	(¥59,358)	¥43,307	¥452,983	¥471,393	¥4,862	¥476,255
Profit for the period					42,472	42,472	109	42,581
Other comprehensive income				10,640		10,640	4	10,643
Total comprehensive income for the period	–	–	–	10,640	42,472	53,112	113	53,225
Purchase of treasury shares			(23)			(23)		(23)
Cash dividends					(20,142)	(20,142)	(3)	(20,145)
Share-based payments		30				30		30
Transfer from other components of equity to retained earnings				(2,809)	2,809	–		–
Total transactions with the owners	–	30	(23)	(2,809)	(17,333)	(20,135)	(3)	(20,138)
Balance at December 31, 2016	¥17,358	¥17,133	(¥59,381)	¥51,138	¥478,122	¥504,370	¥4,972	¥509,342

	Millions of yen							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2017	¥17,358	¥17,144	(¥59,382)	¥51,752	¥492,237	¥519,110	¥5,101	¥524,211
Profit for the period					41,439	41,439	100	41,539
Other comprehensive income				24,181		24,181	24	24,205
Total comprehensive income for the period	–	–	–	24,181	41,439	65,620	124	65,744
Purchase of treasury shares			(38,772)			(38,772)		(38,772)
Retirement of treasury shares			60,007		(60,007)	–		–
Cash dividends					(23,453)	(23,453)	(3)	(23,457)
Share-based payments		24				24		24
Transfer from other components of equity to retained earnings				(2,078)	2,078	–		–
Total transactions with the owners	–	24	21,235	(2,078)	(81,382)	(62,202)	(3)	(62,205)
Balance at December 31, 2017	¥17,358	¥17,168	(¥38,147)	¥73,855	¥452,294	¥522,528	¥5,222	¥527,750

	Thousands of US $							
	Equity attributable to owners of the parent company							
	Share capital	Capital reserves	Treasury shares	Other components of equity	Retained earnings	Equity attributable to owners of the parent company	Non-controlling interests	Total equity
Balance at April 1, 2017	**$153,613**	**$151,720**	**($525,503)**	**$457,981**	**$4,356,082**	**$4,593,893**	**$45,143**	**$4,639,036**
Profit for the period					**366,716**	**366,716**	**887**	**367,603**
Other comprehensive income				**213,989**		**213,989**	**213**	**214,202**
Total comprehensive income for the period	–	–	–	**213,989**	**366,716**	**580,705**	**1,100**	**581,805**
Purchase of treasury shares			**(343,116)**			**(343,116)**		**(343,116)**
Retirement of treasury shares			**531,035**		**(531,035)**	–		–
Cash dividends					**(207,553)**	**(207,553)**	**(28)**	**(207,580)**
Share-based payments		**211**				**211**		**211**
Transfer from other components of equity to retained earnings				**(18,388)**	**18,388**	–		–
Total transactions with the owners	–	**211**	**187,919**	**(18,388)**	**(720,199)**	**(550,457)**	**(28)**	**(550,485)**
Balance at December 31, 2017	**$153,613**	**$151,931**	**($337,585)**	**$653,582**	**$4,002,600**	**$4,624,141**	**$46,215**	**$4,670,356**

Consolidated Statement of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen		Thousands of US$
	3rd Quarter 9 months ended Dec. 31, 2016	**3rd Quarter 9 months ended Dec. 31, 2017**	**3rd Quarter 9 months ended Dec. 31, 2017**
Cash flows from operating activities			
Profit before tax	¥ 56,193	**¥ 55,333**	**$ 489,669**
Depreciation and amortization	5,651	**6,681**	**59,124**
Impairment losses	736	**–**	**–**
Interest and dividend income	(2,836)	**(2,885)**	**(25,531)**
Interest expense	10	**10**	**91**
(Increase) Decrease in inventories	(1,278)	**(4,986)**	**(44,120)**
(Increase) Decrease in trade and other receivables	(25,959)	**(19,581)**	**(173,287)**
Increase (Decrease) in trade and other payables	6,432	**(2,965)**	**(26,241)**
Increase (Decrease) in provisions	53	**3,985**	**35,264**
Increase (Decrease) in retirement benefit liabilities	304	**282**	**2,491**
Increase (Decrease) in long-term advances received	(319)	**(237)**	**(2,097)**
Other	6,735	**(10,683)**	**(94,543)**
Subtotal	45,723	**24,952**	**220,818**
Interest received	114	**66**	**587**
Dividends received	2,732	**2,817**	**24,933**
Interest paid	(10)	**(10)**	**(91)**
Income taxes paid	(11,401)	**(36,363)**	**(321,793)**
Net cash provided by (used in) operating activities	37,159	**(8,537)**	**(75,547)**
Cash flows from investing activities			
Purchases of property, plant, and equipment	(12,608)	**(11,989)**	**(106,102)**
Purchases of intangible assets	(6,719)	**(10,862)**	**(96,120)**
Purchases of investments	(2,437)	**(40)**	**(354)**
Proceeds from sales and redemption of investments	22,341	**16,761**	**148,324**
Payments into time deposits	(20,600)	**(30,600)**	**(270,796)**
Other	596	**105**	**932**
Net cash provided by (used in) investing activities	(19,427)	**(36,625)**	**(324,116)**
Cash flows from financing activities			
Dividends paid to owners of the parent company	(19,347)	**(22,478)**	**(198,924)**
Dividends paid to non-controlling interests	(3)	**(3)**	**(28)**
Repayments of long-term borrowings	(290)	**(315)**	**(2,786)**
Net increase (decrease) in short-term borrowings	(37)	**(24)**	**(213)**
Purchases of treasury shares	(22)	**(38,775)**	**(343,142)**
Net cash provided by (used in) financing activities	(19,699)	**(61,595)**	**(545,092)**
Net increase (decrease) in cash and cash equivalents	(1,968)	**(106,757)**	**(944,755)**
Cash and cash equivalents at the beginning of the period	110,485	**146,323**	**1,294,898**
Effects of exchange rate changes on cash and cash equivalents	(14)	**142**	**1,259**
Cash and cash equivalents at the end of the period	¥ 108,503	**¥ 39,708**	**$ 351,402**

Sales of Major Products

Supplemental Data

		Hundreds of Millions of yen					
		3rd Quarter 9 months ended December 31, 2017			Year ending March 31, 2018		
		Results	Increase/Decrease		Forecasts	Increase/Decrease	
Opdivo	Agent for treatment of unresectable melanoma, unresectable, advanced or recurrent non-small cell lung cancer, unresectable or metastatic renal cell carcinoma, relapsed or refractory classical hodgkin lymphoma, recurrent or metastatic head and neck cancer, and unresectable advanced or recurrent gastric cancer which has progressed after chemotherapy	¥ **690**	¥ △ 136	△ 16.5 %	¥ **890**	¥ △ 149	△ 14.3 %
Glactiv	Agent for type II diabetes	**223**	△ 4	△ 1.6 %	**295**	1	0.4 %
Orencia SC	Agent for rheumatoid arthritis	**109**	22	25.6 %	**145**	29	25.2 %
Opalmon	Circulatory system agent	**116**	△ 17	△ 13.0 %	**140**	△ 30	△ 17.8 %
Recalbon	Agent for osteoporosis	**85**	△ 2	△ 1.9 %	**110**	△ 3	△ 2.6 %
Forxiga	Agent for type II diabetes	**85**	27	47.0 %	**110**	32	40.9 %
Rivastach	Agent for Alzheimer's disease	**70**	2	3.2 %	**100**	11	12.9 %
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting	**78**	2	2.4 %	**100**	1	1.2 %
Kyprolis	Agent for relapsed or refractory multiple myeloma	**45**	34	325.7 %	**60**	40	206.1 %
Onoact	Agent for tachyarrhythmia during and post operation	**46**	2	3.5 %	**60**	3	4.8 %
Onon	Agent for bronchial asthma and allergic rhinitis	**39**	△ 8	△ 17.5 %	**55**	△ 13	△ 19.0 %
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)	**33**	△ 4	△ 11.1 %	**45**	△ 3	△ 5.7 %
Parsabiv	Agent for secondary hyperparathyroidism	**25**		Launched in February 2017	**30**	28	1439.8 %
Onon dry syrup	Agent for pediatric bronchial asthma and allergic rhinitis	**26**	△ 5	△ 17.7 %	**30**	△ 11	△ 26.9 %
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis	**24**	△ 6	△ 19.3 %	**30**	△ 8	△ 21.7 %
Kinedak	Agent for diabetic peripheral neuropathy	**18**	△ 5	△ 23.1 %	**25**	△ 4	△ 13.2 %

Note: Sales of products are shown in a gross sales basis.

Breakdown of Revenue

Supplemental Data

(Hundreds of Millions of yen)

	3rd Quarter 9 months ended December 31, 2016	3rd Quarter 9 months ended December 31, 2017
Revenue of Goods and Products	1,671	1,599
Royalty and Other Revenue	218	406
Total	1,888	2,006

Note: In "Royalty and Other Revenue", royalty revenue of "Opdivo Intravenous Infusion" is included, which is 189 hundreds of millions of yen for the 3rd quarter 9 months ended December 31, 2016 and 284 hundreds of millions of yen for the 3rd quarter 9 months ended December 31, 2017.

Information about Revenue by Geographic Area

Supplemental Data

(Hundreds of Millions of yen)

	3rd Quarter 9 months ended December 31, 2016	3rd Quarter 9 months ended December 31, 2017
Japan	1,671	1,591
Americas	194	381
Asia	21	32
Europe	3	1
Total	1,888	2,006

Note: Revenue by geographic area is attributable to countries or regions based on the customer location.

Supplemental Information

Status of Development Pipeline

as of January 30, 2018

I. Main Status of Development Pipelines (Oncology)

1. Development Status in Japan

< Filed>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Malignant pleural mesothelioma *1	Injection	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection	Additional indication	Renal cell carcinoma *2	Injection	In-license (Co-development with Bristol-Myers Squibb)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018

*1: A supplemental application for Opdivo Intravenous Infusion was filed in Japan for the treatment of unresectable advanced or metastatic malignant pleural mesothelioma for a partial change in the approved items of the manufacturing and marketing approval.
*2: A supplemental application for Opdivo and Yervoy combination therapy was filed in Japan for the treatment of unresectable or metastatic renal cell carcinoma for a partial change in the approved items of the manufacturing and marketing approval.

Note: “In-house” compounds include a compound generated from collaborative research.

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Yervoy Injection *3	Additional indication	Non-small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-license (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Change in dosage and administration	Multiple myeloma / Proteasome inhibitor	Injection	III	In-license (Amgen Inc.)
ONO-7643 / Anamorelin	New chemical entities	Cancer anorexia / cachexia / Ghrelin mimetic	Tablet	III	In-license (Helsinn Healthcare, S.A.)
ONO-7702 / Encorafenib	New chemical Entities	Melanoma / BRAF inhibitor	Capsule	III	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical Entities	Melanoma / MEK inhibitor	Tablet	III	In-license (Array Biopharma Inc.)
ONO-7701*4 (BMS-986205)	New chemical Entities	Melanoma / IDO1 inhibitor	Capsule	III	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central nervous system lymphoma, Primary testicular lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Yervoy Injection*3	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-5371 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	I / II	In-license (Valeant Pharmaceuticals North America LLC.)
ONO-4686 (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Central nervous system lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I / II	In-house
ONO-4482*5 (BMS-986016) / Relatlimab	New chemical entities	Melanoma / Anti-LAG-3 antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-4481 (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 (BMS-986227) / Cabiralizumab	New chemical entities	Solid tumor and hematologic cancer / Anti-CSF-1R antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 (BMS-986015) / Lirilumab	New chemical entities	Solid tumor / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4578	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018
*3: Combination with Opdivo
*4: Phase III of ONO-7701 (IDO1 inhibitor) in combination with Opdivo was initiated for the treatment of melanoma.
*5: Phase I / II of ONO-4482 (Anti-LAG-3 antibody) in combination with Opdivo was initiated for the treatment of melanoma.

Note: "In-house" compounds include a compound generated from collaborative research.

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

2. Development Status in S. Korea and Taiwan

< Approved>

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Gastric cancer*6	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018

*6: Approval for the partial change in approved items of the importing and marketing approval for Opdivo was obtained in Taiwan for the treatment of patients with advanced or recurrent gastric cancer or gastro-esophageal junction cancer after two or more prior chemotherapy regimens

Note: "In-house" compounds include a compound generated from collaborative research.

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Gastric cancer	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection *3	Additional indication	Renal cell carcinoma	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Non-small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-7702 / Encorafenib	New chemical entities	Colon cancer / BRAF inhibitor	Capsule	III	South Korea	In-license (Array Biopharma Inc.)
	New chemical entities	Melanoma / BRAF inhibitor	Capsule	III	South Korea	In-license (Array Biopharma Inc.)
ONO-7703 / Binimetinib	New chemical entities	Colon cancer / MEK inhibitor	Tablet	III	South Korea	In-license (Array Biopharma Inc.)
	New chemical entities	Melanoma / MEK inhibitor	Tablet	III	South Korea	In-license (Array Biopharma Inc.)
Opdivo Intravenous Infusion	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
Yervoy Injection*3	Additional indication	Virus positive / negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-license (Co-development with Bristol-Myers Squibb)

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018

*3: Combination with Opdivo

Note: “In-house” compounds include a compound generated from collaborative research.

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

3. Development Status in Europe and the United States

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Glioblastoma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Malignant pleural mesothelioma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Diffuse large B cell lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Follicular lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central Nervous System Lymphoma, Primary Testicular Lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Colon cancer	Injection	II	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Prostate cancer *7	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7579	New chemical entities	Solid tumor / Tropomyosin receptor kinase (Trk) inhibitor	Tablet	I / II	Europe USA	In-house
Opdivo Intravenous Infusion	Additional indication	Solid tumors (Triple negative breast cancer, Gastric cancer, Pancreatic cancer, Small cell lung cancer, Urothelial cancer, Ovarian cancer)	Injection	I / II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive/negative solid carcinoma	Injection	I / II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hematologic cancer (T-cell lymphoma, Multiple myeloma, Chronic leukemia, etc.)	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Chronic myeloid leukemia	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	USA	In-house (Out-license to Gilead Sciences, Inc.)
ONO-7475	New chemical entities	Acute leukemia / Axl / Mer inhibitor	Tablet	I	USA	In-house

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018

*7: Phase II of Opdivo Intravenous Infusion was initiated for the treatment of prostate cancer.

Note: "In-house" compounds include a compound generated from collaborative research.

In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

II. Main Status of Development Pipelines (Non-Oncology)

1. Development Status in Japan

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Orencia IV	Additional indication	Juvenile Idiopathic Arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)

Note: "In-house" compounds include a compound generated from collaborative research.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia IV	Additional indication	Lupus nephritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Primary sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
	Additional indication	Polymyositis / Dermatomyositis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
ONO-1162 / Ivabradine	New chemical entities	Chronic heart failure / If channel inhibitor	Tablet	III	In-license (Les Laboratoires Servier)
ONO-5704 / SI-613	New chemical entities	Osteoarthritis / Hyaluronic acid-NSAID	Injection	III	In-license (Seikagaku Corporation)
Onoact for Intravenous Infusion 50 mg / 150 mg (ONO-1101)	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short acting beta 1 blocker	Injection	II / III	In-house
	Additional indication	Ventricular arrhythmia / Short acting beta 1 blocker	Injection	II / III	In-house
	Additional indication	Tachyarrhythmia upon sepsis*8 / Short acting beta 1 blocker	Injection	II / III	In-house
ONO-2370 / Opicapone	New chemical entities	Parkinson's disease / Long acting COMT inhibitor	Tablet	II	In-license (Bial)
ONO-5704 / SI-613	New chemical entities	Enthesopathy / Hyaluronic acid-NSAID	Injection	II	In-license (Seikagaku Corporation)
Opdivo Intravenous Infusion	Additional indication	Sepsis	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	Autoimmune disease*9 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	I	In-house

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018

*8: Phase II / III of Onoact for Intravenous Infusion was initiated for the treatment of tachyarrhythmia upon sepsis.

*9: Phase I of ONO-4059 (Btk inhibitor) was initiated for healthy adults.

*Phase II of ONO-8577 (Bladder smooth muscle relaxant) for the treatment of overactive bladder was discontinued due to no expected treatment effect.

Note: "In-house" compounds include a compound generated from collaborative research.

2. Development Status in Overseas

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / In-license
ONO-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	Europe USA	In-house (Out-license to Gilead Sciences, Inc.)
Opdivo Intravenous Infusion	Additional indication	Hepatitis C	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Sepsis	Injection	I	USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-8055	New chemical entities	Underactive bladder / PG receptor (EP2 / EP3) agonist	Tablet	I	Europe	In-house

Changes from Second Quarter Flash Report for the Fiscal Year ending March 2018

* Phase II of ONO-4474 (Trk inhibitor) for the treatment of osteoarthritis was discontinued due to the strategic reason.

Note: "In-house" compounds include a compound generated from collaborative research.