## ONO PHARMACEUTICAL CO., LTD.

November 2, 2011

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for six months ended September 30, 2011.

This First - Second Quarter Flash Report 2012 (unaudited) is summary information extracted from financial statements announced, and the financial statements contained herein are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.

### **Financial Highlights**

			(No	ote) All yen amou	nts ar	e rounded off to t	he nea	rest million yen.	
			N	Millions of yen			Th	ousands of US\$	
	1st-2nd Quarter 1 6 months		1s	t-2nd Quarter 6 months		Annual 12 months	1st-2nd Quarter 6 months		
	en	ded Sep 30 2011		nded Sep 30 2010	en	ded Mar 31 2011	er	2011	
Net sales	¥	70,170	¥	63,778	¥	135,255	\$	923,289	
Net income		8,383		9,325		24,222		110,303	
Total Net assets		394,564		398,411		394,573		5,191,632	
Total assets		424,556		423,039		424,443		5,586,263	
				Yen				US\$	
Net income per common share	¥	<b>79.07</b>	¥	85.76	¥	223.88	\$	1.04	

## First-Second Quarter (April 1 – September 30, 2011) Flash Report (unaudited) Six months ended September 30, 2011

# **Consolidated Financial Forecast for the Year Ending March 31,2012**

	Year ending March 31,2012						
	Millions of yen		Thousands of US\$				
Net sales	¥ 145,400	\$	1,913,158				
Operating income	36,200		476,316				
Ordinary income	38,400		505,263				
Net income	21,000		276,316				
	Yen		US\$				
Net income per common share	198.08		2.61				

- (\*) The forecasts for the year ending March 31, 2012 are changed from May 11, 2011.
- (\*)The foregoing are forward-looking statements based on a number of assumptions and beliefs in light of the information currently available to management and are subject to risks and uncertainties. Actual financial results may differ materially depending on a number of economic factors, including conditions and currency exchange rate fluctuations.

## $\begin{tabular}{ll} First-Second \ Quarter \ (April \ 1-September \ 30, \ 2011) \ Flash \ Report \ (unaudited) \\ Six \ months \ ended \ September \ 30, \ 2011 \end{tabular}$

### **Consolidated Balance Sheets**

(N	(lote	All	l amounts	are round	ded of	f to the	nearest	million yen.
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			Tł	ousands of US\$				
ASSETS		1st-2nd Quarter September 30 2011		1st-2nd Quarter September 30 2010		Annual March 31 2011		e-2nd Quarter eptember 30 2011
Current assets								
Cash and bank deposits	¥	20,647	¥	16,084	¥	22,445	\$	271,671
Notes and accounts receivable		35,502		30,290		36,704		467,132
Marketable securities		111,260		116,113		103,524		1,463,947
Inventories		13,590		14,163		13,048		178,816
Others		16,249		15,819		15,658		213,803
Allowance for doubtful receivables		(5)		(11)		(9)		(66)
<b>Total current assets</b>		197,243		192,458		191,370	_	2,595,303
Property, plant and equipment								
Land		22,552		22,554		22,552		296,737
Buildings and structures		22,298		22,916		22,542		293,395
Machinery, equipment and others		2,832		3,257		2,864		37,263
Construction in progress		423		390		658		5,565
Net property, plant and equipment		48,105		49,117		48,616		632,960
Investments and other assets								
Investment securities		161,801		166,872		167,953		2,128,961
Intangible assets		829		909		956		10,908
Others		16,578		13,683		15,548		218,131
Total investments and other assets		179,208		181,464		184,457		2,358,000
Total assets	¥	424,556	¥	423,039	¥	424,443	\$	5,586,263

(Note) All amounts are rounded off to the nearest million yen.

			ousands of US\$						
	1st-2nd Q	uarter		ions of yen nd Quarter		Annual	nual 1st-2nd Quarte		
LIABILITIES AND EQUITY	Septemb		Sep	September 30		March 31	S	eptember 30	
	2011	<u> </u>		2010		2011		2011	
Current liabilities									
Current portion of long-term debt	¥	2	¥	2	¥	2	\$	26	
Notes and accounts payable	4	,077		3,778		5,325		53,645	
Income tax payable	6	,489		5,061		7,422		85,382	
Others	15	,441		12,200		13,449		203,171	
Total current liabilities	26	,009		21,041		26,198		342,224	
Long-term liabilities									
Long-term debt, less current portion		12		13		12		158	
Liabilities for retirement benefits		864		441		547		11,368	
Asset retirement obligations		53		51		52		697	
Others	3	,054		3,082		3,061		40,184	
Total long-term liabilities	3	,983		3,587		3,672		52,407	
Equity									
Common stock	17	,358		17,358		17,358		228,395	
Capital surplus	17	,080		17,080		17,080		224,737	
Retained earnings	419	,351		430,425		435,536		5,517,776	
Treasury stock-at cost	(59	,200)		(63,446)		(74,219)		(778,947)	
<b>Total equity</b>	394	,589		401,417		395,755		5,191,961	
Other comprehensive income									
Unrealized gain on securities (*)	5	,145		2,417		4,163		67,697	
Land revaluation surplus	(8	,939)		(8,938)		(8,938)		(117,618)	
Foreign currency translation adjustments		(264)		(216)		(267)		(3,474)	
Total other comprehensive income	(4	,058)		(6,737)		(5,042)		(53,395)	
Minority interests	4	,033		3,731		3,860		53,066	
Total net assets	394	,564		398,411		394,573		5,191,632	
Total liabilities and total net assets	¥ 424	,556	¥	423,039	¥	424,443	\$	5,586,263	

 $<sup>\</sup>begin{tabular}{ll} \begin{tabular}{ll} \beg$ 

## $\begin{tabular}{ll} First-Second Quarter (April 1-September 30, 2011) & Flash Report (unaudited) \\ Six months ended September 30, 2011 & \\ \end{tabular}$

### **Consolidated Statements of Income**

			(No	ote) All amount	s are	rounded off to	the near	rest million yen.
			Mi	llions of yen			Tho	ousands of US\$
	(	2nd Quarter 5 months ded Sep 30 2011		2nd Quarter 6 months ded Sep 30 2010		Annual 12 months 12 ded Mar 31 2011	(	2nd Quarter 6 months ded Sep 30 2011
Net sales	¥	70,170	¥	63,778	¥	135,255	\$	923,289
Cost of sales		13,494		11,182		24,759		177,552
Gross profit	_	56,676	_	52,596	-	110,496		745,737
Selling, general and administrative expenses	;	38,997		39,497		75,295		513,119
Operating income	_	17,679	_	13,099	-	35,201		232,618
Other income (expenses)								
Interest and dividend income		1,550		1,626		2,947		20,395
Interest expenses		(0)		(0)		(1)		(0)
Other, net		(3,891)		(121)		(1,247)		(51,197)
	_	(2,341)	_	1,505	_	1,699	· <u></u>	(30,802)
Income before income taxes and								
minority interests		15,338		14,604		36,900		201,816
Income taxes		6,782		5,171		12,420		89,237
Income before minority interests		8,556		9,433		24,480		112,579
Minority interests		(173)		(108)		(258)		(2,276)
Net income	¥	8,383	¥	9,325	¥	24,222	\$	110,303
				Yen				US\$
Per share of common stock				- •				
Basic net income	¥	79.07	¥	85.76	¥	223.88	\$	1.04
Cash dividends applicable to the period	¥	90.00	¥	90.00	¥	180.00	\$	1.18

#### First-Second Quarter (April 1 – September 30, 2011) Flash Report (unaudited) Six months ended September 30, 2011

## Consolidated Statements of Comprehensive Income Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

(Note)	All amounts	are rounded	off to the	nearest million ven	

		(Note) A	ii aiiiouiii	s are r	ounded on to the	to the nearest million yen.			
		Millions	of yen			Thousands of US\$			
6 end	months ed Sep 30	1 st-2nd Quarter 6 months ended Sep 30 2010		Annual 12 months ended Mar 31 2011		1st-2nd Quarte 6 months ended Sep 30 2011			
¥	8,556	¥	,433	¥	24,480	\$	112,579		
	986	(7	7,289)		(5,563)		12,974		
	3		(42)		(93)		39		
ates	(1)		(4)		(4)		(13)		
	988	(7	7,335)		(5,660)		13,000		
	9,544	2	2,098		18,820		125,579		
	9,367	1	,993		18,585		123,250		
	177		105		235		2,329		
	6 end	6 months ended Sep 30 2011  ¥ 8,556  986 3 ates (1) 988  9,544	Millions   Millions	Millions of yen     1st-2nd Quarter   6 months   6 months   ended Sep 30   2011     ¥ 8,556	Millions of yen	Millions of yen         Ist-2nd Quarter 6 months ended Sep 30 2011       Ist-2nd Quarter 6 months ended Sep 30 2011       Annual 12 months ended Mar 31 2010         ¥       8,556       ¥       9,433       ¥       24,480         986       (7,289)       (5,563)         3       (42)       (93)         ates       (1)       (4)       (4)         988       (7,335)       (5,660)         9,544       2,098       18,820         9,367       1,993       18,585	1st-2nd Quarter 6 months 6 months ended Sep 30 2011       1st-2nd Quarter 12 months ended Mar 31 2010       1st-2nd Quarter 12 months ended Mar 31 2011       2nd Quart		

## First-Second Quarter (April 1 – September 30, 2011) Flash Report (unaudited)

Six months ended September 30, 2011

### **Consolidated Statements of Cash Flows**

(N	ote)	) All	amounts	are ro	unded	off to	the	nearest	mill	lion	ven.
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	(Note	/	ounded off to the	nearest million yer Thousands of US\$
j	1st-2nd Quarter 6 months ended Sep 30 2011	Millions of yen  1st-2nd Quarter 6 months ended Sep 30 2010	Annual 12 months ended Mar 31 2011	1st-2nd Quarte 6 months ended Sep 30 2011
Operating activities:				
Income before income taxes and minority interests	¥ 15,338	¥ 14,604	¥ 36,900	\$ 201,816
Adjustments for:				
Depreciation and amortization	1,422	1,470	3,052	18,711
Decrease in allowance for doubtful receivables	(1)	(2)	(4)	(13
Increase (decrease) in provision for retirement benefits, n		(159)	(52)	4,763
Interest and dividend income  Loss on valuation of investment securities	(1,551)	(1,626)	(2,947)	(20,408
	3,854 0	138	614 1	50,711 0
Interest expenses Increase in notes and accounts receivable	1,202	1,334	(5,082)	15,816
(Increase) decrease in inventories	(542)	463	1,580	(7,132
Increase (decrease) in trade notes and accounts payable	(1,413)	1,332	2,952	(18,592
Others	1,061	4,483	3,277	13,960
Interest and dividend income received	1,647	1,749	3,178	21,671
Interest paid	0	(0)	(1)	0
Income taxes paid	(7,767)	(8,594)	(13,672)	(102,198
Net cash (used in) provided by operating activities	13,612	15,192	29,796	179,105
Investing activities:				
Payments for purchases of marketable securities	(17,195)	(12,804)	(35,548)	(226,250)
Proceeds from sales of marketable securities	37,090	22,300	63,550	488,026
Payments for purchases of property, plant and equipment	(1,067)	(530)	(1,294)	(14,039
Payments for purchases of investment securities	(12,846)	(4,473)	(15,321)	(169,026
Proceeds from sales of investment securities	176	9	14	2,316
Other payments	(91)	(143)	(286)	(1,198
Net cash generated from provided by (used in) investment	nent 6,067	4,359	11,115	79,829
Financing activities:				
Repayment of current portion of long-term debt	(1)	(1)	(2)	(13
Payments for obtaining treasury stock	(5)	(6)	(10,779)	(66
Cash dividends	(9,528)	(9,783)	(19,555)	(125,368
Net cash used in financing activities	(9,534)	(9,790)	(30,336)	(125,447
Foreign currency translation adjustments				
on cash and cash equivalents	5	(41)	(95)	66
Net decrease in cash and cash equivalents	10,150	9,720	10,480	133,553
Cash and cash equivalents, beginning	82,577	72,097	72,097	1,086,539
Cash and cash equivalents, ending	¥ 92,727	¥ 81,817	¥ 82,577	\$ 1,220,092

## First-Second Quarter (April 1 – September 30, 2011) Flash Report (unaudited) Six months ended September 30, 2011

#### **Notes to Consolidated Financial Statements**

- Note 1 This First-Second Quarter Flash Report 2012 (unaudited) is a summary information extracted from the financial statements announced by the Company on November 2, 2011.

  The financial statements announced have been prepared and stated in accordance with accounting principles generally accepted in Japan.

  The financial statements and figures contained in this First-Second Quarter Flash Report 2012
  - (unaudited) are prepared for the reference only for the convenience of readers outside Japan with certain modifications and reclassifications made from the original financial statements presented in Japanese language.
- Note 2 All amounts expressed herein in millions of Japanese yen are rounded off to the nearest million yen, which are to follow the basis of presentation in the above original announcement.
- Note 3 U.S. Dollar amounts herein are given solely for the convenience of readers outside Japan and are stated, as a matter of arithmetical computation only, at the rate of Japanese yen 76 = US\$ 1, the approximate exchange rate prevailing on September 30, 2011.

#### First-Second Quarter (April 1 – September 30, 2011) Flash Report (unaudited)

Six months ended September 30, 2011

## **Sales of Major Products**

**Supplemental Data** 

For information purpose only

(Note) All amounts are rounded off to the nearest hundred million yen.

				arter 6 mo Sep 30 201			
		R	esults	Increase/Decrease			
Opalmon	Circulatory system agent		201	¥	<b>A</b> 3	<b>▲</b> 1.3%	
Glactiv	Agent for type II diabetes		128		+94	274.6%	
Onon	Agent for bronchial asthma and allergic rhinitis		88		<b>A</b> 3	▲3.8%	
Kinedak	Agent for diabetic peripheral neuropathy		59		<b>1</b> 0	<b>▲</b> 14.6%	
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis		52		<b>4</b> 4	<b>▲</b> 7.2%	
Onon dry syrup	Agent for pediatric bronchial asthma		33		<b>4</b> 4	<b>▲</b> 11.9%	
Emend	Agent for Chemotherapy-induced nausea and vomiting		32		+12	60.9%	
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)		29		+2	9.2%	
Elaspol	Agent for acute lung injury associated with SIRS		21		<b>A</b> 3	<b>▲</b> 13.6%	
Onoact	Agent for tachyarrhythmia during and post operation		17		<b>A</b> 0	<b>▲</b> 2.2%	
Recalbon	Agent for osteoporosis		13		+4	40.2%	
Rivastach	Agent for Alzheimer's disease		4		_	_	

Note: 1 Sales of products are shown in a gross sales basis.

<sup>2</sup> Rivastach was launched in Fiscal 2011, and year-on-year changes in value and percentage are therefore not available.

#### First-Second Quarter (April 1 –September 30, 2011) Flash Report (unaudited) Six months ended September 30, 2011

**Supplemental Information** 

#### **Status of Development Pipeline**

as of November 2, 2011

#### **Developments in Japan**

NDA approved (New Chemical Entities)

Proemend® for i.v. infusion (ONO-7847 / MK-0517) (In-licensed from Merck & Co., Inc.) Chemotherapy-induced nausea and vomiting [NK1 receptor antagonist]

NDA approved (Additional Indications)
Glactiv® Tablets (ONO-5435 / MK-0431) (Co-development with Merck & Co., Inc.) Type II diabetes: combination therapy with an insulin product [ĎPP-4 inhibitor]

NDA filed (Additional Indications):
■ Emend® Capsules (ONO-7436 / MK-0869) (In-licensed from Merck & Co., Inc.) Chemotherapy-induced nausea and vomiting in pediatric patients [NK1 receptor antagonist]

Ongoing clinical studies (New Chemical Entities):

ONO-7165 / EMD531444 (injection) (Co-development with Merck KGaA) Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]

**ONO-4641** (tablet) Multiple sclerosis (Phase II) [S1P receptor agonist]

- ONO-3849 / Methylnaltrexone bromide (injection) (In-licensed from Progenics Pharmaceuticals, Inc.) Opioid-induced constipation (Phase II) [Mu-opioid receptor antagonist]
- ONO-7643 / RC-1291 (tablet) (In-licensed from Helsinn Therapeutics (U.S.), Inc.) Cancer anorexia / cachexia (Phase II) [Ghrelin mimetic]
- ONO-2745 / CNS 7056 (injection) (In-licensed from PAION AG) Short acting general anesthetic (Phase II) [GABA<sub>A</sub> receptor modulator]
- ONO-4538 / BMS-936558 (injection) Melanoma (Phase II) [Fully human anti-PD-1 antibody]
- ONO-7057 / Carfilzomib (injection) (In-licensed from Onyx Pharmaceuticals, Inc.) Multiple Myeloma (Phase I / II) [Proteasome inhibitor]
- ONO-5334 (tablet) Osteoporosis (Phase I) [Cathepsin K inhibitor]
- ONO-3951 / Asimadoline (tablet) (In-licensed from Tioga Pharmaceuticals, Inc.) Irritable bowel syndrome (Phase I) [Kappa-opioid receptor agonist]
- ONO-6950 (tablet) Bronchial asthma (Phase I) [LT receptor antagonist]

- Ongoing clinical studies (Additional Indications):

  Glactiv® Tablets (ONO-5435 / MK-0431) (Co-development with Merck & Co., Inc.) Type II diabetes: combination therapy with a rapid-acting insulin secretagogue (Phase III) [DPP-4 inhibitor]
- Onoact® for Injection (ONO-1101) Tachyarrhythmia in low cardiac function (Phase II / III) [Short acting beta-1 blocker]
- **Opalmon® Tablets (OP-1206)** (Co-development with Dainippon Sumitomo Pharma Co., Ltd.) Carpal-tunnel Syndrome (Phase II) [PGE1 analogue]

Ongoing clinical studies (New Formulations):
ONO-4164 SC / BMS-188667SC (Co-development with Bristol-Myers Squibb Company) Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]

#### **Developments abroad**

Ongoing clinical studies (New Chemical Entities):

- ONO-5334 (tablet) Osteoporosis (Phase II) [Cathepsin K inhibitor]
- ONO-4641 (tablet) (Out-licensed to Merck KGaA) Multiple sclerosis (Phase II) [S1P receptor agonist]
- ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company) Renal Cell Cancer (Phase II) Hepatitis C (Phase Ì) [Fully human anti-PD-1 antibody]
- ONO-7746 (capsule) (In-licensed from Nissan Chemical Industries, Ltd.) Thrombocytopenia (Phase I) [TPO receptor agonist]
- ONO-6950 (tablet) Bronchial asthma (Phase I) [LT receptor antagonist]
- ONO-2952 (tablet) Irritable bowel syndrome (Phase I) [TSPO antagonist]
- ONO-4053 (tablet) Allergic rhinitis (Phase I) [PGD2 receptor antagonist]

#### Changes from the First Quarter Flash Report for the Fiscal Year ending March 2012 announced on August 2, 2011

- An NDA of Glactiv<sup>®</sup> Tablets (ONO-5435 / MK-0431) for combination therapy with an insulin product in type II diabetes patients was approved by the Ministry of Health, Labour and Welfare of Japan on September 16, 2011 (additional indication).
- An NDA of Proemend® for i.v. infusion (ONO-7847 / MK-0517) for chemotherapy-induced nausea and vomiting was approved by the Ministry of Health, Labour and Welfare of Japan on September 26, 2011.
- An NDA of Emend<sup>®</sup> Capsules (ONO-7436 / MK-0869) for chemotherapy-induced nausea and vomiting in pediatric patients was filed to the Ministry of Health, Labour and Welfare of Japan (additional indication).
- Phase III study of Glactiv<sup>®</sup> Tablets (ONO-5435 / MK-0431) was commenced for combination therapy with a rapid-acting insulin secretagogue in type II diabetes patients in Japan (additional indication).
- Co-development of ONO-4164SC / BMS-188667SC, a drug for the treatment of rheumatoid arthritis, was commenced with Bristol-Myers Squibb Company in Japan under the collaboration agreement.
- Co-development of ONO-7165 / EMD531444, a drug for nonsmall cell cancer, was commenced with Merck KGaA in Japan under the license agreement. Phase II study is currently ongoing in Japan.
- Phase II study of ONO-4538 / BMS-936558, fully human anti-PD-1 antibody, was commenced for the treatment of melanoma was commenced in Japan.