# **ONO PHARMACEUTICAL CO., LTD.**

February 2, 2012

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for nine months ended December 31, 2011.

This First - Third 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**

				te) All yen amou lillions of yen	ints ar	e rounded off to	arest million yen. housands of US\$
	9	3rd Quarter 9 months ded Dec 31 2011		-3rd Quarter 9 months ded Dec 31 2010		Annual 12 months ded Mar 31 2011	-3rd Quarter 9 months nded Dec 31 2011
Net sales	¥	112,786	¥	101,609	¥	135,255	\$ 1,464,753
Net income		17,675		19,007		24,222	229,545
Total Net assets		391,364		398,387		394,573	5,082,649
Total assets		421,719		426,090		424,443	5,476,870
				Yen			US\$
Net income per common share	¥	166.71	¥	174.98	¥	223.88	\$ 2.17

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

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Year ending March 31,2012						
_	Millions of yen		Thousands of US\$				
 Net sales	¥ 145,400	\$	1,888,312				
Operating income	36,200		470,130				
Ordinary income	38,400		498,701				
Net income	18,800		244,156				
	Yen		US\$				
Net income per common share	177.33		2.30				

(\*)The forecasts for the year ending March 31, 2012 are changed from November 2, 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.

## **Consolidated Balance Sheets**

			Mi	llions of yen			Thousands of US		
ASSETS		3rd Quarter ecember 31 2011		-3rd Quarter ecember 31 2010		Annual March 31 2011	1st-3rd Quarte December 31 2011		
Current assets									
Cash and bank deposits	¥	20,007	¥	33,004	¥	22,445	\$	259,831	
Notes and accounts receivable		45,593		40,943		36,704		592,117	
Marketable securities		104,820		84,324		103,524		1,361,299	
Inventories		15,143		12,917		13,048		196,662	
Others		16,943		16,296		15,658		220,039	
Allowance for doubtful receivables		(5)		(9)		(9)		(65)	
Total current assets		202,501		187,475		191,370		2,629,883	
Property, plant and equipment									
Land		22,552		22,554		22,552		292,883	
Buildings and structures		22,412		22,611		22,542		291,065	
Machinery, equipment and others		2,634		3,036		2,864		34,208	
Construction in progress		178		742		658		2,312	
Net property, plant and equipment		47,776		48,943		48,616		620,468	
Investments and other assets									
Investment securities		152,111		174,360		167,953		1,975,468	
Intangible assets		928		997		956		12,052	
Others		18,403		14,315		15,548		238,999	
Total investments and other assets		171,442		189,672		184,457		2,226,519	
Total assets	¥	421,719	¥	426,090	¥	424,443	\$	5,476,870	

			Millions of yen		T	nousands of US\$
		-	1st-3rd Quarter	Annual		t-3rd Quarter
LIABILITIES AND EQUITY	De	cember 31	December 31	March 31	Ι	December 31
		2011	2010	2011		2011
Current liabilities						
Current portion of long-term debt	¥	2	¥ 2	¥ 2	\$	26
Notes and accounts payable		4,040	4,191	5,325		52,468
Income tax payable		7,221	5,305	7,422		93,779
Others		15,093	14,555	13,449		196,013
Total current liabilities		26,356	24,053	26,198		342,286
Long-term liabilities						
Long-term debt, less current portion		12	13	12		156
Liabilities for retirement benefits		1,245	514	547		16,169
Asset retirement obligations		53	52	52		688
Others		2,689	3,071	3,061		34,922
Total long-term liabilities		3,999	3,650	3,672		51,935
Equity						
Common stock		17,358	17,358	17,358		225,429
Capital surplus		17,080	17,080	17,080		221,818
Retained earnings		419,102	430,321	435,536		5,442,883
Treasury stock-at cost		(59,201)	(66,105)	(74,219)		(768,844)
Total equity		394,339	398,654	395,755		5,121,286
Other comprehensive income						
Unrealized gain on securities (*)		2,816	5,127	4,163		36,571
Land revaluation surplus		(8,578)	(8,938)	(8,938)		(111,403)
Foreign currency translation adjustments		(309)	(243)	(267)		(4,013)
Total other comprehensive income		(6,071)	(4,054)	(5,042)		(78,845)
Minority interests		3,096	3,787	3,860		40,208
Total net assets		391,364	398,387	394,573		5,082,649
Total liabilities and total net assets	¥	421,719	¥ 426,090	¥ 424,443	\$	5,476,870

(\*) Unrealized gain on securities classified as available for sale, net of tax

## **Consolidated Statements of Income**

					s are	e rounded off to t		arest million yen.
	9	3rd Quarter 9 months ded Dec 31	1st	9 months ded Dec 31		Annual 12 months inded Mar 31	1st	-3rd Quarter 9 months nded Dec 31
Net sales Cost of sales	¥	2011 112,786 21,754	¥	2010 101,609 17,931	¥	2011 135,255 24,759	\$	2011 1,464,753 282,519
Gross profit Selling, general and administrative expenses	; _	91,032 57,613	_	83,678 56,398	-	110,496 75,295		1,182,234 748,221
Operating income Other income (expenses)		33,419		27,280		35,201		434,013
Interest and dividend income Interest expenses Other, net	_	2,518 (0) (4,158)	_	2,601 (0) (199)	_	2,947 (1) (1,247)		32,701 (0) (54,000)
Income before income taxes and minority interests		(1,640) 31,779		2,402 29,682		1,699 36,900		(21,299) 412,714
Income taxes		13,875		10,500		12,420		180,195
Income before minority interests		17,904		19,182		24,480		232,519
Minority interests Net income	¥	(229) 17,675	¥	(175) 19,007	¥	(258) 24,222	\$	(2,974) 229,545
		,		Yen		,		US\$
<b>Per share of common stock</b> Basic net income Cash dividends applicable to the period	¥ ¥	166.71 90.00	¥ ¥	174.98 90.00	¥ ¥	223.88 180.00	\$ \$	2.17 1.17

# **Consolidated Statements of Comprehensive Income**

		(Note) All amounts are rounded off to the ne Millions of yop							
	9	rd Quarter months led Dec 31 2011	Millions of yen 1st-3rd Quarter 9 months ended Dec 31 2010	Annual 12 months ended Mar 31 2011	Thousands of US\$ <b>1st-3rd Quarter</b> <b>9 months</b> <b>ended Dec 31</b> <b>2011</b>				
Net income before minority interests	¥	17,904	¥ 19,182	¥ 24,480	\$ 232,519				
Other comprehensive income									
Unrealized loss on available-for-sale secur	rities	(1,341)	(4,590)	(5,563)	(17,415)				
Revaluation reserve for land		361	_	_	4,688				
Foreign currency translation adjustments		(43)	(69)	(93)	(558)				
Share of other comprehensive income in as	ssociates	1	(3)	(4)	13				
Total other comprehensive income		(1,022)	(4,662)	(5,660)	(13,272)				
Comprehensive income		16,882	14,520	18,820	219,247				
Total comprehensive income attributable	to								
Owners of the parent		16,646	14,358	18,585	216,182				
Minority interests		236	162	235	3,065				

### First-Third Quarter (April 1 – December 31, 2011) Flash Report (unaudited)

Nine months ended December 31, 2011

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

	(110)	te) All amounts are millions of yen	Thousands of US\$	
	1st-3rd Quarter 9 months ended Dec 31 2011	1st-3rd Quarter 9 months ended Dec 31 2010	Annual 12 months ended Mar 31 2011	1st-3rd Quarter 9 months ended Dec 31 2011
Operating activities:				
Income before income taxes and minority interests	¥ 31,779	¥ 29,682	¥ 36,900	\$ 412,714
Adjustments for:				
Depreciation and amortization	2,205	2,249	3,052	28,636
Decrease in allowance for doubtful receivables	(1)	(4)	(4)	(13
Increase (decrease) in provision for retirement benefits, ne		-	(52)	9,636
Interest and dividend income	(2,518)	(2,601)	(2,947)	(32,701
Loss on valuation of investment securities	3,891	_	614	50,532
Interest expenses	0	0	1	0
Increase in notes and accounts receivable	(8,889)	(9,320)	(5,082)	(115,442
(Increase) decrease in inventories	(2,095)	1,709	1,580	(27,208)
Increase (decrease) in trade notes and accounts payable Others	(1,254)	1,834	2,952	(16,286
Interest and dividend income received	(1,123) 2,676	4,590 2,814	3,277 3,178	(14,583) 34,753
Interest paid	2,070	2,014 (0)	(1)	
Income taxes paid	(14,074)	(13,654)	(13,672)	(182,779
Net cash (used in) provided by operating activities	11,339	17,299	29,796	147,259
Investing activities:				
Payments for purchases of marketable securities	(22,604)	(26,151)	(35,548)	(293,558
Proceeds from sales of marketable securities	53,370	46,750	63,550	693,117
Payments for purchases of property, plant and equipment	(1,616)	(978)	(1,294)	(20,987
Payments for purchases of investment securities	(14,889)	(14,821)	(15,321)	(193,364
Proceeds from sales of investment securities	466	11	14	6,052
Other payments	(945)	(322)	(286)	(12,273
Net cash generated from provided by (used in) investme	nent 13,782	4,489	11,115	178,987
Financing activities:				
Repayment of current portion of long-term debt	(1)	(1)	(2)	(13
Payments for obtaining treasury stock	(7)	(2,664)	(10,779)	(91
Cash dividends	(18,548)	(19,025)	(19,555)	(240,883
Net cash used in financing activities	(18,556)	(21,690)	(30,336)	(240,987)
Foreign currency translation adjustments				
on cash and cash equivalents	(41)	(68)	(95)	(532
Net decrease in cash and cash equivalents	6,524	30	10,480	84,727
Cash and cash equivalents, beginning	82,577	72,097	72,097	1,072,429
Cash and cash equivalents, ending	¥ 89,101	¥ 72,127	¥ 82,577	\$ 1,157,156

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

**Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries** 

Note 1 This First-Third Quarter Flash Report 2012 (unaudited) is summary information extracted from the financial statements announced by the Company on February 2, 2012. 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-Third 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 77 = US\$ 1, the approximate exchange rate prevailing on December 31, 2011.

## First-Third Quarter (April 1 – December 31, 2011) Flash Report (unaudited)

Nine months ended December 31, 2011

## **Sales of Major Products**

**Supplemental Data** 

For information purpose only

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

			onths 1			
		R	esults		/Decrease	
Opalmon	Circulatory system agent	¥	312	¥	▲ 3	▲0.8%
Glactiv	Agent for type II diabetes		208		+143	218.6%
Onon	Agent for bronchial asthma and allergic rhinitis		139		▲ 8	▲5.3%
Kinedak	Agent for diabetic peripheral neuropathy		90		▲ 15	▲14.4%
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis		81		▲ 6	▲6.7%
Onon dry syrup	Agent for pediatric bronchial asthma		57		▲ 7	▲11.3%
Emend	Agent for Chemotherapy-induced nausea and vomiting		50		+16	44.7%
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)		46		+4	8.3%
Elaspol	Agent for acute lung injury associated with SIRS		34		▲ 5	▲13.4%
Onoact	Agent for tachyarrhythmia during and post operation		27		<b>▲</b> 1	▲4.9%
Recalbon	Agent for osteoporosis		24		+9	60.2%
Rivastach	Agent for Alzheimer's disease		8		_	_

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

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

## First-Third Quarter (April 1 – December 31, 2011) Flash Report (unaudited)

Nine months ended December 31, 2011

#### **Supplemental Information**

### **Status of Development Pipeline** as of February 2, 2012

#### **Developments in Japan**

- Onon<sup>®</sup> Dry Syrup (ONO-1078) Allergic Rhinitis [LT receptor antagonist]
- NDA filed (Additional Indications): Emend<sup>®</sup> 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 ÅG) 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] ONO-7056 / Salirasib (tablet)
- (In-licensed from Concordia Pharmaceuticals, Inc.) Solid tumor (Phase I) [Ras signal inhibitor]

- Ongoing clinical studies (Additional Indications):
   Glactiv<sup>®</sup> 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<sup>®</sup> for Injection (ONO-1101)** Tachyarrhythmia in low cardiac function (Phase II / III) [Short acting beta-1 blocker]
- **Opalmon<sup>®</sup> 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 I) [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]
- ONO-9054 (eye drop) Glaucoma, ocular hypertension (Phase I) [PG receptor (FP / EP3) agonist]

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

- An NDA of Onon® Dry Syrup (ONO-1078) for allergic rhinitis patients was approved by the Ministry of Health, Labour and Welfare of Japan on December 22, 2011 (additional indication).
- Phase I of ONO-7056 / Salirasib, Ras signal inhibitor, was commenced in Japan.
- Phase I of ONO-9054, PG receptor (FP / EP3) agonist, was commenced outside Japan.