# ONO PHARMACEUTICAL CO., LTD.

August 2, 2012

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for three months ended June 30, 2012.

This First Quarter Flash Report 2013 (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**

			(Not	te) All yen amou	unts ar	e rounded off to	the near	rest million yen.
			M	illions of yen			Tho	ousands of US\$
	1st Quarter 3 months ended Jun 30		1	st Quarter		Annual	1	st Quarter
				3 months	]	12 months		3 months
			en	ided Jun 30	en	ded Mar 31	en	ded Jun 30
		2012		2011		2012		2012
Net sales	¥	37,652	¥	36,329	¥	145,779	\$	470,650
Net income		8,422		8,346		24,361		105,275
Total Net assets		396,583		392,963		400,968		4,957,288
Total assets		432,162		423,629		436,414		5,402,025
				Yen				US\$
Net income per common share	¥	79.43	¥	78.72	¥	229.78	\$	0.99

# First Quarter (April 1 – June 30, 2012) Flash Report (unaudited) Three months ended June 30, 2012

# Consolidated Forecast of Consolidated Results for the Six Months Ending September 30, 2012 and for the Year Ending March 31, 2013

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Six months ending					Year ending					
	<b>September 30, 2012</b>				March 31, 2013						
	М	fillions of yen	Tho	ousands of US\$	N	Tillions of yen	Th	ousands of US\$			
Net sales	¥	70,200	\$	877,500	¥	146,200	\$	1,827,500			
Operating income		14,900		186,250		32,700		408,750			
Ordinary income		16,100		201,250		34,100		426,250			
Net income		10,800		135,000		23,000		287,500			
		Yen		US\$		Yen		US\$			
Net income per common share	<u> </u>	101.87		1.27		216.94		2.71			

(\*)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.

Three months ended June 30, 2012

# **Consolidated Balance Sheets**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millio	Thousands of US\$		
ASSETS	1st Quarter June 30 2012	March 31 2012	1st Quarter June 30 2012	
Current assets				
Cash and bank deposits	¥ 18,452	¥ 20,960	\$ 230,650	
Notes and accounts receivable	43,028	37,853	537,850	
Marketable securities	98,761	104,814	1,234,513	
Inventories	22,666	18,638	283,325	
Others	22,490	19,977	281,125	
Allowance for doubtful receivables	(6)	(6)	(75)	
Total current assets	205,391	202,236	2,567,388	
Property, plant and equipment				
Land	22,544	22,550	281,800	
Buildings and structures	22,211	22,644	277,638	
Machinery, equipment and others	2,464	2,524	30,799	
Construction in progress	430	262	5,375	
Net property, plant and equipment	47,649	47,980	595,612	
Investments and other assets				
Investment securities	161,568	168,691	2,019,600	
Intangible assets	1,119	995	13,988	
Others	16,435	16,512	205,437	
Total investments and other assets	179,122	186,198	2,239,025	
Total assets	¥ 432,162	¥ 436,414	\$ 5,402,025	

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

	N	Thousands of US\$			
LIABILITIES AND EQUITY	1st Quar June 30 2012		March 31 2011		Ist Quarter June 30 2012
Current liabilities					
Current portion of long-term debt	¥	<b>2</b> ¥	2	\$	25
Notes and accounts payable	7,8	338	5,767		97,975
Income tax payable	4,3	183	8,876		52,287
Others	19,2	298	16,397		241,225
Total current liabilities	31,	321	31,042		391,512
Long-term liabilities					
Long-term debt, less current portion		11	11		138
Liabilities for retirement benefits	1,4	185	1,628		18,562
Asset retirement obligations		53	53		663
Others		709	2,712		33,862
Total long-term liabilities	4,2	258	4,404	_	53,225
Equity					
Common stock	17,	358	17,358		216,975
Capital surplus	17,0	080	17,080		213,500
Retained earnings	424,0	668	425,787		5,308,350
Treasury stock-at cost	(59,2	208)	(59,204)		(740,100)
Total equity	399,	898	401,021		4,998,725
Other comprehensive income					
Unrealized gain on securities (*)	2,	546	5,725		31,825
Land revaluation surplus	(8,	578)	(8,577)		(107,225)
Deferred losses on hedges		(21)	_		(263)
Foreign currency translation adjustments	(3	373)	(277)		(4,662)
Total other comprehensive income	(6,4	126)	(3,129)		(80,325)
<b>Minority interests</b>	3,	111	3,076		38,888
Total net assets	396,	583	400,968		4,957,288
Total liabilities and total net assets	¥ 432,	162 ¥	436,414	\$	5,402,025

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

Three months ended June 30, 2012

## **Consolidated Statements of Income**

				rest million yen.				
		st Quarter 3 months ded Jun 30 2012	1	st Quarter 3 months aded Jun 30 2011		Annual 12 months aded Mar 31 2012	19	st Quarter 3 months ded Jun 30 2012
Net sales	¥	37,652	¥	36,329	¥	145,779	\$	470,650
Cost of sales		8,442		6,808		28,987		105,525
Gross profit	_	29,210	_	29,521	-	116,792		365,125
Selling, general and administrative expenses	S	17,130		17,339		78,888		214,125
Operating income	_	12,080	_	12,182	-	37,904		151,000
Other income (expenses) Interest and dividend income		1,204		1,228		2,800		15,050
Interest expenses		0				(1)		(0)
Other, net		(462)		(392)		(693)		(5,775)
Income before income taxes and	_	742	_	836	-	2,106		9,275
minority interests		12,822		13,018		40,010		160,275
Income taxes		4,360		4,572		15,376		54,500
Income before minority interests		8,462		8,446		24,634		105,775
Minority interests		(40)		(100)		(273)		(500)
Net income	¥	8,422	¥	8,346	¥	24,361	\$	105,275
				Yen				US\$
Per share of common stock								
Basic net income	¥	79.43	¥	78.72	¥	229.78	\$	0.99
Cash dividends applicable to the period	¥	_	¥	_	¥	180.00	\$	_

#### First Quarter (April 1 – June 30, 2012) Flash Report (unaudited) Three months ended June 30, 2012

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

-	(Note)	A11	amounts	are	rounde	d off	to the	nearest	million	ven

		he nearest million yen.						
				ons of yen			Tho	ousands of US\$
		Quarter		Quarter		Annual		st Quarter
	_	months ed Jun 30	_	months		2 months		3 months
				ed Jun 30 2011	enc	led Mar 31 2012	en	ded Jun 30 2012
Net income before minority interests	¥	8,462	¥	8,446	¥	24,634	\$	105,775
Other comprehensive income  Unrealized gain (loss) on available-for-sale securitie	G.	(3,177)		(532)		1,578		(39,712)
	S	(3,177)		(332)		1,376		(39,/12)
Land revaluation difference		_		_		361		_
Deferred losses on hedges		(21)		_		_		(263)
Foreign currency translation adjustments		(96)		25		(10)		(1,200)
Share of other comprehensive income in associates		(0)		(0)		4		(0)
Total other comprehensive income		(3,294)		(507)		1,933		(41,175)
Comprehensive income		5,168		7,939		26,567		64,600
Total comprehensive income attributable to								
Owners of the parent		5,125		7,840		26,274		64,062
Minority interests		43		99		293		538

Three months ended June 30, 2012

## **Consolidated Statements of Cash Flows**

(Note) All amounts are rounded off to the nearest hundred million
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		Hundred m	illions of	yen	Hundr	ed thousands of US\$
	3 m ended	Quarter nonths I Jun 30 012	3 n ende	1st Quarter 3 months ended Jun 30 2011		st Quarter 3 months ided Jun 30 2012
Operating activities: (*)	¥	(22)	¥	49	\$	(275)
Investing activities:		115		46		1,438
Financing activities:		(87)		(86)		(1,088)
Net decrease in cash and cash equivalents		6		9		75
Cash and cash equivalents, ending	¥	856	¥	835	\$	10,700
(*)Depreciation and amortization is included in "Operating ac	tivities' ¥	7		7	\$	88

Three months ended June 30, 2012

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

- Note 1 This First Quarter Flash Report 2013 (unaudited) is a summary information extracted from the financial statements announced by the Company on August 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 Quarter Flash Report 2013 (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 80 = US\$ 1, the approximate exchange rate prevailing on June 30, 2012.

Three months ended June 30, 2012

# **Sales of Major Products**

**Supplemental Data** 

For information purpose only

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

# 1st Quarter 3 months ended Jun 30 2012

			C.	ilucu	Jun 50 20.	-		
				Increase/Decrease				
Opalmon	Circulatory system agent	¥	91	¥	△ 10	△10.1%		
Glactiv	Agent for type II diabetes		86		+25	39. 7%		
Onon	Agent for bronchial asthma and allergic rhinitis		42		△ 10	△19.3%		
Kinedak	Agent for diabetic peripheral neuropathy		25		△ 6	△18.4%		
Foipan	Agent for chronic pancreatitis and postoperative reflux esophagitis		24		△ 2	△9.1%		
Emend/Proemend	Agent for Chemotherapy-induced nausea and vomiting		20		+5	29. 8%		
Onon dry syrup	Agent for pediatric bronchial asthma		18		△ 1	△3.3%		
Staybla	Agent for overactive bladder (pollakiuria and urinary incontinence)		18		+2	12.8%		
Recalbon	Agent for osteoporosis		16		+11	199.0%		
Elaspol	Agent for acute lung injury associated with SIRS		10		Δ1	△8.2%		
Onoact	Agent for tachyarrhythmia during and post operation		9		+1	6.4%		
Rivastach	Agent for Alzheimer's disease		6		_	_		

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.

Three months ended June 30, 2012

**Supplemental Information** 

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

as of August 2, 2012

**Developments in Japan** 

NDA approved (Additional Indications)

• Emend® Capsules (ONO-7436 / MK-0869) \*1 (In-licensed from Merck & Co., Inc.) Chemotherapy-induced nausea and vomiting in pediatric patients [NK1 receptor antagonist]

NDA filed (New Formulations):
Orencia® SC (ONO-4164 SC / BMS-188667SC) \*2 (Co-development with Bristol-Myers Squibb Company) Rheumatoid Arthritis [T-cell activation inhibitor]

#### 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-3951 / Asimadoline (tablet) \*3 (In-licensed from Tioga Pharmaceuticals, Inc.) Irritable bowel syndrome (Phase II) [Kappa-opioid receptor agonist]

ONO-7057 / Carfilzomib (injection) (In-licensed from Onyx Pharmaceuticals, Inc.)
Multiple Myeloma (Phase I / II) [Proteasome inhibitor]

ONO-6950 (tablet) Bronchial asthma (Phase I) [LT receptor antagonist]

ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Corporation LLC) Solid tumor (Phase I) [Ras signal inhibitor]

• ONO-5163 / KAI-4169 (injection) (In-licensed from Amgen Inc.) Secondary hyperparathyroidism (Phase I) [Calcium sensing receptor agonist]

ONO-7268 MX1 (injection) (In-licensed from OncoTherapy Science, Inc.) \*4 Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]

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]

Proemend® for i.v. infusion (ONO-7847 / MK-0517) \*5 Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK1 receptor antagonist]

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-tunn el Syndrome (Phase II) [PGE1 analogue]

Ongoing clinical studies (Additional Dosing Regimen):
• Rivastach® Patch (ONO-2540 / ENA713D) \*6 (Co-development with Novartis Pharma K.K.) Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

Ongoing clinical studies (New Formulations):

Glactiv® and Metformin Combination Tablets (ONO-5435A / MK-0431A) (Co-development with Merck & Co., Inc.) Type II diabetes (Phase III) / Combination product with Glacitiv and biguanide

**Developments abroad** 

Ongoing clinical studies (New Chemical Entities):

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-6950 (tablet) Bronchial asthma (Phase II) [LT receptor antagonist]

ONO-7746 (capsule) (In-licensed from Nissan Chemical Industries, Ltd.) Thrombocytopenia (Phase I) [TPO receptor agonist]

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]

ONO-4059 (tablet) B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]

ONO-8539 (tablet) \*7 Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]

#### Changes from Annual Flash Report for the Fiscal Year ending March 2012 announced on May 9, 2012

- \*1: NDA of Emend® Capsules (ONO-7436 / MK-0869) for chemotherapy-induced nausea and vomiting in pediatric patients was approved by the Ministry of Health, Labour and Welfare of Japan on June 22, 2012 (additional indications).
- \*2: NDA of Orencia® SC (ONO-4164 SC / BMS-188667SC) for Rheumatoid Arthritis was filed to the Ministry of Health, Labour and Welfare of Japan on July 4, 2012 (new formulations).
- \*3: Phase II clinical study of ONO-3951, kappa-opioid receptor agonist, for irritable bowel syndrome was commenced
- \*4: Phase I clinical study of ONO-7268 MX1, Therapeutic cancer peptide vaccines, for hepatocellular carcinoma was commenced in Japan.
- \*5: Phase III clinical study of Proemend® for i.v. infusion (ONO-7847 / MK-0517) for chemotherapy-induced nausea and vomiting in pediatric patients was commenced in Japan.
- \*6: Phase III clinical study of Rivastach® Patch (ONO-2540 / ENA713D) for Alzheimer's disease was commenced to obtain additional dosing regimen in Japan.
- \*7: Phase I clinical study of ONO-8539, PG receptor (EP1) antagonist, was commenced outside Japan.