

## First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)

Nine months ended December 31, 2012

# ONO PHARMACEUTICAL CO., LTD.

February 4, 2013

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for nine months ended December 31, 2012.

This First - Third 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

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	(Note) All yen amounts are rounded off to the nearest million yen.			Thousands of US\$
	Millions of yen			
	<b>1st-3rd Quarter 9 months ended Dec 31 2012</b>	1st-3rd Quarter 9 months ended Dec 31 2011	Annual 12 months ended Mar 31 2012	<b>1st-3rd Quarter 9 months ended Dec 31 2012</b>
Net sales	¥ 112,369	¥ 112,786	¥ 145,779	\$ 1,291,598
Net income	20,942	17,675	24,361	240,713
Total Net assets	405,229	391,364	400,968	4,657,805
Total assets	433,727	421,719	436,414	4,985,368
		Yen		US\$
Net income per common share	¥ 197.53	¥ 166.71	¥ 229.78	\$ 2.27

**First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)**  
Nine months ended December 31, 2012

**Consolidated Financial Forecast for the Year  
Ending March 31, 2013**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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	<b>Year ending March 31, 2013</b>	
	<b>Millions of yen</b>	<b>Thousands of US\$</b>
<b>Net sales</b>	<b>¥ 146,200</b>	<b>\$ 1,680,460</b>
<b>Operating income</b>	<b>32,700</b>	<b>375,862</b>
<b>Ordinary income</b>	<b>34,100</b>	<b>391,954</b>
<b>Net income</b>	<b>23,000</b>	<b>264,368</b>
	<b>Yen</b>	<b>US\$</b>
<b>Net income per common share</b>	<b>216.95</b>	<b>2.49</b>

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(\*)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.

**First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)**  
 Nine months ended December 31, 2012

## Consolidated Balance Sheets

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

ASSETS	Millions of yen			Thousands of US\$
	1st-3rd Quarter December 31 2012	1st-3rd Quarter December 31 2011	Annual March 31 2012	1st-3rd Quarter December 31 2012
<b>Current assets</b>				
Cash and bank deposits	¥ 19,744	¥ 20,007	¥ 20,960	\$ 226,943
Notes and accounts receivable	45,476	45,593	37,853	522,713
Marketable securities	98,581	104,820	104,814	1,133,115
Inventories	21,835	15,143	18,638	250,977
Others	20,633	16,943	19,977	237,160
Allowance for doubtful receivables	(6)	(5)	(6)	(69)
<b>Total current assets</b>	<b>206,263</b>	<b>202,501</b>	<b>202,236</b>	<b>2,370,839</b>
<b>Property, plant and equipment</b>				
Land	22,544	22,552	22,550	259,126
Buildings and structures	21,942	22,412	22,644	252,207
Machinery, equipment and others	3,015	2,634	2,525	34,656
Construction in progress	966	178	262	11,103
<b>Net property, plant and equipment</b>	<b>48,467</b>	<b>47,776</b>	<b>47,980</b>	<b>557,092</b>
<b>Investments and other assets</b>				
Investment securities	163,628	152,111	168,691	1,880,782
Intangible assets	1,198	928	995	13,770
Others	14,171	18,403	16,512	162,885
<b>Total investments and other assets</b>	<b>178,997</b>	<b>171,442</b>	<b>186,198</b>	<b>2,057,437</b>
<b>Total assets</b>	<b>433,727</b>	¥ 421,719	¥ 436,414	\$ 4,985,368

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

LIABILITIES AND EQUITY	Millions of yen			Thousands of US\$
	1st-3rd Quarter December 31 2012	1st-3rd Quarter December 31 2011	Annual March 31 2012	1st-3rd Quarter December 31 2012
<b>Current liabilities</b>				
Current portion of long-term debt	¥ 102	¥ 2	¥ 2	\$ 1,172
Notes and accounts payable	4,083	4,040	5,767	46,931
Income tax payable	4,270	7,221	8,876	49,080
Others	15,916	15,093	16,397	182,943
<b>Total current liabilities</b>	<b>24,371</b>	<b>26,356</b>	<b>31,042</b>	<b>280,126</b>
<b>Long-term liabilities</b>				
Long-term debt, less current portion	160	12	11	1,839
Liabilities for retirement benefits	1,209	1,245	1,628	13,897
Asset retirement obligations	54	53	53	621
Others	2,704	2,689	2,712	31,080
<b>Total long-term liabilities</b>	<b>4,127</b>	<b>3,999</b>	<b>4,404</b>	<b>47,437</b>
<b>Equity</b>				
Common stock	17,358	17,358	17,358	199,517
Capital surplus	17,080	17,080	17,080	196,322
Retained earnings	427,646	419,102	425,787	4,915,472
Treasury stock-at cost	(59,212)	(59,201)	(59,204)	(680,598)
<b>Total equity</b>	<b>402,872</b>	<b>394,339</b>	<b>401,021</b>	<b>4,630,713</b>
<b>Other comprehensive income</b>				
Unrealized gain on securities (*)	7,819	2,816	5,725	89,874
Land revaluation surplus	(8,578)	(8,578)	(8,577)	(98,598)
Deferred gain on hedges	45	-	-	517
Foreign currency translation adjustments	(129)	(309)	(277)	(1,483)
<b>Total other comprehensive income</b>	<b>(843)</b>	<b>(6,071)</b>	<b>(3,129)</b>	<b>(9,690)</b>
<b>Minority interests</b>	<b>3,200</b>	<b>3,096</b>	<b>3,076</b>	<b>36,782</b>
<b>Total net assets</b>	<b>405,229</b>	<b>391,364</b>	<b>400,968</b>	<b>4,657,805</b>
<b>Total liabilities and total net assets</b>	<b>433,727</b>	<b>¥ 421,719</b>	<b>¥ 436,414</b>	<b>\$ 4,985,368</b>

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

## First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)

Nine months ended December 31, 2012

### Consolidated Statements of Income

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millions of yen			Thousands of US\$
	1st-3rd Quarter 9 months ended Dec 31 2012	1st-3rd Quarter 9 months ended Dec 31 2011	Annual 12 months ended Mar 31 2012	1st-3rd Quarter 9 months ended Dec 31 2012
<b>Net sales</b>	¥ 112,369	¥ 112,786	¥ 145,779	\$ 1,291,598
<b>Cost of sales</b>	25,746	21,754	28,987	295,931
Gross profit	86,623	91,032	116,792	995,667
<b>Selling, general and administrative expenses</b>	57,750	57,613	78,888	663,793
Operating income	28,873	33,419	37,904	331,874
<b>Other income (expenses)</b>				
Interest and dividend income	2,367	2,518	2,800	27,207
Interest expenses	(1)	(0)	(1)	(11)
Other, net	336	(4,158)	(693)	3,861
	2,702	(1,640)	2,106	31,057
Income before income taxes and minority interests	31,575	31,779	40,010	362,931
<b>Income taxes</b>	10,495	13,875	15,376	120,632
Income before minority interests	21,080	17,904	24,634	242,299
<b>Minority interests</b>	(138)	(229)	(273)	(1,586)
<b>Net income</b>	20,942	¥ 17,675	¥ 24,361	\$ 240,713
<b>Per share of common stock</b>				
Basic net income	¥ 197.53	¥ 166.71	¥ 229.78	\$ 2.27
Cash dividends applicable to the period	¥ 90.00	¥ 90.00	¥ 180.00	\$ 1.03

**First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)**

Nine months ended December 31, 2012

**Consolidated Statements of Comprehensive Income**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Millions of yen			Thousands of US\$
	<b>1st-3rd Quarter 9 months ended Dec 31 2012</b>	1st-3rd Quarter 9 months ended Dec 31 2011	Annual 12 months ended Mar 31 2012	<b>1st-3rd Quarter 9 months ended Dec 31 2012</b>
<b>Net income before minority interests</b>	<b>¥ 21,080</b>	¥ 17,904	¥ 24,634	<b>\$ 242,299</b>
<b>Other comprehensive income</b>				
Unrealized loss on available-for-sale securities	<b>2,085</b>	(1,341)	1,578	<b>23,966</b>
Deferred gain on hedges	<b>45</b>	—	—	<b>517</b>
Land revaluation difference	—	361	361	—
Foreign currency translation adjustments	<b>147</b>	(43)	(10)	<b>1,690</b>
Share of other comprehensive income in associates	<b>3</b>	1	4	<b>34</b>
Total other comprehensive income	<b>2,280</b>	(1,022)	1,933	<b>26,207</b>
<b>Comprehensive income</b>	<b>23,360</b>	16,882	26,567	<b>268,506</b>
<b>Total comprehensive income attributable to</b>				
Owners of the parent	<b>23,228</b>	16,646	26,274	<b>266,989</b>
Minority interests	<b>132</b>	236	293	<b>1,517</b>

## First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)

Nine months ended December 31, 2012

### Consolidated Statements of Cash Flows

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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

	Hundred millions of yen		Hundred thousands of US\$
	1st-3rd Quarter 9 months ended Dec 31 2012	1st-3rd Quarter 9 months ended Dec 31 2011	1st-3rd Quarter 9 months ended Dec 31 2012
Operating activities: <sup>(*)</sup>	¥ 56	¥ 113	\$ 644
Investing activities:	153	138	1,759
Financing activities:	(183)	(186)	(2,103)
Net decrease in cash and cash equivalents	25	65	287
Cash and cash equivalents, ending	¥ 876	¥ 891	\$ 10,069
(*)Depreciation and amortization is included in "Operating activities"	¥ 21	22	\$ 241

**First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)**  
Nine months ended December 31, 2012

## **Notes to Consolidated Financial Statements**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This First-Third Quarter Flash Report 2013 (unaudited) is a summary information extracted from the financial statements announced by the Company on February 4, 2013. 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 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 87 = US\$ 1, the approximate exchange rate prevailing on December 28, 2012.



## First-Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)

Nine months ended December 31, 2012

### Sales of Major Products

Supplemental Data

For information purpose only

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

		1st-3rd Quarter 9 months ended Dec 31 2012			Year ending March 31,2013
		Results	Increase/Decrease		Forecast
<b>Opalmon</b>	Circulatory system agent	¥ 268	¥ ▲ 44	▲14.0%	¥ 335
<b>Glactiv</b>	Agent for type II diabetes	268	+59	28.5%	350
<b>Onon</b>	Agent for bronchial asthma and allergic rhinitis	113	▲ 26	▲18.9%	165
<b>Kinedak</b>	Agent for diabetic peripheral neuropathy	70	▲ 20	▲22.5%	90
<b>Foipan</b>	Agent for chronic pancreatitis and postoperative reflux esophagitis	70	▲ 11	▲13.7%	85
<b>Emend/Proemend</b>	Agent for Chemotherapy-induced nausea and vomiting	62	+11	21.9%	75
<b>Recalbon</b>	Agent for osteoporosis	57	+33	138.1%	80
<b>Staybla</b>	Agent for overactive bladder (pollakiuria and urinary incontinence)	50	+4	7.8%	70
<b>Onon dry syrup</b>	Agent for pediatric bronchial asthma	55	▲ 3	▲5.1%	75
<b>Elaspol</b>	Agent for acute lung injury associated with SIRS	31	▲ 3	▲8.3%	40
<b>Onoact</b>	Agent for tachyarrhythmia during and post operation	30	+3	9.6%	36
<b>Rivastach</b>	Agent for Alzheimer's disease	29	+20	242.9%	38

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

## First- Third Quarter (April 1 – December 31, 2012) Flash Report (unaudited)

Nine months ended December 31, 2012

### Supplemental Information

## Status of Development Pipeline

as of February 4, 2013

### Developments in Japan

#### *NDA filed (New Formulations):*

- **Orencia® SC (ONO-4164 SC / BMS-188667SC)**  
(Co-development with Bristol-Myers Squibb Company)  
Rheumatoid Arthritis [T-cell activation inhibitor]
- **Glactiv® Tablets 12.5mg (ONO-5435 / MK-0431)**  
(Co-development with Merck & Co., Inc.)  
Type II diabetes with severe renal dysfunction [DPP-4 inhibitor]

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-2745 / CNS 7056 (injection)**  
(In-licensed from PAION AG)  
Short acting general anesthetic (Phase II / III)  
[GABA<sub>A</sub> receptor modulator]
- **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 / Methylalntrexone 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-4538 / BMS-936558 (injection)**  
Melanoma (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection) \*1**  
Non-small-cell lung cancer (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-3951 / Asimadoline (tablet)**  
(In-licensed from Tioga Pharmaceuticals, Inc.)  
Irritable bowel syndrome (Phase II)  
[Kappa-opioid receptor agonist]
- **ONO-2745 / CNS 7056 (injection)**  
(In-licensed from PAION AG)  
ICU sedation (Phase II)  
[GABA<sub>A</sub> receptor modulator]
- **ONO-7057 / Carfilzomib (injection)**  
(In-licensed from Onyx Pharmaceuticals, Inc.)  
Multiple Myeloma (Phase I / II) [Proteasome inhibitor]
- **ONO-5163 / AMG-416 (injection)**  
(In-licensed from Amgen Inc.)  
Secondary hyperparathyroidism (Phase I / II) [Calcium sensing receptor agonist]
- **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-7268 MX1 (injection)**  
(In-licensed from OncoTherapy Science, Inc.)  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-1162 / Ivabradine (tablet)**  
(In-licensed from Les Laboratoires Servier)  
Chronic heart failure (Phase I) [If channel inhibitor]

#### *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)**  
(In-licensed from Merck & Co., Inc.)  
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]

#### *Ongoing clinical studies (Additional Dosing Regimen):*

- **Rivastach® Patch (ONO-2540 / ENA713D)**  
(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 Glactiv and biguanide

### Developments abroad

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Renal cell cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Non-small-cell lung cancer (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection) \*2**  
(Out-licensed to Bristol-Myers Squibb Company)  
Melanoma (Phase III) [Fully human anti-PD-1 antibody]
- **ONO-4641 (tablet)**  
(Out-licensed to Merck KGaA)  
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-6950 (tablet)**  
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**  
Allergic rhinitis (Phase II) [PGD2 receptor antagonist]

- **ONO-8539 (tablet)**  
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
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-2952 (tablet)**  
Irritable bowel syndrome (Phase I) [TSPO 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-8055 (tablet)**  
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]

**Changes from Second Quarter Flash Report for the Fiscal Year ending March 2013 announced on November 5, 2012**

- \*1: Phase II clinical study of ONO-4538, fully human anti-PD-1 antibody, for non-small-cell lung cancer was commenced in Japan.
- \*2: Phase III clinical study of ONO-4538, fully human anti-PD-1 antibody for melanoma was commenced overseas.
- \*: Phase II clinical study of Opalmon<sup>®</sup> Tablets (OP-1206) for additional indication of carpal-tunnel syndrome was discontinued because initially expected efficacy was not confirmed.