

## ONO PHARMACEUTICAL CO., LTD.

February 4, 2014

Ono Pharmaceutical Co., Ltd. has announced its consolidated financial results for nine months ended December 31, 2013.

This First - Third Quarter Flash Report 2014 (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.

	Millions of yen			Thousands of US\$
	<b>1st-3rd Quarter 9 months ended Dec 31 2013</b>	1st-3rd Quarter 9 months ended Dec 31 2012	Annual 12 months ended Mar 31 2013	<b>1st-3rd Quarter 9 months ended Dec 31 2013</b>
Net sales	¥ 112,922	¥ 112,369	¥ 145,393	\$ 1,075,448
Net income	18,396	20,942	24,120	175,200
Total Net assets	435,044	405,229	423,291	4,143,276
Total assets	473,796	433,727	455,573	4,512,343
		Yen		US\$
Net income per common share	¥ 173.52	¥ 197.53	¥ 227.51	\$ 1.65

**First-Third Quarter (April 1 – December 31, 2013) Flash Report (unaudited)**

Nine months ended December 31, 2013

**Consolidated Financial Forecast for the Year**

**Ending March 31,2014**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

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	<b>Year ending March 31,2014</b>	
	<b>Millions of yen</b>	<b>Thousands of US\$</b>
<b>Net sales</b>	<b>¥ 148,300</b>	<b>\$ 1,412,381</b>
<b>Operating income</b>	<b>27,900</b>	<b>265,714</b>
<b>Ordinary income</b>	<b>29,000</b>	<b>276,190</b>
<b>Net income</b>	<b>20,400</b>	<b>194,286</b>
	<b>Yen</b>	<b>US\$</b>
<b>Net income per common share</b>	<b>192.42</b>	<b>1.83</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, 2013) Flash Report (unaudited)

Nine months ended December 31, 2013

### 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 2013	1st-3rd Quarter December 31 2012	Annual March 31 2013	1st-3rd Quarter December 31 2013
<b>Current assets</b>				
Cash and bank deposits	¥ 21,372	¥ 19,744	¥ 24,262	\$ 203,543
Notes and accounts receivable	47,591	45,476	37,823	453,248
Marketable securities	97,873	98,581	105,877	932,124
Inventories	24,370	21,835	23,409	232,095
Others	22,314	20,633	23,377	212,514
Allowance for doubtful receivables	(6)	(6)	(6)	(57)
<b>Total current assets</b>	<b>213,514</b>	<b>206,263</b>	<b>214,742</b>	<b>2,033,467</b>
<b>Property, plant and equipment</b>				
Land	23,482	22,544	23,479	223,638
Buildings and structures	21,255	21,942	21,780	202,429
Machinery, equipment and others	2,555	3,015	2,933	24,333
Construction in progress	4,200	966	1,438	40,000
<b>Net property, plant and equipment</b>	<b>51,492</b>	<b>48,467</b>	<b>49,630</b>	<b>490,400</b>
<b>Investments and other assets</b>				
Investment securities	196,547	163,628	180,200	1,871,876
Intangible assets	2,870	1,198	1,384	27,333
Others	9,373	14,171	9,617	89,267
<b>Total investments and other assets</b>	<b>208,790</b>	<b>178,997</b>	<b>191,201</b>	<b>1,988,476</b>
<b>Total assets</b>	<b>473,796</b>	<b>433,727</b>	¥ 455,573	\$ 4,512,343

(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 2013	1st-3rd Quarter December 31 2012	Annual March 31 2013	1st-3rd Quarter December 31 2013
<b>Current liabilities</b>				
Current portion of long-term debt	¥ 101	¥ 102	¥ 104	\$ 962
Notes and accounts payable	4,745	4,083	4,244	45,190
Income tax payable	2,404	4,270	5,606	22,895
Others	19,280	15,916	15,833	183,620
<b>Total current liabilities</b>	<b>26,530</b>	<b>24,371</b>	<b>25,787</b>	<b>252,667</b>
<b>Long-term liabilities</b>				
Long-term debt, less current portion	291	160	176	2,771
Liabilities for retirement benefits	1,337	1,209	1,076	12,733
Asset retirement obligations	55	54	54	524
Others	10,539	2,704	5,189	100,372
<b>Total long-term liabilities</b>	<b>12,222</b>	<b>4,127</b>	<b>6,495</b>	<b>116,400</b>
<b>Equity</b>				
Common stock	17,358	17,358	17,358	165,314
Capital surplus	17,080	17,080	17,080	162,667
Retained earnings	430,138	427,646	430,824	4,096,552
Treasury stock-at cost	(59,243)	(59,212)	(59,214)	(564,219)
<b>Total equity</b>	<b>405,333</b>	<b>402,872</b>	<b>406,048</b>	<b>3,860,314</b>
<b>Other comprehensive income</b>				
Unrealized gain on securities (*)	34,320	7,819	22,451	326,857
Land revaluation surplus	(8,578)	(8,578)	(8,577)	(81,695)
Deferred gains on hedges	41	45	—	390
Foreign currency translation adjustments	483	(129)	67	4,600
<b>Total other comprehensive income</b>	<b>26,266</b>	<b>(843)</b>	<b>13,941</b>	<b>250,152</b>
<b>Minority interests</b>	<b>3,445</b>	<b>3,200</b>	<b>3,302</b>	<b>32,810</b>
<b>Total net assets</b>	<b>435,044</b>	<b>405,229</b>	<b>423,291</b>	<b>4,143,276</b>
<b>Total liabilities and total net assets</b>	<b>473,796</b>	¥ 433,727	¥ 455,573	\$ 4,512,343

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

## First-Third Quarter (April 1 – December 31, 2013) Flash Report (unaudited)

Nine months ended December 31, 2013

### 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\$
	<b>1st-3rd Quarter 9 months ended Dec 31 2013</b>	1st-3rd Quarter 9 months ended Dec 31 2012	Annual 12 months ended Mar 31 2013	<b>1st-3rd Quarter 9 months ended Dec 31 2013</b>
<b>Net sales</b>	¥ <b>112,922</b>	¥ 112,369	¥ 145,393	\$ <b>1,075,448</b>
<b>Cost of sales</b>	<b>26,576</b>	25,746	33,983	<b>253,105</b>
Gross profit	<b>86,346</b>	86,623	111,410	<b>822,343</b>
<b>Selling, general and administrative expenses</b>				
R&D expenses	<b>36,204</b>	32,412	45,437	<b>344,800</b>
Others	<b>26,839</b>	25,338	34,052	<b>255,610</b>
	<b>63,043</b>	57,750	79,489	<b>600,410</b>
Operating income	<b>23,303</b>	28,873	31,921	<b>221,933</b>
<b>Other income (expenses)</b>				
Interest and dividend income	<b>2,441</b>	2,367	2,575	<b>23,248</b>
Interest expenses	<b>(6)</b>	(1)	(2)	<b>(57)</b>
Other, net	<b>356</b>	336	165	<b>3,390</b>
	<b>2,791</b>	2,702	2,738	<b>26,581</b>
Income before income taxes and minority interests	<b>26,094</b>	31,575	34,659	<b>248,514</b>
<b>Income taxes</b>	<b>7,554</b>	10,495	10,318	<b>71,943</b>
Income before minority interests	<b>18,540</b>	21,080	24,341	<b>176,571</b>
<b>Minority interests</b>	<b>(144)</b>	(138)	(221)	<b>(1,371)</b>
<b>Net income</b>	<b>18,396</b>	¥ 20,942	¥ 24,120	\$ <b>175,200</b>
<b>Per share of common stock</b>				
Basic net income	¥ <b>173.52</b>	¥ 197.53	¥ 227.51	\$ <b>1.65</b>
Cash dividends applicable to the period	¥ <b>180.00</b>	¥ 90.00	¥ 180.00	\$ <b>1.71</b>

**First-Third Quarter (April 1 – December 31, 2013) Flash Report (unaudited)**

Nine months ended December 31, 2013

**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 2013</b>	1st-3rd Quarter 9 months ended Dec 31 2012	Annual 12 months ended Mar 31 2013	<b>1st-3rd Quarter 9 months ended Dec 31 2013</b>
<b>Net income before minority interests</b>	¥ <b>18,540</b>	¥ 21,080	¥ 24,341	\$ <b>176,571</b>
<b>Other comprehensive income</b>				
Unrealized gain (loss) on available-for-sale securities	<b>11,867</b>	2,085	16,722	<b>113,019</b>
Deferred gain (loss) on hedges	<b>41</b>	45	—	<b>390</b>
Foreign currency translation adjustments	<b>416</b>	147	344	<b>3,962</b>
Share of other comprehensive income in associates	<b>4</b>	3	17	<b>39</b>
Total other comprehensive income	<b>12,328</b>	2,280	17,083	<b>117,410</b>
<b>Comprehensive income</b>	<b>30,868</b>	23,360	41,424	<b>293,981</b>
<b>Total comprehensive income attributable to</b>				
Owners of the parent	<b>30,722</b>	23,228	41,190	<b>292,591</b>
Minority interests	<b>146</b>	132	234	<b>1,390</b>

## First-Third Quarter (April 1 – December 31, 2013) Flash Report (unaudited)

Nine months ended December 31, 2013

### 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 2013	1st-3rd Quarter 9 months ended Dec 31 2012	1st-3rd Quarter 9 months ended Dec 31 2013
Operating activities: <sup>(*)</sup>	¥ 112	¥ 56	\$ 1,067
Investing activities:	128	153	1,219
Financing activities:	(187)	(183)	(1,781)
Net decrease in cash and cash equivalents	53	25	505
Cash and cash equivalents, ending	¥ 945	¥ 876	\$ 9,000
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(*)Depreciation and amortization is included in "Operating activities"	¥ 20	21	\$ 190

## **Notes to Consolidated Financial Statements**

Ono Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

- Note 1 This First-Third Quarter Flash Report 2014 (unaudited) is a summary information extracted from the financial statements announced by the Company on February 4, 2014.
- 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 2014 (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 105 = US\$ 1, the approximate exchange rate prevailing on December 30, 2013.



## First-Third Quarter (April 1 – December 31, 2013) Flash Report (unaudited)

Nine months ended December 31, 2013

### 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 2013			Year ending March 31,2014
		Results	Increase/Decrease		Forecast
<b>Glactiv (*)</b>	Agent for type II diabetes	¥ 288	¥ +20	+7.5 %	¥ 375
<b>Opalmon (*)</b>	Circulatory system agent	256	Δ 12	Δ 4.6 %	325
<b>Onon (*)</b>	Agent for bronchial asthma and allergic rhinitis	97	Δ 16	Δ 13.9 %	135
<b>Recalbon</b>	Agent for osteoporosis	81	+25	+43.6 %	105
<b>Emend/Proemend</b>	Agent for Chemotherapy-induced nausea and vomiting	67	+5	+8.4 %	95
<b>Foipan</b>	Agent for chronic pancreatitis and postoperative reflux esophagitis	63	Δ 6	Δ 8.9 %	80
<b>Kinedak</b>	Agent for diabetic peripheral neuropathy	58	Δ 12	Δ 17.8 %	80
<b>Onon dry syrup</b>	Agent for pediatric bronchial asthma and allergic rhinitis	52	Δ 2	Δ 4.5 %	70
<b>Staybla</b>	Agent for overactive bladder (pollakiuria and urinary incontinence)	48	Δ 2	Δ 3.9 %	70
<b>Rivastach</b>	Agent for Alzheimer's disease	47	+19	+64.5 %	65
<b>Onoact</b>	Agent for tachyarrhythmia during and post operation	34	+5	+15.2 %	45
<b>Elaspol</b>	Agent for acute lung injury associated with SIRS	28	Δ 3	Δ 9.9 %	35
<b>Orencia SC</b>	Agent for rheumatoid arthritis	4	—	—	12

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

2 Orencia SC was launched in Fiscal 2013, and year-on-year changes in value and percentage are therefore not available.

(\*) The sales of major products forecasts for the year ending March 31, 2014 are changed from May 13, 2013.

## First-Third Quarter (April 1 –December 31, 2013) Flash Report (unaudited)

Nine months ended December 31, 2013

### Supplemental Information

## Status of Development Pipeline

as of February 4, 2014

### Developments in Japan

#### *NDA approved (Additional Indication):*

- **Onoact<sup>®</sup> 50 for Injection (ONO-1101) \*1**  
Tachyarrhythmia in low cardiac function  
[Short acting beta-1 blocker]

#### *NDA filed (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection) \*2**  
Melanoma [Fully human anti-PD-1 antibody]

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

- **Opalmon<sup>®</sup> Tablets (Co-development with Dainippon Sumitomo Pharma Co., Ltd.)**  
Thromboangitis obliterans and lumbar spinal canal stenosis  
[Blood vessel dilation]

#### *NDA filed (Additional Indication):*

- **Glactiv<sup>®</sup> Tablets (ONO-5435 / MK-0431) (Co-development with Merck & Co., Inc.)**  
Type 2 diabetes: combination therapy with a rapid-acting insulin secretagogue [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 / 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-4538 / BMS-936558 (injection) \*3**  
Esophagus cancer (Phase II)  
[Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
Non-small cell lung cancer (Phase II) [Fully human anti-PD-1 antibody]
- **ONO-1162 / Ivabradine (tablet) \*4 (In-licensed from Les Laboratoires Servier)**  
Chronic heart failure (Phase II) [If channel inhibitor]
- **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-7268 MX2 (injection) \*5 (In-licensed from OncoTherapy Science, Inc.)**  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-2160/CD (tablet)**  
Parkinson's disease (Phase I) [levodopa pro-drug]

#### *Ongoing clinical studies (Additional Indications):*

- **Proemend<sup>®</sup> 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]
- **Orencia<sup>®</sup> IV (ONO-4164 / BMS-188667) (Co-development with Bristol-Myers Squibb Company)**  
Juvenile Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]
- **Orencia<sup>®</sup> IV (ONO-4164 / BMS-188667) (Co-development with Bristol-Myers Squibb Company)**  
Lupus nephritis (Phase III) [T-cell activation inhibitor]

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

- **Rivastach<sup>®</sup> Patch (ONO-2540 / ENA713D) (Co-development with Novartis Pharma AG)**  
Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

### 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) (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-2952 (tablet)**  
Irritable bowel syndrome (Phase II) [TSPO antagonist]

- **ONO-9054 (eye drop) \*6**  
Glaucoma, ocular hypertension (Phase II) [PG receptor (FP / EP3) agonist]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
Solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer (Phase I/II) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
Hematological cancer (Phase I) [Fully human anti-PD-1 antibody]
- **ONO-4538 / BMS-936558 (injection)**  
**(Out-licensed to Bristol-Myers Squibb Company)**  
Hepatocellular carcinoma (Phase I) [Fully human anti-PD-1 antibody]
- **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-4059 (capsule)**  
B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**  
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-8539 (tablet)**  
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-1266 (capsule)**  
Portal hypertension (Phase I) [S1P receptor antagonist]
- **ONO-4232 (injection)**  
Acute heart failure (Phase I) [PG receptor (EP4) agonist]

**Changes from Second Flash Report for the Fiscal Year ending March 2014 announced on November 5, 2013**

- \*1: Marketing authorization of Onoact<sup>®</sup> 50 for Injection (ONO-1101) was obtained in Japan for additional indication of tachyarrhythmia in low cardiac function.
- \*2: NDA of ONO-4538/BMS-936558 (Fully human anti-PD-1 antibody) was filed in Japan for the indication of melanoma.
- \*3: Phase II clinical study of ONO-4538/BMS-936558 (Fully human anti-PD-1 antibody) was initiated for the treatment of esophagus cancer in Japan.
- \*4: Phase II clinical study of ONO-1162/Ivabradine (If channel inhibitor) was initiated for the treatment of chronic heart failure in Japan.
- \*5: Phase I clinical study of ONO-7268 MX2 (Therapeutic cancer peptide vaccines) was initiated for the treatment of hepatocellular carcinoma in Japan.
- \*6: Phase II clinical study of ONO-9054 (PG receptor (FP / EP3) agonist) was initiated for the treatment of glaucoma, ocular hypertension outside Japan.